Medicare Claims Processing Manual
Chapter 30 - Financial Liability Protections

Table of Contents
(Rev. 12934, Issued: 10-31-24)

Transmittals for Chapter 30

10 - Financial Liability Protections (FLP) Provisions

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

- 20.1 - LOL Coverage Denials to Which the Limitation on Liability Applies
- 20.2 - Denials When the LOL Provision Does Not Apply
  - 20.2.1 - Categorical Denials

30 - Determining Liability for Disallowed Claims Under §1879

- 30.1 - Beneficiary's Knowledge and Liability
  - 30.1.1 - Other Evidence of Knowledge
- 30.2 - Healthcare Provider or Supplier Knowledge and Liability
  - 30.2.1 - Evidence of Healthcare Provider or Supplier Knowledge
  - 30.2.2 - Medical Record Evidence of Healthcare Provider or Supplier Knowledge
  - 30.2.3 - Acceptable Standards of Practice

30.3 – The Right to Appeal

30.4 - Fraud, Abuse, Patently Unnecessary Items and Services

40 - Written Notice as Evidence of Knowledge

- 40.1 - Sources of Written Notice
- 40.2 - Written Notice Standards
  - 40.2.1 - Other Written Notice Standards
  - 40.2.2 - Written Notice Special Considerations
- 40.3 - Medical Emergency or Otherwise Under Great Duress Situations
  - 40.4- Emergency Medical Treatment and Active Labor Act (EMTALA) Situations

50 - Advance Beneficiary Notice of Non-coverage (ABN)

- 50.1 - ABN Scope
- 50.2 - ABN Uses
  - 50.2.1 - Optional ABN Uses

50.3 - Issuance of the ABN

50.4 - ABN Triggering Events

50.5 - ABN Standards

50.6 - Completing the ABN

50.7 - Retention Requirements

50.8 - ABN Delivery Requirements

50.8.1 – Options for Delivery Other than In-Person

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

50.10 - Using ABNs for Medical Equipment and Supplies Claims When Denials Under §1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts) Are Expected

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

50.12 - ABNs for Claims Denied in Advance Under §1834(a)(15) of the Act

50.13 - ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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

50.15 - Collection of Funds and Refunds

50.15.1 - Physicians' Services RR

50.15.2 - DMEPOS RR Provision for Claims for Medical Equipment and Supplies

50.15.3 - Time Limits and Penalties for Healthcare Providers and Suppliers in Making Refunds

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

50.16 - CMS Regional Office (RO) Referral Procedures

50.17 - ABN Special Considerations

60 - Home Health Change of Care Notice (HHCCN), Form CMS-10280

60.1 - Background on the HHCCN

60.2 - Scope of the HHCCN

60.3 - Triggering Events for HHCCN/ Written Notice

60.4 - Completing the HHCCN

60.5 - HHCCN Delivery

70 - Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN)

70.1 - SNF ABN Standards

70.2 - Situations in Which a SNF ABN Should Be Given

70.3 – Situations in Which a SNF ABN Is Not Needed to Transfer Financial Liability to the Beneficiary

70.4 - SNF ABN Specific Delivery Issues

70.5 - Special Rules for SNF ABNs

70.6 - Establishing When Beneficiary Is On Notice of Non-coverage

70.6.1 - Source of Beneficiary Notification

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

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

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

100.2 - Conditions for Indemnification

100.3 - Development and Documentation of Indemnification Requests

100.3.1 - Proof of Payment

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

100.5 - Questionable Indemnification Requests Procedure

100.6 - Determining the Amount of Indemnification

100.7 - Notifying the Provider, Practitioner, or Supplier

100.8 - Making Payment Under Indemnification

100.9 - Limitation on Liability Determination Does Not Affect Medicare Exclusion

100.10 - Exhibits

Exhibit 1 - Letter to Provider

Exhibit 2 - Letter to Beneficiary Who Requests Indemnification

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

Exhibit 4 - Letter to Practitioner or Supplier (Noninstitutional Services)

Exhibit 5 - Letter to Beneficiary Who Requests Indemnification (Noninstitutional Services)

Exhibit 6 - Letter to Someone Other Than Beneficiary Who Requests Indemnification (Noninstitutional Services)

Exhibit 7 - Statement of Claimant or Other Person

110 - Contractor Instructions for Application of Limitation On Liability

110.1 - Payment Under Limitation on Liability

110.2 - When to Make Limitation on Liability Decisions

110.3 - Preparation of Denial Notices

110.4 - Bill Processing

110.5 - Contractor Review of ABNs

110.5.1 - General Rules

110.5.2 - Situations in Which Contractor Review of ABNs is Indicated

110.5.3 - Other Reasons for Contractor Request for Copies of ABNs

120 - Contractor Specific Instructions for Application of Limitation on Liability

120.1 - Documentation of Notices Regarding Coverage

120.2 - Availability of Coverage Notices to Operating Personnel

120.3 - Applicability of Limitation on Liability Provision to Claims for Outpatient Physical Therapy Services Furnished by Clinics

120.4 - Limitation on Liability Notices to Beneficiaries From Contractors

120.5 - Contractor Redeterminaions or Reconsiderations in Assignment Cases Conducted at the Request of Either the Beneficiary or the Assignee

120.5.1 - Guide Paragraphs for Contractors to Use Where §1879 Is Applicable at Redetermination Level

130 - A/B MAC (A) and (HHH) Specific Instructions for Application of Limitation on Liability

130.1 - Applicability of the Limitation on Liability Provision to Claims for Ancillary, Outpatient Provider and Rural Health Clinic Services Payable Under Part B

130.1.1 - Determining Beneficiary Liability in Claims for Ancillary and Outpatient Services

130.1.2 - Determining Provider Liability in Claims for Ancillary and Outpatient Services

130.2 - Prior Hospitalization and Transfer Requirements for SNF Coverage as Related to Limitation on Liability

130.3 - Application of Limitation on Liability to SNF and Hospital Claims for Services Furnished in Noncertified or Inappropriately Certified Beds

130.4 - Determining Liability for Services Furnished in a Noncertified SNF or Hospital Bed

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

140.1 - Services Furnished Before October 1, 1987

140.2 - Services Furnished Beginning October 1, 1987

140.3 - Time Limits for Making Refunds

140.4 - Situations Where a Refund Is Not Required

140.5 - Appeal Rights

140.6 - Processing Initial Denials

140.6.1 - Initial Beneficiary Notices

140.6.2 - Initial Physician Notices

140.7 - Processing Beneficiary Requests for Appeal

140.8 - Processing Physician Requests for Appeal

140.8.1 - Appeal of the Denial or Reduction in Payment

140.8.2 - Beneficiary Given ABN and Agreed to Pay

140.8.3 - Physician Knowledge

140.9 - Guide Paragraphs for Inclusion in Appeal Determination

140.10 - Physician Fails to Make Refund

140.11 - OIG Referral Procedures

140.12 - Imposition of Sanctions

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

150.1 - Definition of Medical Equipment and Supplies

150.1.1 - Unassigned Claims Denied on the Basis of the Prohibition on Unsolicited Telephone Contacts

150.1.2 - Unassigned Claims Denied on the Basis of Not Being Reasonable and Necessary

150.1.3 - Unassigned Claims Denied on the Basis of Failure of the Supplier to Meet Supplier Number Requirements

150.1.4 - Assigned Claims Denied on the Basis of the Prohibition on Unsolicited Telephone Contacts

150.1.5 - Assigned Claims Denied on the Basis of Failure of the Supplier to Meet Supplier Number Requirements

150.1.6 - Assigned Claims Denied on the Basis of Not Being Reasonable and Necessary

150.2 - Items and Services Furnished on an Unassigned Basis on or After January 1, 1995

150.3 - Items and Services Furnished On an Assigned Basis On or After January 1, 1995

150.4 - Time Limits for Making Refunds

150.5 - Supplier Knowledge Standards for Waiver of Refund Requirement

150.5.1 - Knowledge Standards for §1862(a)(1) Denials

150.5.2 - Knowledge Standards for §1834(a)(15) Denials

150.5.2.1 - Denial of Payment in Advance

150.5.2.2 - When a Request for an Advance Determination of Coverage Is Mandatory

150.5.2.3 - When a Request for an Advance Determination of Coverage Is Optional

150.5.2.4 - Presumption for Constructive Notice

150.5.2.5 - Presumption When Advance Determination was Requested

150.5.2.6 - Presumption for Listed Overutilized Items

150.5.2.7 - Presumption for Listed Suppliers

150.5.2.8 - Presumption for Medical Necessity

150.5.2.9 - Presumption About Beneficiary Knowledge

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

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

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

150.6 - Advance Beneficiary Notice Standards for Waiver of Refund Requirement

150.7 - Appeal Rights

150.8 - Processing Initial Denials

150.9 - Processing Beneficiary Requests for Appeal

150.10 - Processing Supplier Requests for Appeal

150.10.1 - Appeal of the Denial of Payment

150.10.2 - Beneficiary Given Advance Beneficiary Notice and Agreed to Pay

150.10.3 - Supplier Knowledge

150.11 - Guide Paragraphs for Inclusion in Appeal Determination

150.12 - Supplier Fails to Make Refund

150.13 - CMS Regional Office (RO) Referral Procedures

150.14 - Imposition of Sanctions

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

200 - Expedited Determinations of Inpatient Hospital Discharges

200.1- Statutory Authority

200.2 - Scope

200.2.1 - Exceptions

200.3 - Important Message from Medicare (IM)

200.3.1 - Alterations to the IM

200.3.2 - Completing the IM

200.3.3 - Hospital Delivery of the IM

200.3.4 - Required Delivery Timeframes

200.3.4.1 First IM

200.3.4.2 Follow-up copy of the IM

200.3.5 - Refusal to Sign the IM

200.3.6 - Amending the Date of the IM

200.3.7 - IM Delivery to Representatives

200.3.8 - Notice Retention for the IM

200.4 - Expedited Determination Process

200.4.1 - Beneficiary Responsibilities

200.4.1.1 - Timeframe for Requesting an Expedited Determination

200.4.1.2 - Provide Information to BFCC-QIO

200.4.2 - Beneficiary Liability During BFCC-QIO Review

200.4.3 - Untimely Requests for Review

200.4.4 - Hospital Responsibilities

200.4.5 - The Detailed Notice of Discharge (DND)

200.5 - BFCC-QIO Responsibilities

200.5.1 - Receive Beneficiary Requests for Expedited Review

200.5.2 - Notify Hospitals and Allow Explanation of Why Covered Services Should End

200.5.3 - Validate Delivery of IM

200.5.4 - Solicit the Views of the Beneficiary

200.5.5 - Solicit the Views of the Hospital

200.5.6 - Make Determination and Notify Required Parties

200.6 - Effect of a BFCC-QIO Expedited Determination

200.6.1 - Right to Pursue an Expedited Reconsideration

200.6.2 - Effect of BFCC-QIO Determination on Continuation of Care

200.6.3 - Right to Pursue the Standard Claims Appeal Process

220 - Hospital Requested Expedited Review
220.1 - Responsibilities of the Hospital
220.2 - Responsibilities of the QIO
220.3 - Effect of the Hospital Requested Expedited Determination
220.4 - General Notice Requirements
220.5 - Exhibit 3 - Model Language Notice of Hospital Requested Review (HRR)
240 - Preadmission/Admission Hospital Issued Notice of Noncoverage (HINN)
240.1 - Delivery of the Preadmission/Admission HINN
240.2 - Notice Delivery Timeframes and Liability
240.3 - Timeframes for Submitting a Request for a QIO Review
240.4 - Results of the QIO Review
240.5 - Effect of the QIO Review
240.6 - Exhibit 4 - Model Language Preadmission/Admission Hospital Issued Notice of Noncoverage
260 - Expedited Determinations of Provider Service Terminations
260.1 - Statutory Authority
260.2 - Scope
260.2.1 - Exceptions
260.3 - Notice of Medicare Non-Coverage
260.3.1 - Alterations to the NOMNC
260.3.2 - Completing the NOMNC
260.3.3 - Provider Delivery of the NOMNC
260.3.4 - Required Delivery Timeframes
260.3.5 - Refusal to Sign the NOMNC
260.3.6 - Financial Liability for Failure to Deliver a Valid NOMNC
260.3.7 - Amending the Date of the NOMNC
260.3.8 - NOMNC Delivery to Representatives
260.3.9 - Notice Retention for the NOMNC
260.3.10- Hours of NOMNC Delivery
260.4 - Expedited Determination Process
260.4.1 - Beneficiary Responsibilities
260.4.1.1 - Timeframe for Requesting an Expedited Determination
260.4.1.2 - Provide Information to QIO

260.4.1.3 - Obtain Physician Certification of Risk (Home Health and CORF services only)

260.4.2 - Beneficiary Liability During QIO Review

260.4.3 - Untimely Requests for Review

260.4.4 - Provider Responsibilities

260.4.5 - The Detailed Explanation of Non-Coverage

260.5 - QIO Responsibilities

260.5.1 - Receive Beneficiary Requests for Expedited Review

260.5.2 - Notify Providers and Allow Explanation of Why Covered Services Should End

260.5.3 -Validate Delivery of NOMNC

260.5.4 - Solicit the Views of the Beneficiary

260.5.5 - Solicit the Views of the Provider

260.5.6 - Make Determination and Notify Required Parties

260.6 - Effect of a QIO Expedited Determination

260.6.1 - Right to Pursue an Expedited Reconsideration

260.6.2 - Effect of QIO Determination on Continuation of Care

260.6.3 - Right to Pursue the Standard Claims Appeal Process

261 - Expedited Determination Notice Association with Advance Beneficiary Notices

300 - Expedited Reconsiderations

300.1 - The Role of the Beneficiary and Liability

300.2 - The Responsibilities of the IRE

300.3 - The Responsibilities of the QIO

300.4 - The Responsibilities of the Provider

300.5 - Coverage During an Expedited Reconsideration

400 - Part A Medicare Outpatient Observation Notice

400.1 - Statutory Authority

400.2 - Scope

400.3 - Medicare Outpatient Observation Notice

400.3.1 - Alterations to the MOON

400.3.2 - Completing the MOON

400.3.3 - Hospital Delivery of the MOON

400.3.4 - Required Delivery Timeframes

400.3.5 - Refusal to Sign the MOON

400.3.6 - MOON Delivery to Representatives

400.3.7 - Ensuring Beneficiary Comprehension

400.3.8 - Completing the Additional Information Field of the MOON

400.3.9 - Notice Retention for the MOON

400.4 - Intersection with State Observation Notices

450 - Expedited Determinations When a Beneficiary is Reclassified from an Inpatient to an Outpatient Receiving Observation Services

450.1 –Authority

450.2 - Scope

450.3 – Medicare Change of Status Notice (MCSN)

450.3.1 Alterations to the MCSN

450.3.2 - Hospital Delivery of the MCSN

450.3.3- Required Delivery Timeframes of the MCSN

450.3.4 - Refusal to Sign the MCSN

450.3.5 - Ensuring Beneficiary Comprehension

450.3.6 - MCSN Delivery to Representatives

450.3.7- Notice Retention for the MCSN

450.4 Expedited Determination Process

450.4.1 - Beneficiary Responsibilities

450.4.1.1- Timeframes for Requesting an Expedited Determination

450.4.1.2- Provide Information to BFCC-QIO

450.4.2 - Beneficiary Liability During BFCC-QIO Review

450.4.3 - Hospital Responsibilities

450.5 – BFCC-QIO Responsibilities

450.5.1 – Receive Beneficiary Requests for Expedited Review

450.5.2 – Notify Hospitals

450.5.3 – Validate Delivery of the MCSN

450.5.4 - Solicit the Views of the Beneficiary

450.5.5 - Solicit the Views of the Hospital

450.5.6 – Make Determination and Notify Required Parties

450.6 - Effect of a BFCC-QIO Expedited Determination

460- Expedited Reconsiderations

460.1- Beneficiary Responsibilities

460.1.1- Timeframe for Requesting an Expedited Reconsideration

460.1.2- Provide Information to the BFCC-QIO

460.1.3- Beneficiary Liability During BFCC-QIO

460.2- Hospital Responsibilities

460.3- BFCC-QIO Responsibilities

460.3.1- Receive Beneficiary requests for Expedited Reconsiderations

460.3.2- Notify Hospitals

460.3.3- Solicit the Views of the Beneficiary

460.3.4- Solicit the Views of the Hospital

460.3.5- Make Determination and Notify Required Parties

460.4- Effect of a BFCC-QIO Expedited Reconsideration

500- Glossary

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

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

The FLP provisions of the Social Security Act (hereinafter referred to as the Act) protect beneficiaries, healthcare providers, and suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay. The FLP provisions apply after an item or service's coverage determination is made. This chapter discusses the following FLP provisions:

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

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

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

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

The LOL provisions apply to all Part A services and all assigned claims for Part B services. The RR apply to both assigned and unassigned claims for medical equipment and supplies and to unassigned claims for physicians' services. However, RR do not apply to claims for Part A services.

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

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

In general, application of the LOL provisions depends upon two primary factors:

1. Whether the claim for the item and/or service provided was denied for certain specific reasons. See §21 of this chapter for more examples.

Type of Denial	Description	Example
Statutory Basis	The LOL provisions apply only to claims for items and/or services submitted by healthcare providers or suppliers that have	Items and services found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the

Type of Denial	Description	Example
	taken assignment, and only to claims for items and/or 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.	functioning of a malformed body member. (§1862(a)(1)(A) of the Act)
Dependent Services	When Medicare payment is made under the LOL provisions, the payment determination includes claims for any dependent services that are denied as an indirect result of the original denial. Thus, where a particular qualifying service is denied as not reasonable and necessary under §1862(a)(1)(A) of the Act, any dependent services are also denied as not reasonable and necessary under §1862(a)(1)(A) of the Act. If the LOL provisions apply to the denial of the qualifying service, it will also apply to the dependent service, and Medicare will make payment for both services, provided all other conditions for coverage and payment are met.	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 LOL provision for the primary services, it would be made for the dependent services as well, provided the services meet all conditions for coverage and payment (i.e. a physician's certification of the need for the dependent services and proof that the services are reasonable and necessary).
Higher Levels of Care and "Excess Components"	Normally, Medicare payment is denied for items and/or services that are not reasonable and necessary on the basis of §1862(a)(1)(A) of the Act. However, the LOL provisions may apply if a reduction in payment occurs because the furnished items or services are at a higher level of care and provide more extensive items or services than was reasonable and necessary to meet the needs of the beneficiary.	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).

2. Whether the beneficiary and/or the healthcare provider or supplier knew or could reasonably have been expected to know that the item or service was not covered.

Knowledge of the Non-covered Item/Service	Liability	Payment Responsibility
If the beneficiary knew, or should have known (e.g. a valid liability notice such as an ABN, Form CMS-R-131 was issued and the beneficiary consented to receiving the item or service).	Rests with the beneficiary	The beneficiary is responsible for making payment for the usual and customary charges to the healthcare provider or supplier for the denied item and/or service.
If the beneficiary did not know (and should not have known), and the healthcare provider or supplier knew, or should have known.	Rests with the healthcare provider or supplier	The beneficiary may not be charged for any costs related to the denied item and/or service, including copayments and deductibles.
If neither the beneficiary nor the healthcare provider or supplier knew, and could not reasonably be expected to have known.	Neither the beneficiary or the healthcare provider or supplier	The Medicare program makes payment for the assigned claim.

20.1 - LOL Coverage Denials (Rev. 1, 10-01-03)

(Rev.:4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

A. Statutory Basis

The following table provides examples of denials based on §1862(a)(1), §1862(a)(9), §1879(e), or §1879(g) of the Act:

Statutory Provision (section of the Act)	Description
§1862(a)(1)(A)	Items and services 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)(B) & §1861(s)(10)	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)(C)	In the case of hospice care, items and services that are not reasonable and necessary for the palliation or management of terminal illness.

Statutory Provision (section of the Act)	Description
§1862(a)(1)(E)	Items and services that, in the case of research conducted pursuant to §1142 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)(F)	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)	Screening for glaucoma, which is performed more frequently than is provided under §1861(uu) of the Act.
§1862(a)(1)(G)	Prostate cancer screening tests (as defined in §1861(oo) of the Act), which are performed more frequently than is covered under such section.
§1862(a)(1)(H)	Colorectal cancer screening tests, which are performed more frequently than is covered under §1834(d) of the Act.
§1862(a)(1)(I)	The frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation.
§1862(a)(1)(J)	Drugs or biologicals specified in §1847A(c)(6)(C) of the Act, for which payment is made under part B, furnished in a competitive area under §1847B of the Act, but not furnished by an entity under a contract under §1847(B) of the Act.
§1862(a)(1)(K)	An initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under Medicare Part B.
§1862(a)(1)(L)	Cardiovascular screening blood tests (as defined in §1861(xx)(1) of the Act), which are performed more frequently than is covered under §1861(xx)(2).
§1862(a)(1)(M)	A diabetes screening test (as defined in §1861(yy)(1) of the Act), which is performed more frequently than is covered under §1861(yy)(3) of the Act.
§1862(a)(1)(N)	An ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under §1861(s)(2)(AA) of the Act.
§1862(a)(1)(O)	Kidney disease education services (as defined in §1861(ggg)(1) of the Act) which are furnished in excess of the number of sessions covered under §1861(ggg)(4) of the Act.
§1861(dd)(3)(A)	Hospice care determined to be non-covered because the beneficiary was not "terminally ill," as referenced by §1879(g)(2) of the Act since the Balanced Budget Act of 1997.
§1862(a)(1)(O)	Personalized prevention plan services (as defined in § 1861 (hhh)(1) of the Act), which are performed more frequently than is covered under such section.

Statutory Provision (section of the Act)	Description
§1814(a)(2)(C) & §1835(a)(2)(A) on or after July 1, 1987 §1879(g)(1) before December 31, 1995	Home health services determined to be non-covered because the beneficiary was not "homebound" or did not require "intermittent" skilled nursing care.
§1879(e)	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.
§1862(a)(9)	Custodial care, unless otherwise permitted under paragraph §1862(a)(1)(C) of the Act.

20.2 - Denials When the LOL Provision Does Not Apply

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

Type of Denial	Description	Example(s)
Categorical	Categorical Denials are circumstances in which the LOL provision does not apply because the Medicare payment denial is based on a statutory provision not referenced in §1879 of the Act. Refer to §1862(a) of the Act for a complete listing.	• Personal comfort items (§1862(a)(6) of the Act). • Routine physicals and most screening tests (§1862(a)(7) of the Act). • Most immunizations (vaccinations) (§1862(a)(7) of the Act). • Routine eye care, most eyeglasses and examinations (§1862(a)(7) of the Act). • Hearing aids and hearing aid examinations (§1862(a)(7) of the Act). • Cosmetic surgery (§1862(a)(10) of the Act). • Orthopedic shoes and foot supports (orthotics) (§1862(a)(8) of the Act).

Type of Denial	Description	Example(s)
		NOTE: §22.1 of this chapter provides a more expansive list of examples.
Technical	When coverage requirements are not met for a particular item or service, it is not a Medicare benefit; therefore, Medicare denies payment or when 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.	• Payment for the additional cost of a private room in a hospital or SNF is denied when the private accommodations are not required for medical reasons (§1861(v)(2) of the Act). • Payment for a dressing is denied because it does not meet the definition for "surgical dressings" (§1861(s)(5) of the Act). • Payment for SNF stays not preceded by the required 3-day hospital stay or 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 (§1861(i) of the Act). • Drugs and biologicals which are usually self-administered by the patient. • 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. (See the Medicare Benefit Policy Manual, Chapter 10) • Other items or services that must be denied under 42 CFR 410.12 through 410.105 of the Medicare regulations.

20.2.1 - Categorical Denials

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

Below is a more expansive list of examples of categorical denials:

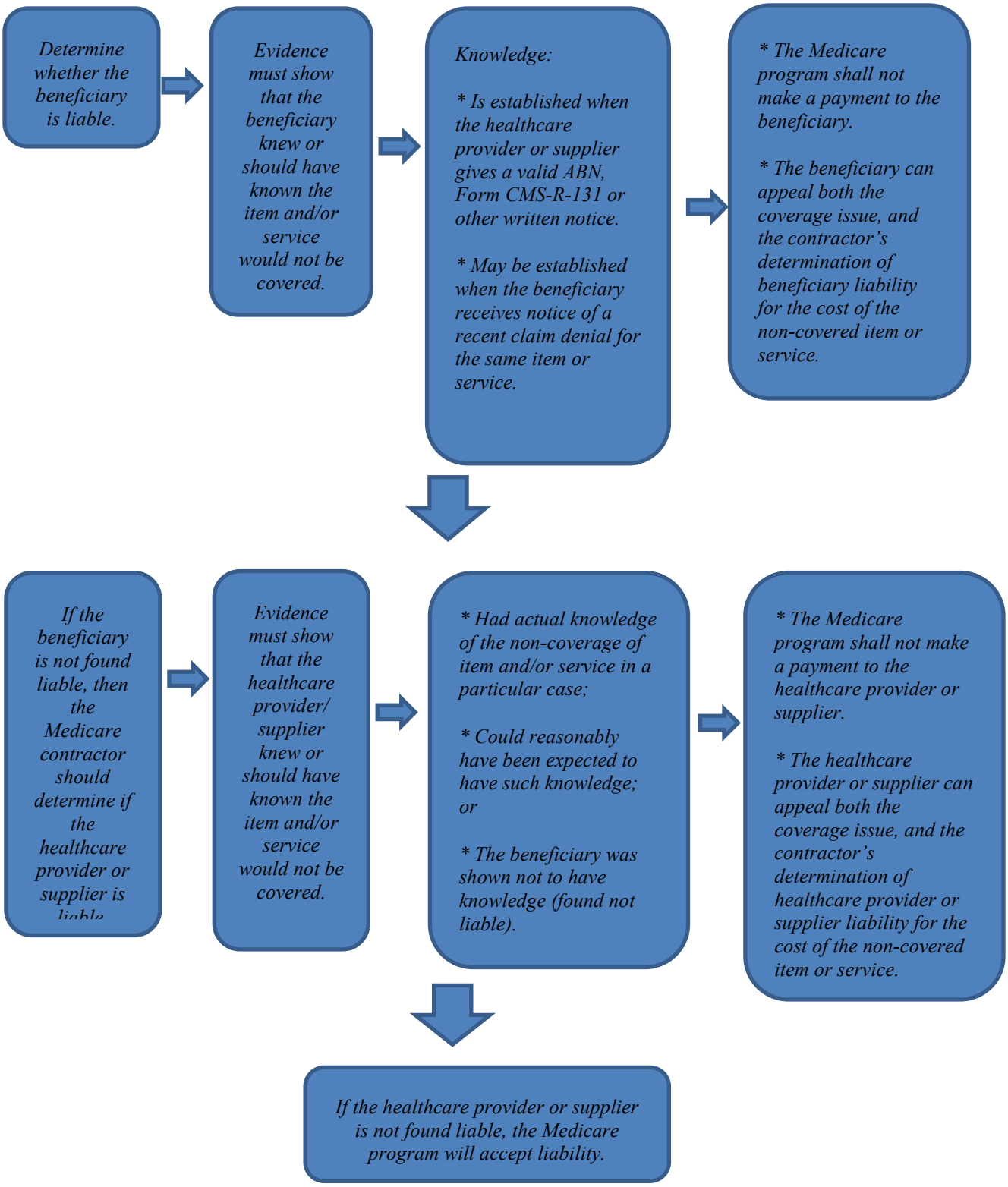
Statutory Provision (section of the Act)	Description
§1862(a)(12)	Dental care and dentures (in most cases).
§1862(a)(13)	Routine foot care and flat foot care.
§1862(a)(19)	Services under a physician's private contract.
§1862(a)(3)	Services paid for by a governmental entity that is not Medicare.
§1862(a)(4)	Health care received outside of the U. S. not covered by Medicare.
§1862(a)(11)	Services by immediate relatives.
§1862(a)(5)	Services required as a result of war.
§1862(a)(2)	Services for which there is no legal obligation to pay.
§1862(a)(21)	Home health services furnished under a plan of care, if the agency does not submit the claim.
§1862(a)(16)	Items and services excluded under the Assisted Suicide Funding Restriction Act of 1997.
§1862(a)(17)	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)(14)	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)(18)	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)(15)	Services of an assistant at surgery without prior approval from the peer review organization.
§1862(a)(20)	Outpatient occupational and physical therapy services furnished incident to a physician's services.
§1862(a)(22)	Claims submitted other than in an electronic form specified by the Secretary, subject to the exceptions set forth in §1862(h) of the Act.

Statutory Provision (section of the Act)	Description
§1862(a)(23)	Claims for the technical component of advanced diagnostic imaging services described in §1834(e)(1)(B) of the Act for which payment is made under the fee schedule established under §1848(b) of the Act and that are furnished by a supplier (as defined in §1861(d) of the Act), if such supplier is not accredited by an accreditation organization designated by the Secretary under §1834(e)(2)(B) of the Act.
§1862(a)(24)	Claims for renal dialysis services (as defined in §1881(b)(14)(B) of the Act) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services.

30 - Determining Liability for Disallowed Claims Under §1879

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

When a Medicare contractor determines that a review under the LOL provisions is appropriate under §20 of this chapter, the Medicare contractor must next determine who is liable, based on who knew, or should have known that Medicare was going to deny payment on the item or service. In order to make this determination, the contractor must take the following steps:



NOTE: If both the beneficiary and the healthcare provider or supplier are found to have knowledge, the beneficiary will be held liable.

30.1 - Beneficiary's Knowledge and Liability

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

Beneficiary knowledge standards vary between the §1879 LOL provision and the two Refund Requirement (RR) provisions as shown in the table below.

Provision	Description	Beneficiary Knowledge
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.	• Knowledge based on written notice having been provided to the beneficiary. • Knowledge based on any other means from which it is determined that the beneficiary knew, or should have known, that payment would not be made.
Medical Equipment and Supplies RR	§1834(a)(18)(A)(ii) of the Act [which is incorporated by reference into §1834(j)(4) and §1879(h) of the Act] 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.	• Knowledge must be evidenced by a signed written notice and agreement to pay personally in case of a denial.
Physician RR	§1842(l)(1)(C)(ii) of the Act 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.	• Knowledge must be evidenced by a signed written notice and agreement to pay personally in case of a denial.

Knowledge is determined on a case by case basis. In certain circumstances, being in receipt of a valid ABN or other written notice does not guarantee that the beneficiary had knowledge that an item or service would not be covered. For instance, in a case where a beneficiary received a valid ABN and then, upon initial determination, the claim was paid as covered, that original ABN cannot be used as evidence of knowledge for future claims relating to a similar or reasonably comparable item or service, since the original ABN was belied by the favorable payment decision.

In reviewing a determination of liability on appeal, a beneficiary's allegation that s/he did not know, in the absence of evidence to the contrary, is acceptable evidence for LOL purposes.

30.1.1 - Other Evidence of Knowledge
(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

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 LOL provision. If it is clear and obvious that a beneficiary in fact did know, prior to receiving an item or service, that Medicare payment for that item or service would be denied, the administrative presumption favorable to the beneficiary is rebutted. For example, if the beneficiary admits that s/he had prior knowledge that payment for an item or service would be denied, no further evidence is required.

In the case in which the Medicare contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the LOL provision, even if no written notice was given by the appropriate source.

30.2 - Healthcare Provider or Supplier Knowledge and Liability
(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

In order to determine whether the healthcare provider or supplier had prior knowledge that the item and/or service furnished to the beneficiary would likely be denied or whether knowledge of the denial could have been expected, the Medicare contractors review the information they maintain and/or disseminate to a particular healthcare provider or supplier and the denial's relevant facts.

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

30.2.1 - Evidence of Healthcare Provider or Supplier Knowledge

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

In accordance with regulations at 42 CFR 411.406, evidence that the healthcare provider or supplier did, in fact, know or should have known that Medicare would not pay for an item or service includes:

- A Medicare contractor's prior written notice to the healthcare provider or supplier of Medicare denial of payment for similar or reasonably comparable item or service. This also includes notification of Quality Improvement Organization (QIO) screening criteria specific to the condition of the beneficiary for whom the furnished item and/or service are at issue and of medical procedures subject to preadmission review by the QIO. Instructions for application of the LOL provision to QIO determinations are in the QIO Manual;

- Medicare's general notices to the medical community of Medicare payment denial of item or service under all or certain circumstances (such notices include, but are not limited to, manual instructions, bulletins, and Medicare contractors' written guidance);

- Provision of the item and service being inconsistent with acceptable standards of practice in the local medical community.

- Written notification from the healthcare provider or supplier's utilization review committee informing the healthcare provider or supplier that the item and/or service was not covered;

- The healthcare provider or supplier issuing a written notice of the likelihood of Medicare payment denial for an item and/or service to the beneficiary; or

- The healthcare provider or supplier being previously notified by telephone and/or in writing that an item or service is not covered or that coverage has ended.

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

30.2.2 - Medical Record Evidence of Healthcare Provider or Supplier Knowledge

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

The healthcare provider or supplier is also accountable for information contained in the beneficiary's medical records, such as the beneficiary's medical chart, attending physicians' notes, or similar records. When the medical records clearly show that the beneficiary received only non-covered services as described in the Medicare Benefit

Policy Manual, the healthcare provider or supplier will be presumed to have knowledge of non-coverage.

Examples:

- A physician clearly indicated in the beneficiary'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 beneficiary'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 healthcare provider or supplier did not submit the evidence within the stipulated time.

30.2.3 - Acceptable Standards of Practice

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

When an item and/or service furnished do not meet locally acceptable standards of practice, the healthcare provider or supplier is considered to have known that Medicare payment would be denied. Because healthcare provider and supplier licensure is premised on the assumption that they are knowledgeable about locally acceptable standards of practice, healthcare providers and suppliers are presumed to have knowledge about locally acceptable standards of practice for liability determinations. No other evidence of knowledge of local medical standards of practice is necessary.

In order to determine what "acceptable standards of practice" exist within the local medical community, Medicare contractors will rely on the following:

- published medical literature;[1]
- a consensus of expert medical opinion;[2] and

---

[1] "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."

[2]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.

- consultations with their medical staff, medical associations, including local medical societies, and other health experts.

NOTE: A healthcare provider or supplier may indicate on the claim (via Occurrence Code 32 or the applicable Healthcare Common Procedure Coding System code modifier (i.e. GA, GX, ext.) on contractor claims) that they gave the beneficiary a valid written notice before furnishing the item and/or service. In that instance, the Medicare contractor will hold the beneficiary, not the healthcare provider or supplier liable for the denied charges. If it is determined that the written notice was invalid, the contractor will override the GA code, and the healthcare provider or supplier will be found liable.

30.3 – The Right to Appeal

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

The beneficiary, healthcare provider, or supplier has the right to appeal both the issue of coverage for the claim and determination of liability. For purposes of determining the amount in controversy for an appeal of the coverage determination, payment made under §1879 of the Act should be disregarded. For more information see Chapter 29 of this manual, Appeals of Claims Decisions.

30.4 - Fraud, Abuse, Patently Unnecessary Items and Services

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

Generally, the protection under the FLP provisions cannot be afforded to a healthcare provider or supplier if a formal finding of fraud or abuse has been made with regard to a healthcare provider's or supplier's billing practices. In cases where a formal finding of fraud or abuse is made, an immediate finding of liability for the healthcare provider or supplier results. Abuse exists when a healthcare provider or supplier furnishes item and/or service 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. The Medicare contractor will also make an immediate finding of liability in situations where a healthcare provider or supplier furnishes items and/or services that are so patently unnecessary that all healthcare providers or suppliers could reasonably be expected to know that they are not covered.

40 - Written Notice as Evidence of Knowledge

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

One regulatory basis for determining beneficiary knowledge can be found at 42 CFR 411.404. Under these regulations, there is a presumption that the beneficiary knew, or could reasonably have been expected to know, that Medicare payment for an item or service would be denied if written notice was given to the beneficiary that the items or services were not covered. A written notice that a beneficiary received may be considered as evidence of prior knowledge with respect to such same or similar item(s) and/or service(s) that is denied Medicare payment for the same reason in both cases.

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 of the item and/or service that otherwise might be paid for, that Medicare certainly or probably will not pay for in that particular occasion.

The written notice allows the beneficiary to:

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

If the healthcare provider or supplier expects payment for the item and/or service to be denied by Medicare, the healthcare provider or supplier must advise the beneficiary in advance 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.

40.1 - Sources of Written Notice

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

Generally, the written notice of the likelihood of Medicare payment denial (e.g. an ABN, Form CMS-R-131) should be furnished to the beneficiary:

- By a healthcare provider or supplier before the item and/or service is furnished;
- After the Medicare contractor, during the course of the beneficiary's stay, advised the healthcare provider or supplier that covered care had ceased;
- By a healthcare provider or supplier utilization review committee that, on admission or during the patient's stay, advised that the beneficiary no longer required covered care;
- By the Medicare contractor; or

- By a qualified notifier so that the beneficiary may have confidence in and rely upon the accuracy and credibility of the notice.

40.2 - Written Notice Standards

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

The healthcare provider or supplier should issue a written notice each time, and as soon as, it makes the assessment that Medicare payment certainly or probably will not be made in order to transfer potential financial liability to the beneficiary. A healthcare provider or supplier, should notify a beneficiary by means of timely and effective delivery of a written notice document to a qualified recipient. Any written notice should meet the following written notice standards as evidence of the beneficiary's knowledge for the purposes of the FLP provisions, except as otherwise explicitly specified. A notification which does not meet the following written notice standards may be ruled invalid and may not serve to protect the interests of the notifier.

A written notice will not be considered as acceptable evidence of knowledge if the written notice is:

- Unreadable, illegible, or otherwise incomprehensible, or the individual beneficiary is incapable of understanding the written notice due to the particular circumstances (even if others may understand);

- Given during any emergency, or the beneficiary is under great duress, or the beneficiary is, in any way, coerced or misled by the notifier, by the contents of the written notice, and/or by the manner of delivery of the written notice;

- Routinely given to all beneficiaries for whom the notifier furnishes items and/or services;

- No more than a statement to the effect that there is a possibility that Medicare may not pay for the items or services; or

- Delivered to the beneficiary more than one year before the items and/or services are furnished.

NOTE: A previously furnished written notice is acceptable evidence of written notice for current items and/or services if the previous written notice cites similar or reasonably comparable items and/or services for which denial is expected on the same basis in both cases. A written denial (on the same basis in both cases) of payment from a Medicare contractor for a claim for the same or similar item and/or service received by the beneficiary is acceptable evidence of written notice for current item and/or service.

Written Notice Standard	Description
Proper Written Notice Documents	• An approved standard form (e.g., Form CMS-R-131); or • A CMS approved model notice language (e.g., Form CMS-10055)
Qualified Notifiers	"Notifiers" are generally the healthcare provider or supplier that furnished or ordered the item(s) and/or service(s).
Capable Recipient	The beneficiary must: • Be able to read, understand, act on his/her rights, and comprehend the notice; • Be issued the written notice in a manner that allows her/him to comprehend the contents of the written notice. (e.g., when the beneficiary (or authorized representative) is unable to read the notice due to a disability such as blindness, visual impairment or deafness) This can be done by a verbal or electronic reading of the notice, by providing the written notice in Braille or large print, or by the use of other assistive technology. The notifier should document any actions taken to assist with the delivery of the written notice on the notice; and • Be afforded the verbal or written assistance in other languages to assist in understanding the notice. If a translator who can speak the beneficiary's language is not available, the notifier should assist by calling 1-800-MEDICARE so a customer service representative can connect the beneficiary with the Language Line for translation services.
Identification of Notifier	The header of the written notice must identify the notifier or notifier(s). In situations where the notifier is not the billing entity, it is permissible to enter the names of more than one entity in the header of the notice.

Written Notice Standard	Description
	If the header identifies the entity or person that obtained the written notice, rather than the entity or person that is billing for the item and/or service, the Medicare contractor will consider the written notice form to be valid so long as it was otherwise properly executed.

40.2.1 - Other Written Notice Standards

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

A. Timeliness

Written notice delivery:

- Must be issued far enough in advance of an event (e.g., receiving a medical service) so that the beneficiary can make a rational, informed decision without undue pressure; or
- 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.

Written notice is permissible:

- If a situation arises when a notifier sees a need for a previously unforeseen item or service and expects that Medicare will not pay for it only in certain specific denial reasons, 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); or

- 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).

NOTE: Last minute notification can be coercive, and a coercive notice is an invalid notice.

B. Written Notice Delivery

A written notice:

- Should be delivered in person to the beneficiary or authorized representative whenever possible. Delivery is the notifier's responsibility;

- Must be prepared with an original and at least two copies. The notifier should retain the original and give the copy to the beneficiary or authorized representative. Legible duplicates (carbons, etc.), fax copies, electronically scanned copies, or photocopies will suffice;

- Copy should be given to the beneficiary (or authorized representative) immediately after the beneficiary (or authorized representative) signs it.

If a beneficiary is not given a copy of the written notice and if the beneficiary later alleges that the written notice presented to the Medicare contractor by the notifier is different in any material respect from the written notice s/he signed, the Medicare contractor will give credence to the beneficiary's allegations. If the notifier is unable to deliver the notice to the beneficiary, the Medicare contractor will hold that the beneficiary did not receive proper written notice and will hold the notifier liable.

In a case where the notifier that gives a written notice is not the entity which ultimately bills Medicare for the item(s) and/or service(s), (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 written notice to the billing entity as well as the beneficiary.

C. Reason for Predicting Denial

The written notice 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 decision whether or not to receive the item or service and pay for it. Statements of reasons for predicting Medicare denial of payment at a level of detail similar to the approved "Medical Necessity" messages for Medicare Summary Notices are acceptable for written notice purposes. 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 Medicare contractor will not invalidate a written notice on the basis of citing more than one reason for denial.

The following could result in an invalid written notice:

- Simply stating "medically unnecessary" or the equivalent is not an acceptable reason, as it does not explain why the healthcare provider or supplier believes the item and/or service will be denied as not reasonable and necessary.

- 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.

40.2.2 - Written Notice Special Considerations

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

A. Responsiveness to Inquiries

A notifier must answer any questions from a beneficiary regarding the written notice. This includes requests for further information and/or assistance in understanding and responding to a notice. The Medicare contractor will hold that a beneficiary did not receive proper written notice in any case where it finds that the notifier refused to answer inquiries.

B. Dealing With Beneficiary Refusals

A beneficiary who has been given a written notice may decide to receive the item(s) and/or service(s). In this case, the beneficiary should indicate that s/he is willing to be personally and fully responsible for payment. When a beneficiary decides to decline an item or service, s/he should so indicate. If a beneficiary refuses to sign a valid written notice, 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 written notice indicating the circumstances and persons involved. The notifier should have the annotation witnessed.

- **Claims to Which LOL Provisions Apply -** If the beneficiary demands the item or service and refuses to pay, the notifier should have a second person witness the provision of the written notice and the beneficiary's refusal to sign. 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 written notice by telephone and may sign the written notice annotation at a later time. An unused patient signature line on the written notice 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 written notice. The beneficiary will be held liable in case of a denial.

- **Claims to Which RR Provisions 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 written notice and to the beneficiary's agreement to pay. The beneficiary must receive a valid written notice so that s/he 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 as the cases of claims to which LOL provisions apply. If the beneficiary demands the item or 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 written notice 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 written notice. If the items or services are furnished despite the beneficiary's refusal to pay, the physician or supplier should file the claim as not having obtained a signed written notice. The Medicare contractor will not hold the beneficiary liable and will hold the physician or supplier liable.

NOTE: 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.

C. Routine Notice Prohibition

In general, the "routine" use of written notices is not effective and therefore is not an acceptable practice. By "routine" use, CMS means giving written notice to beneficiaries where there is no specific, identifiable reason to believe Medicare will not pay. Notifiers should only give written notices to beneficiaries when there is some genuine doubt that Medicare will make payment. If the Medicare contractor identifies a pattern of routine notices in situations where such notices clearly are not valid, it will write to the notifier and remind it of these standards. While in general, routine written notices are invalid and will not protect the notifier from liability, there are some exceptions.

- **Generic Written Notices** – "Generic written notices" are routine written notices 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 written notices" are not considered to be acceptable evidence of written notice and will not protect the notifier from liability. The written notice must specify the item and/or service and a genuine reason that denial by Medicare is expected. Written notice 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 item and/or service.

- **Blanket Written Notices** - Giving written notices for all claims or items or services (i.e., "blanket written notices") 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.

- **Signed Blank Written Notices** - A notifier is prohibited from obtaining beneficiary signatures on blank written notices and then completing the written notices later. In order for a written notice to be effective, it must be completed before delivery to the beneficiary. The Medicare contractor will hold any written notice that was blank when it was signed to be an invalid notice that will not protect the notifier from liability.

- **Routine Written Notice Prohibition Exceptions** - In general, routine written notices will not be considered valid. There are, however, a few limited circumstances when a routine notice can be given to a beneficiary and considered effective.

Exception	Description
Items or Services Which Are Always Denied for Medical Necessity	In any case where a national coverage decision provides that a particular item or 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), a written notice 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.
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 items or 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 a written notice that gives as the reason for expecting denial that: "Medicare does not pay for items or services which it considers to be experimental or for research use." Language with respect to "Medicare coverage for clinical trials" may be substituted as the reason for expecting denial.
Frequency Limited Items and Services	When Medicare has established a frequency limit for any item or service, a routine written notice can be given. This is applicable anytime a frequency limitation is made through statute or regulation, through medical national coverage determinations, or on the basis of the Medicare contractor's local

Exception	Description
	coverage determinations. In any such routine written notice, the notifier must state the frequency limitation as the reason for expecting denial (e.g., "Medicare does not pay for this item or service more often than frequency limit").
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, and under §1834(a)(17)(B) of the Act, apply to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally, the usual prohibition on routine notices to all beneficiaries does not apply in these cases.

NOTE: A routine written notice, like any other written notice, is valid only for the denial reason specified on the notice. A written notice will not be considered a valid notice in the case of any Medicare denial of the claim for any reason other than that specified on the notice.

40.3 - Medical Emergency or Otherwise Under Great Duress Situations

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

A written notice 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 decision. A beneficiary (or authorized representative) cannot be expected to make an informed, rational decision when in an emergency situation and therefore cannot be considered a capable recipient. If the beneficiary is not capable of receiving the notice, then the beneficiary has not received proper written notice and cannot be held liable where the LOL or RR provisions apply, and the notifier may be held liable.

Examples:

- Ambulance companies may not give written notices to beneficiaries (or authorized representatives) in any emergency transport because such beneficiaries are under great duress.

- Skilled nursing facilities may not give written notices in the case of "middle-of-the-night" emergencies or in any other emergency circumstances, since the beneficiary clearly cannot make an informed decision.

NOTE: The Medicare contractor will consider any written notice given in any kind of coercive circumstances, including medical emergencies, to be invalid. The Medicare

contractor will determine the healthcare provider's or supplier's liability by the appropriate knowledge standards which are used in cases where written notices are not given and beneficiary agreements to pay are not obtained.

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

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

A written notice should not be given to a beneficiary in any case in which EMTALA (§1867 of the Act) applies, until the hospital has met its obligations under EMTALA. These include 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). This policy also includes times when a beneficiary does not appear to have a life threatening condition, rather, h/she is seeking primary care services at an ER, if EMTALA applies.

A written notice that is otherwise appropriate may be given to a Medicare beneficiary who is seen in the ER after completion of an MSE, but a written notice should not be given unless there is a genuine reason to expect that Medicare will deny payment for the item and/or service. EMTALA does not prohibit asking payment questions entirely, rather, only doing so before screening/stabilization. After screening/stabilization, EMTALA no longer applies and written notices may be given, as applicable, to beneficiaries who come to emergency care settings after they have received a medical screening examination and are stabilized.

50 - Advance Beneficiary Notice of Non-coverage (ABN)

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

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

Section 1879 of the Act (where the LOL provisions are located) requires a healthcare provider or supplier (i.e. notifier) to notify a beneficiary in advance of furnishing an item or service when s/he believes that items or services will likely be denied by Medicare for any of the reasons specified in the statutory provision in order to shift financial liability to the beneficiary for the denial. For example, advance notice is required if the item or service may be denied as not reasonable and necessary under §1862(a)(1) of the Act or because the item or service constitutes custodial care under §1862(a)(9) of the Act.

Notice (e.g., the ABN) is a way for healthcare providers or suppliers to establish beneficiary knowledge of non-coverage and therefore, shift financial liability for these items or services if Medicare denies the claim.

B. Compliance with Limitation on Liability Provisions

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

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

ABN - Quick Glance Guide[3]

Notice Name: Advance Beneficiary Notice of Non-coverage (ABN)
Notice Number: Form CMS-R-131
Issued by: Healthcare providers and suppliers of Medicare Part B items and services;
Hospice and Religious Non-medical HealthCare Institute (RNHCI) providing Medicare Part A items and services;
and home health agencies(HHAs) for Part A and Part B items and services
Recipient: Original Medicare FFS (fee for service) beneficiary;

Type of notice:	Must be issued:	Timing of notice:	Optional use:
Financial liability notice	Prior to providing an item or service that is usually paid for by Medicare under Part B (or under Part A for hospice, HHA, and RNHCI providers only) but may not be paid for in this particular case because it is not considered medically reasonable and necessary Prior to providing custodial care For hospice providers, prior to caring for a patient who is not terminally ill For Durable Medicare Equipment (DME) suppliers For HHA providers, prior to providing care when the individual is not confined to the home or does not need intermittent skilled nursing care.	Prior to delivery of the item or service in question. Provide enough time for the beneficiary to make an informed decision on whether or not to receive the service or item in question and accept potential financial liability.	Yes. Prior to providing an item or service that is never covered by Medicare (i.e. not a Medicare benefit).

[3] This is an abbreviated reference tool and is not meant to replace or supersede any of the directives contained in Section 50.

50.1 - ABN Scope

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

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

The ABN is given to beneficiaries enrolled in the Medicare FFS program. It is not used for items or services provided under the Medicare Advantage (MA) Program or for prescription drugs provided under the Medicare Prescription Drug Program (Part D).

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

50.2 - ABN Uses

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

The following provisions necessitate delivery of the ABN:

- §1862(a)(1) of the Act (not reasonable and necessary);
- §1834(a)(17)(B) of the Act (violation of the prohibition on unsolicited telephone contacts);
- §1834(j)(1) of the Act (medical equipment and supplies supplier number requirements not met);
- §1834(a)(15) of the Act (medical equipment and/or supplies denied in advance);
- §1862(a)(9) of the Act (custodial care);
- §1879(g)(2) of the Act (hospice patient who is not terminally ill);
- §1879(g)(1) of the Act (home health services requirements are not met – not confined to the home or no need for intermittent skilled nursing care);
- §1862(a)(1)(P) of the Act, Medicare covered personalized prevention plan services (as defined in §1861(hhh)(1)) that are performed more frequently than indicated per

coverage guidelines are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member);

- Under 42 CFR §414.408(e)(3)(ii) when a noncontract supplier furnishes an item included in the Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for a Competitive Bidding Area (CBA). Although all other denial reasons triggering mandatory use of the ABN are found in §1879 of the Act, in this situation, §1847(b)(5)(D) of the Act permits use of the ABN with respect to these items and services; or

- When Medicare considers an item or service experimental (e.g., a "Research Use Only" or "Investigational Use Only" laboratory test), payment for the experimental item or service is denied under §1862(a)(1) of the Act as not reasonable and necessary. In circumstances such as this, the beneficiary must be given an ABN.

50.2.1 - Optional ABN Uses

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

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

- Care that fails to meet the definition of a Medicare benefit as defined in §1861 of the Social Security Act;

- Care that is explicitly excluded from coverage under §1862 of the Social Security Act. Examples include:

  - Services for which there is no legal obligation to pay;
  - Services paid for by a government entity other than Medicare (this exclusion does not include services paid for by Medicaid on behalf of dual-eligibles);
  - Services required as a result of war;
  - Personal comfort items;
  - Routine eye care;
  - Dental care; and
  - Routine foot care.

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

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

50.3 - Issuance of the ABN

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

Notifiers	May direct an employee or a subcontractor to deliver an ABN. The billing entity will always be held responsible for effective delivery regardless of who gives the notice. 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" healthcare providers or supplier (e.g. a physician orders a lab test and an independent laboratory delivers the ordered tests); • One healthcare provider or supplier 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). When the notifier is not the billing entity, the notifier must know how to direct the beneficiary who received the ABN to the billing entity for questions and should annotate the Additional Information section of the ABN with this information. It is permissible to enter the names of more than one entity

	in the header of the notice.
Representatives of Beneficiaries	If the beneficiary has a known, legally authorized representative, the ABN must be issued to the existing representative. If a beneficiary does not have a representative and one is necessary, a representative may be appointed for purposes of receiving notice following CMS guidelines and as permitted by State and Local law. When a representative is signing the ABN on behalf of a beneficiary, the ABN should be annotated to identify that the signature was penned by the "rep" or "representative". If the representative's signature is not clearly legible, the representative's name should be printed on the ABN. See section 500 of this manual under "Authorized representative" for more information.

50.4 - ABN Triggering Events

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

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

	prior to delivery of this non-covered care.	

50.5 - ABN Standards

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

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

The online replicable copies of the OMB approved ABN (CMS-R-131) and instructions for notice completion are available on the CMS website at: http://www.cms.gov/Medicare/Medicare-General- Information/BNI/ABN.html

A. Language Choice

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

B. Effective Versions

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

C. General Notice Preparation Requirements

Number of Copies	A minimum of two copies, including the original, should be made so the beneficiary and notifier each have one. The notifier should retain the original whenever possible.
Reproduction	Notifiers may reproduce the ABN by using self-carbonizing paper, photocopying, digitized technology, or another appropriate method. All

	reproductions should conform to applicable requirements.
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 attachments are used, they should allow for clear matching of the items or services in question with the reason and cost estimate information. The ABN is designed as a letter- sized form. If necessary, it may be expanded to a legal-sized page.
Contrast of Paper and Print	A visually high-contrast combination of dark ink on a pale background should be used. Do not use reversed print (i.e. white print on black paper), or block-shaded (highlighted) text.
Font	Fonts as they appear in the ABN downloaded from the CMS web site should be used. In cases where changes need to occur, notifiers should use alternative fonts that are easily readable, such as Arial, Arial Narrow, Times New Roman, and Courier. Any other changes to the font, such as italics, embossing, bold, etc., should not be used since they can make the ABN more difficult to read. The font size generally should be 12 point. Titles should be 14-16 point, but insertions in blanks of the ABN can be as small as 10 point if needed. Information inserted by notifiers in the blank spaces on the ABN may be typed or legibly hand-written.
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 when the ABN is issued and should not be pre-filled. Lettering of the blanks (A-J) should be removed prior to issuance of an ABN. If pre-printed information is used to describe items/services and/or common reasons for non-coverage, the notifier must clearly indicate on the ABN which portions of the pre- printed information are applicable to the beneficiary Healthcare providers or suppliers who pre-print a menu of items or services may wish to list a cost estimate alongside each item or service.
Modification	The ABN may not be modified except as specifically allowed by these instructions. Notifiers must exercise caution before adding any customizations beyond these guidelines, since changing ABNs too much could result in invalid notice and healthcare provider or supplier liability for non-covered charges. Validity judgments are generally made by Medicare contractors, usually when reviewing ABN-related claims; however, any complaints received may be investigated by contractors and/or CMS central or regional offices.

50.6 - Completing the ABN

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

Step-by-step instructions for notice completion are posted along with the notice on the CMS website and can be downloaded via this link:
http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html

A. Other Considerations During ABN Completion

1. Beneficiary Changes His/her Mind

If after completing and signing the ABN, a beneficiary changes his/her mind, the notifier should present the previously completed ABN to the beneficiary and request that the beneficiary annotate the original ABN. The annotation must include a clear indication of

his/her new option selection along with the beneficiary's signature and date of annotation. In situations where the notifier is unable to present the ABN to the beneficiary in person, the notifier may annotate the form to reflect the beneficiary's new choice and immediately forward a copy of the annotated notice to the beneficiary to sign, date, and return.

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

2. Beneficiary Refuses to Complete or Sign the Notice

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

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

50.7 - ABN Retention

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

The notifier should retain the ABN delivered to the beneficiary on file should there be any question regarding whether the beneficiary had knowledge of the potential financial liability. In certain situations, such as delivery by fax, the notifier may not have access to the original document upon signing. Retention of a copy of the signed document would be acceptable in specific cases such as this.

In a case where the notifier that gives an ABN is not the entity that ultimately bills Medicare for the item or service (e.g. when a physician issues an ABN, draws a test specimen, and sends it to a laboratory for testing), the notifier should give a copy of the signed ABN to the billing entity.

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

50.8 - Effective ABN Delivery

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

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

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

2. Provided using the correct OMB approved notice with all required blanks completed. Failure to use the correct notice may lead to the notifier being found liable since the burden of proof is on the notifier to show that knowledge was conveyed to the beneficiary according to CMS instructions.

3. Delivered to the beneficiary in person if possible.

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

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

   The notifier should direct the beneficiary to call 1-800-MEDICARE if the beneficiary has questions s/he cannot answer. If a Medicare contractor finds that the notifier refused to answer a beneficiary's inquiries or direct them to 1-800-MEDICARE, the notice delivery will be considered defective, and the notifier will be held financially liable for non-covered care.

6. Signed by the beneficiary.

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

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

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

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

For items or services that are repetitive or continuous in nature, notifiers may issue another ABN to a beneficiary after one year for subsequent treatment for the non-

covered condition. However, this is not required unless any of the conditions described above apply to the given situation.

Notifiers may give a beneficiary a single ABN describing an extended or repetitive course of non-covered treatment provided that the ABN lists all items and services that the notifier believes Medicare will not cover. If applicable, the ABN must also specify the duration of the period of treatment. If during the course of treatment additional non-covered items or services are needed, the notifier must give the beneficiary another ABN.

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

B. Incomplete ABNs

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

C. Electronic Issuance of the ABN

Electronic issuance of ABNs is not prohibited. If a healthcare provider or supplier elects to issue an ABN that is viewed on an electronic screen before signing, the beneficiary has the option of requesting paper issuance over electronic if that is what s/he prefers. Also, regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary should be given a paper copy of the signed ABN to keep for his/her own records.

50.8.1- Options for Delivery Other than In-Person

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

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

- Direct telephone contact;
- Mail;
- Secure fax machine; or
- Internet e-mail.

All methods of delivery require adherence to all statutory privacy requirements under

HIPAA. The notifier must receive a response from the beneficiary or his/her representative in order to validate delivery.

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

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

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

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

A. Beneficiary Liability

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

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

B. Healthcare Provider or Supplier Liability

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

A notifier may be protected from financial liability when an ABN is required if s/he is able to demonstrate that s/he did not know or could not reasonably have been expected to know that Medicare would not make payment.

50.10 - Using ABNs for Medical Equipment and Supplies Claims When Denials Under §1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts) Are Expected

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

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

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

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

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

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

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

agreement from the beneficiary every time the beneficiary does business with the supplier.

Exception to ABN Requirement

A supplier which can show that it did not know and could not reasonably have been expected to know that a customer was a Medicare beneficiary, or that a customer was making a purchase for a Medicare beneficiary, can seek protection under the LOL provision or, in the case of unassigned claims, under the applicable RR provision, §1834(j)(4) of the Act. Below are situations where the supplier may seek protection under the LOL provision or the RR provision:

- If the supplier can show that a person who is not a Medicare beneficiary made a purchase on behalf of a person who is a Medicare beneficiary and did not apprise the supplier of the fact that the purchase was being made on behalf of a Medicare beneficiary, the supplier may be protected.

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

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

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

Given the possible difficulty of showing conclusively that it did not know and could not reasonably have been expected to know that a customer was a Medicare beneficiary, or that a customer was making a purchase for a Medicare beneficiary, a supplier would be well advised to consider using signage, giving public notice alerting customers that they need to inform the supplier if they are a Medicare beneficiary or are making a purchase for a Medicare beneficiary. If a supplier which does not have a supplier number provides adequate public notice to a Medicare beneficiary before medical equipment or supplies

are furnished (e.g., by means of clearly visible signs, and if the adequacy of such public notice is not disputed by the beneficiary) the supplier can qualify for waiver of the Refund Requirements. Such public notices must be such that Medicare beneficiaries:

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

2. May reasonably be expected to be able to read them and understand them.

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

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

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

50.12 - ABNs for Claims Denied in Advance Under §1834(a)(15) of the Act

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

A. Mandatory

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

- The item is listed by the Secretary as being subject to unnecessary utilization in your contractor's service area under §1834(a)(15)(A); or

- The supplier is listed by the Secretary under §1834(a)(15)(B) of the Act as a supplier who has submitted a substantial number of claims, which have been denied as not medically reasonable and necessary under §1862(a)(1) of the Act or the Secretary has identified a pattern of overutilization.

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

B. Optional

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

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

50.13 - ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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

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

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

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

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

Section 1862 (a)(17) of the Act excludes Medicare payment for CBP items/ services that are provided by a non-contract supplier in a Competitive Bidding Area (CBA) except in special circumstances. A non-contracted supplier is permitted to provide a beneficiary

with an item or service listed in the CBP when the supplier properly issues an ABN prior to delivery of the item or service per 42 CFR §414.408(e)(3)(ii). In order for the ABN to be considered valid when issued under these circumstances, the reason that Medicare may not pay must be clearly and fully explained on the ABN that is signed by the beneficiary.

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

50.15 - Collection of Funds and Refunds

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

Collection of Funds

A beneficiary's agreement to be responsible for payment on an ABN means that the beneficiary agrees to pay for expenses out-of-pocket or through any insurance other than Medicare that the beneficiary may have. The notifier may bill and collect funds from the beneficiary for non-covered items or services immediately after an ABN is signed, unless prohibited from collecting in advance of the Medicare payment determination by other applicable Medicare policy, State or local law. Regardless of whether they accept assignment or not, healthcare providers and suppliers are permitted to charge and collect the usual and customary fees; therefore, funds collected are not limited to the Medicare allowed amounts.

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

50.15.1 - Physicians' Services RR

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

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

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

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

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

50.15.2 - DMEPOS RR Provision for Claims for Medical Equipment and Supplies

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

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

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

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

50.15.3 - Time Limits and Penalties for Healthcare providers and Suppliers in Making Refunds

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

A required refund must be made within specified time limits:

- The refund must be made to the beneficiary within 30 days after the date the healthcare provider or supplier receives the remittance advice (RA) if the healthcare provider or/supplier does not request review of an initial full or partial denial; or

- The refund must be made to the beneficiary within 15 days after the date the healthcare provider or supplier receives the notice of the review determination if the healthcare provider or supplier requests review within 30 days of receipt of the notice of the initial determination.

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

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

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

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

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

If a supplier makes proper refund under §1834(a)(18) of the Act, Medicare rules do not prohibit the supplier from recovering from the beneficiary items which are resalable or re-rentable. When the contract of sale or rental is cancelled on the basis described above, the supplier may enter into a new sale or rental transaction with the beneficiary as long as

the beneficiary has been informed of their liability. If the circumstances which preclude payment for the item have been removed (e.g. the supplier has now obtained a supplier number when that supplier did not have one before), the supplier may submit to the Medicare contractor a new claim based on the resale or re-rental of the item to the beneficiary. If payment is still precluded, the supplier can issue an ABN.

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

50.16 - CMS Regional Office (RO) Referral Procedure

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

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

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.
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.
Written Correspondence and Written Summaries	Copies of any meetings or telephone contacts with the beneficiary and the supplier regarding the supplier's failure to make a refund.
List of the following for each item or service not refunded to the beneficiary by the supplier (grouped by beneficiary):	•Beneficiary Name and Medicare beneficiary identifier; •Claim Control Number; •Procedure Code (CPT-4 or HCPCS) of non-refunded 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.
Additional Information	Any information that may be of value to the RO.

50.17 – ABN Special Considerations

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

A. Obligation to Bill Medicare

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

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

Note: Healthcare providers or suppliers will not violate mandatory claims submission rules under Section 1848 of the Social Security Act when a claim is not submitted to Medicare at the beneficiary's request by their choice of Option 2 on the ABN.

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

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

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

☐ **OPTION 1.** I want the (D)_____listed above. ~~You may ask to be paid now, but~~ I ~~also~~ want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). ~~I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN.~~

These edits are required because the provider cannot bill the dual eligible beneficiary when the ABN is furnished. Providers must refrain from billing the beneficiary pending adjudication by both Medicare and Medicaid in light of federal law affecting coverage and billing of dual eligible beneficiaries. If Medicare denies a claim where an ABN was needed in order to transfer financial liability to the beneficiary, the claim may be crossed

over to Medicaid or submitted by the provider for adjudication based on State Medicaid coverage and payment policy. Medicaid will issue a Remittance Advice based on this determination.

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

- If the beneficiary has QMB coverage without full Medicaid coverage, the ABN could allow the provider to shift financial liability to the beneficiary per Medicare policy.

- If the beneficiary has full Medicaid coverage and Medicaid denies the claim (or will not pay because the provider does not participate in Medicaid), the ABN could allow the provider to shift financial liability to the beneficiary per Medicare policy, subject to any state laws that limit beneficiary liability.

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

C. Ambulance Transports

Emergency or urgent situations	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.
Non-emergent/urgent ambulance transport	If the provider or supplier wants to transfer liability to the beneficiary, issuance of the ABN is mandatory for ambulance transport services if all of the following 3 criteria are met:: 1. The service being provided is a Medicare covered ambulance benefit under §1861(s)(7) of the SSA and regulations under this section as

	stipulated in 42 CFR §410.40 -.41; 2. The healthcare provider or supplier believes that the service may be denied, in part or in full, as "not reasonable and necessary" under § 1862(a)(1)(A) for the beneficiary on that particular occasion; and 3. The ambulance service is being provided in a non-emergency situation. (The patient is not under duress.)

ABN issuance is mandatory only when a beneficiary's covered ambulance transport is modified to a level that is not medically reasonable and necessary and will incur additional costs. If an ambulance transport is statutorily excluded from coverage because it fails to meet Medicare's definition of the ambulance benefit, a voluntary ABN may be issued to notify the beneficiary of his/her financial liability as a courtesy.

D. Hospice

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

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

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

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

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

End of all Medicare covered hospice care –

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

ABNs are not required for Hospice Services in these situations:

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

- **Respite Care Beyond Five Consecutive Days -** Respite care is limited to five consecutive days under the Act. When respite care exceeds five consecutive days, an ABN is not required since additional days of respite care are not part of the hospice benefit. CMS encourages hospice providers to give the ABN as an optional notice to inform patients of financial liability when more than five days of respite care will be provided.

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

- **Failure to Meet the Face to Face Requirement -** The ABN must not be issued when the face to face requirement for hospice recertification is not met within the required timeframe. Failure to meet the face to face requirement for recertification should not be misrepresented as a determination that the beneficiary is no longer terminally ill.

- **Room and Board Costs for Nursing Facility Residents -** Since room and board are not part of the hospice benefit, an ABN would not be required when the patient elects hospice and continues to pay out of pocket for long term care room and board.

E. Comprehensive Outpatient Rehabilitation Facility (CORF)

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

When all Medicare covered CORF services are going to end, CORF's are required to

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

F. Home Health Agency (HHA)

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

Application of LOL for the Home Health Benefit

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

Triggering Events for ABN issuance by HHAs*

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

EVENT	DESCRIPTION	EXAMPLE
Initiation	An ABN must be issued to the beneficiary prior to receiving care that is usually covered by	A beneficiary requires skilled nursing

	Medicare, but in this particular instance, it is not covered or may not be covered by Medicare because the care is not medically reasonable and necessary, the beneficiary is not confined to his/her home (considered homebound), or the beneficiary does not need skilled nursing care on an intermittent basis, or the beneficiary is receiving custodial care only.	wound care 3 times weekly; however, she is not confined to the home. She wants the care done at her home by the HHA.
Reduction	Reductions involve any decrease in services or supplies, such as frequency, amount, or level of care, provided by the HHA and/or care that is part of the POC. If a reduction occurs for an item or service that will no longer be covered by Medicare but the beneficiary wants to continue to receive the care and assume the financial charges, the HHA must issue the ABN prior to providing the non-covered items or services.	The beneficiary requires physical therapy (PT) for gait retraining 5 times per week for 2 weeks, then reduce to 3 times weekly for 2 weeks. After 2 weeks of PT, the beneficiary wants to continue therapy 5 times a week even though this amount of therapy is no longer medically reasonable and necessary. The HHA would issue an ABN to the beneficiary so that he understands the situation and can consent to financial responsibility for the PT not covered by Medicare.
Termination	When an HHA expects that Medicare coverage will end for all items and services in total.	

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

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

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

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

HHA Exceptions to ABN Notification Requirements

ABN issuance is NOT required in the following HHA situations:

- initial assessments (in cases where beneficiaries are not admitted) for which HHAs do not charge;
- care that is never covered by Medicare under any circumstances (i.e., an HHA offers complimentary hearing aid cleaning and maintenance);
- telehealth monitoring used as an adjunct to regular covered HH care; or
- non-covered items/services that are part of care covered in total under a Medicare bundled payment (e.g., HH prospective payment system (PPS) episode payment).

60 - Home Health Change of Care Notice (HHCCN), Form CMS-10280

(Rev. 2781, Issued: 09-06-13, Effective: 12-09-13, Implementation: 12-09-13)

This section provides the standards for use by home health agencies (HHAs) in implementing the Home Health Change of Care Notice (HHCCN), Form CMS-10280, requirements. The HHCCN is issued to Original Medicare beneficiaries before reducing or terminating most ongoing care provided by the HHA.

HHCCN Quick Glance Guide This is an abbreviated reference tool and is not meant to replace or supersede any of the directives contained in Section 60.			
Notice Name	Home Health Change of Care Notice (HHCCN)		
Notice Number	Form CMS-10280		
Issued by	Home Health Agency (HHA) provider		
Recipient	Original Medicare (fee for service) beneficiary receiving home health care		
Pertinent Information	The HHCN replaces HHABN Option Box 2 and Option Box 3. The Advance Beneficiary Notice of Noncoverage (ABN), CMS-R-131, replaces HHABN Option Box 1. See section 50 for ABN information and instructions.		
Change of care notice	Prior to the HHA reducing or discontinuing care listed in the beneficiary's plan of care (POC) for administrative reasons specific to the HHA on that occasion	Immediately on determination, or if possible, provide enough time for the beneficiary to arrange to obtain the reduced or discontinued home health care service(s) from a different HHA.	No.
	Prior to the HHA reducing or discontinuing Medicare covered care listed in the POC because of a physician ordered change in the plan of care or a lack of orders to continue the care	Notify the beneficiary before the actual reduction or discontinuation, if possible.	No.

The HHCCN replaces the Home Health Advance Beneficiary Notice (HHABN), CMS-R-296, Option Box 2 and Option Box 3. Option Box 1 of the HHABN is replaced by the existing Advance Beneficiary Notice of Noncoverage (ABN),CMS-R-131, which is detailed in Section 50 of this chapter. HHAs should begin using the ABN and HHCCN in place of the HHABN as soon as possible since the HHABN will be discontinued. The date for mandatory use of the HHCCN and ABN in place of the HHABN will be posted on the web link for home health notices at http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html.

Table 1 HHA Notice Changes

Instead of:	**Use:**
HHABN Option Box 1	ABN (CMS-R-131)
HHABN Option Box 2	HHCCN
HHABN Option Box 3	HHCCN

60.1 - Background on the HHCCN

(Rev. 2781, Issued: 09-06-13, Effective: 12-09-13, Implementation: 12-09-13)

HHAs have issued 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) since 2002. The HHABN gained additional notification capabilities in 2006 following the U.S. Court of Appeals (2nd Circuit) decision in Lutwin v. Thompson, 361 F.3d 146; 2004 U.S. App. LEXIS 3774. Following Lutwin, the HHABN was modified so

that it could also be used by HHAs to notify beneficiaries receiving home health services of any care changes in accordance with the HHA conditions of participation (COPs) in §1891 of the Act.

To account for this expanded use, the HHABN was revised to contain three interchangeable Option Boxes within the body of the notice designated as Option Box 1, Option Box 2, and Option Box 3. Option Box 1 language was applicable to situations involving potential beneficiary liability for HHA services as directed by §1879 of the Act. Option Box 2 or Option Box 3 was inserted into the HHABN form to notify beneficiaries of changes in a home health plan of care that are subject to the requirements of § 1891 of the Act.

In order to streamline, reduce, and simplify notices issued to Medicare beneficiaries, the HHABN is being discontinued. HHABN, Option Box 1, which is the liability portion of the notice, is replaced by the existing Advance Beneficiary Notice of Noncoverage (ABN), CMS-R-131. The change of care notification portions of the HHABN, Option Box 2 and Option Box 3, is replaced by the newly approved HHCCN.

60.2 - Scope of the HHCCN

(Rev. 2781, Issued: 09-06-13, Effective: 12-09-13, Implementation: 12-09-13)

A. Statutory Authorization for HHCCN

The requirement to give an HHCCN is based on the HHA COPs in §1891 of the Act. The COPs are further implemented through Title 42 of the Code of Federal Regulations (CFR), Part 484.

§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 –

> all items and services furnished by (or under arrangement with) the agency for which payment may be made under this title,
>
> 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,
>
> 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
>
> any changes in the charges or items and services described in clause (i), (ii) or (iii)."

HHAs are required to use the HHCCN to notify the beneficiary of reductions and terminations in health care in accordance with Medicare COPs.

B. HHAs and Other CMS Notices

HHAs will now use the Advanced Beneficiary Notice (ABN), Form CMS-R-131 for liability notification instead of the HHABN Option Box 1. The ABN and form instructions can be downloaded from the CMS website at: http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html

HHAs must continue to issue an expedited determination notice called the Notice of Medicare Provider Non-Coverage, (NOMNC), CMS-10123, if applicable, when all covered services are being terminated. Please see the "FFS ED Notices" link at: http://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFSEDNotices.html for information on the delivery of expedited determination notices.

C. HHCCN Issuers and Recipients

HHAs are the only type of Medicare provider that issues the HHCCN to notify the beneficiary of care changes involving reductions or terminations of items and/or services. The recipients of the HHCCN are beneficiaries enrolled in Original Medicare only. HHCCNs are not used in Medicare managed care. When a beneficiary transitions to Medicare managed care from Original Medicare during a home health episode, HHCCN issuance is required only if there is a specific need to provide notification of changes in care as the transfer occurs.

Subcontractors may deliver HHCCNs under the direction of a primary HHA; however, notification responsibility, including effective delivery, always rests with the primary HHA. HHAs are always responsible for providing HHCCNs associated with the care that they provide. In the form instructions and instructions in this section, the term "beneficiary" is used to mean the beneficiary or the beneficiary's representative, as applicable. For more information on representatives, see §40.3.5 and §40.3.4.3 of this chapter.

HHAs should contact their CMS Regional Office if they have questions on the HHCCN or related instructions. Beneficiaries who need assistance may be directed to call 1-800-MEDICARE.

60.3 - Triggering Events for HHCCN/Written Notice

(Rev. 2781, Issued: 09-06-13, Effective: 12-09-13, Implementation: 12-09-13)

HHAs may be required to provide an HHCCN to an Original Medicare beneficiary at two points in time, for reasons not related to Medicare coverage called "triggering events":

Table 2

Triggering Events for HHCCN Issuance

EVENT	DESCRIPTION

Reduction of a service	When an HHA reduces or stops an item and/or service during a spell of illness while continuing others, including when one home health discipline ends but others continue.
Termination of all services	When an HHA ends delivery of all services.

A. Reductions

Reductions involve any decrease in items and/or services, such as frequency, amount, or level of care, provided by the HHA. When care that is listed on the POC or provided by the HHA is reduced, the beneficiary must receive the HHCCN listing the items/services being reduced and the reason for the reduction, regardless of who is responsible for paying for that service.

When a reduction occurs because the HHA decides to stop providing the service for administrative reasons or because of a physician's order, the HHCCN must be issued.

Example 1 – Reduction for HHA reasons:

Because of a temporary staffing shortage, an HHA reduces daily physical therapy (PT) to PT 3 times weekly for 2 weeks.

The HHCCN must be issued to the beneficiary prior to this care reduction that is due to an agency administration issue.

Example 2 –Reduction based on physician's orders:

The beneficiary met PT goals sooner than expected, and the attending physician writes an order to discontinue home PT. Physical therapy services are discontinued with no change in existing skilled nursing orders.

The HHCCN must be issued to the beneficiary prior to this care reduction that is a change to the existing POC because of a physician's order. Reductions include cases, such as this, where one type of care ends, but the beneficiary continues to receive another type of home health service.

An ABN is issued (and not the HHCCN) if a reduction occurs for an item or service that will no longer be covered by Medicare but the beneficiary wants to continue to receive the care and assume the financial charges. See Section 50.15.4.

B. Terminations

A termination is the cessation of all services provided by the HHA and can include Medicare covered and noncovered care. When all home health care is ending for reasons not related to Medicare coverage, the HHA issues the HHCCN with information appropriate to the specific situation.

Example 1 – care termination due to agency reasons (such as staffing, closure of the HHA, concerns for staff safety), not related to Medicare coverage.

> An HHA decides to stop providing care because guard dogs at the home where the care is being furnished have posed safety issues for staff.

Because termination is due to an HHA administrative decision, the HHCCN must be given to the beneficiary prior to discontinuation of services.

Example 2 – care termination due to agency reasons (failure to meet face to face encounter requirement)

> An HHA has initiated care for a beneficiary, and the beneficiary has not yet had the required face to face encounter with the certifying physician or an allowed non-physician practitioner (NPP). The HHA believes that the face to face encounter requirement will not be met in the allowed time frame and decides to stop providing care.

This termination is due to an HHA administrative decision; thus, the HHCCN must be given to the beneficiary prior to discontinuation of services. Issuing the HHCCN does not affect financial liability but serves as a written change of care notice as required by the HHA COPs.

Example 3 – care termination due to a physician's orders to discontinue care or a lack of orders to continue care

> A physician orders discontinuation of all home health services or fails to order continued home health services.

The Notice of Medicare Provider Non-Coverage (NOMNC), CMS-10123 must be issued to the beneficiary when all Medicare covered services are ending based on the physician's orders. Since the NOMNC provides written notification of the forthcoming termination of all home health care, it satisfies the regulatory requirement for change of care advisement (HHCCN issuance). Thus, when the NOMNC is issued as required, the HHA doesn't have to issue a separate HHCCN. When home health services end because of physician's orders, HHAs have the option of issuing the NOMNC alone or both the NOMNC and the HHCCN.

Detailed information and instructions for issuing the NOMNC can be found on the CMS website at: http://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFSEDNotices.html

C. Effect of Other Insurers/Payers

HHCCN requirements apply only when home health services are expected to be partially or fully covered by Medicare. When a beneficiary is not receiving any services that are

expected to be covered under the Medicare home health benefit, the HHCCN is not required. For example, if a dual eligible beneficiary (having both Medicare and Medicaid) is not receiving any Medicare covered home health services, HHCCN issuance wouldn't be required when changes of care occur. (**NOTE:** HHAs are required to issue the ABN to dual eligible beneficiaries when applicable. See Section 50.15.4 C)

D. Exceptions to HHCCN Notification Requirements

The HHCCN is NOT required when changes in care involve:

- increase in care;
- changes in HHA caregivers or personnel as decided by the HHA;
- changes in expected arrival or departure time for HHA staff as determined by the HHA;
- changes in brand of product, (i.e., the same item produced by a different manufacturer) as determined by the HHA;
- change in the duration of services that has been included in the POC and communicated to the beneficiary by the HHA, (i.e., shorter therapy sessions as health status improves, such as a reduction from an hour to 45 minutes);
- lessening the number of items or services in cases where a range of services is included in the POC;

  Example: The POC order states: PT 3-5x per week as needed for gait training. The therapist begins therapy at 5 times per week, and as the patient progresses, therapy is reduced to 3 times per week. No HHCCN would be needed in this case.

- changes in the mix of services delivered in a specific discipline (e.g., skilled nursing) with no decrease in frequency with which that discipline is delivered;

  Example: A beneficiary is receiving several skilled nursing services during visits that are scheduled 3 times a week. One service within that discipline, a blood 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 HHCCN is required when the blood draws are discontinued, only when skilled nursing is reduced in frequency.

- changes in the modality affecting supplies employed as part of specific treatment (e.g., wound care) with no decrease in the frequency with which those supplies are provided; or

Example: A specific wound care product like Alldress is stopped, and a Hydrogel pad is started. Since this represents a change in the modality (or intervention) and not a reduction, no HHCCN is necessary.

- changes in care that are the beneficiary's decision and are documented in the medical record.

60.4 - Completing the HHCCN

(Rev. 2781, Issued: 09-06-13, Effective: 12-09-13, Implementation: 12-09-13)

A. Notices and General Notice Requirements

The HHCCN and the general instructions for preparing the HHCCN are available for download at the home health notice link found at http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html.

The notice is available in English and Spanish, and in PDF and Word formats. The HHCCN is the Office of Management and Budget (OMB) approved standard notice for use by Medicare HHAs to inform beneficiaries of changes in the POC when required by the COPs for HHAs. HHAs must use the OMB approved standard notice. HHAs must not add any customizations to the notice beyond what is permitted by the accompanying HHCCN form instructions and the guidelines published in this section.

B. Choosing the Correct Language Version

HHAs should choose the appropriate version of the HHCCN based on the language the beneficiary best understands. When a Spanish-language HHCCN is used, the HHA should make insertions on the notice in Spanish. If this is impossible, the HHA must take additional steps needed to assure beneficiary comprehension and document this on the HHCCN.

If needed, HHAs must provide verbal assistance in other languages to assist beneficiaries in understanding the document. HHAs should document any types of translation assistance used in the "Additional Information" section 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 HHCCN is 0938-1196. The estimated time required to complete this information collection is 4 minutes for a single notice. This includes the time to prepare the notice, review it with the beneficiary, and obtain the beneficiary's signature.

D. Effective Dates

HHCCNs are effective for HHA use per the OMB assigned date given at the bottom of each notice unless CMS instructs HHAs otherwise. The routine approval is for 3-year

use. HHAs are expected to exclusively use the effective version of the HHCCN per CMS directives.

60.5 - HHCCN Delivery

(Rev. 2781, Issued: 09-06-13, Effective: 12-09-13, Implementation: 12-09-13)

HHAs must make every effort to ensure beneficiaries understand the entire HHCCN prior to signing it. When delivering HHCCNs, HHAs are required to explain the notice and its content, and answer beneficiary questions to the best of their ability. If abbreviations are used, the HHA should explain their meaning to the beneficiary. If the beneficiary requests additional information while completing the HHCCN, the HHA must respond timely, accurately, and completely to the information request.

While in-person delivery of the HHCCN is preferable, it is not required consistent with general ABN requirements, see Medicare Claims Processing Manual, Chapter 30, §40.3.4.1.

If a mode other than in person delivery is used, the HHA must adhere to the requirements under the Health Insurance Portability and Accountability Act (HIPAA). Instructions on ABN telephone notice found in §40.3.4.2 of this chapter are also applicable to HHCCNs.

Delivery when change of care is due to agency administrative reasons

The HHA should review the text associated with the box that was checked on the HHCCN by the HHA and verbally explain to the beneficiary that he/she may be able to obtain the same or similar care from another HHA, since coverage through Medicare is not affected. HHAs are encouraged to do as much as possible to offer ideas to beneficiaries for contacting other HHAs and must inform ordering physicians of reductions/terminations consistent with the COPs for HHAs.

Delivery when change of care is due to physician orders

The HHA should review the text associated with the box that was checked on the HHCCN by the HHA, and inform the beneficiary that the HHA will no longer provide certain care because the physician's order has changed. When requested, the HHA may facilitate contact and understanding between the physician and beneficiary. The beneficiary may also seek to contact the physician directly.

Retention of the HHCCN

The HHA keeps a copy of the completed, signed or annotated HHCCN in the beneficiary's record, and the beneficiary receives a copy. HHA's may retain a scanned copy of the paper copy document in an electronic medical record if desired. The primary HHA must retain the HHCCN if a subcontractor is used.

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.

Other Considerations During Completion

1. Beneficiary Unable to Sign

If the beneficiary is physically unable to sign the HHCCN and is fully capable of understanding the notice a representative is not required for signature. The beneficiary may allow the HHA to annotate the HHCCN 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.

2. Timely Notice

There are no exact time frames for HHCCN delivery. Delivery timing of the notice may sometimes occur immediately upon the HHA finding that a change in care is warranted. However, in general, HHCCN should be delivered far enough in advance of the care change so that the beneficiary may pursue alternatives to continue receiving the care noted on the HHCCN. When plans for issuance of the notice are known in advance, the HHCCN should not be issued so far in advance as to cause confusion regarding the information it conveys.

Some allowance is made for "immediate" delivery prior to furnishing the care at issue when unforeseen circumstances arise such as an impending, unforeseen agency staffing shortage or a dangerous home situation. This should be avoided whenever possible, but is permissible when a situation occurs prompting an immediate determination to reduce or end services that could not have been made in advance.

70 - Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN)

(Rev.: 12758; Issued: 08-01-24; Effective: 10-02-24; Implementation: 10-02-24)

The following are the standards for use by Skilled Nursing Facilities (SNFs) in implementing the SNF ABN (CMS-Approved Model Form CMS-10055) requirements. This section provides instructions, consistent with the SNF prospective payment system (SNF PPS), regarding the SNF ABN.

SNF ABN - Quick Glance Guide[3]

Notice Name: SNF ABN
Notice Number: CMS-Approved Model, Form CMS-10055

Issued by: SNFs for non-covered SNF PPS extended care items or services.
Recipient: Original Medicare fee-for-service (FFS) beneficiary

Additional Information:

The ABN, Form CMS-R-131 should be used for Medicare Part B non-covered items or services.

Type of Notice:	Must be issued in order to transfer liability to the beneficiary:	Timing of notice:	Optional/Voluntary use:
Financial liability notice	Before SNF PPS extended care items or services are furnished, reduced, or terminated when the SNF, the UR entity, the QIO, or the Medicare contractor believes that Medicare may not pay for, or will not continue to pay for, those extended care services 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) of the Act); or • Custodial care ("not a covered level of care") (§1862(a)(9) of the Act).	Prior to delivery of the care item or service in question. Provide enough time for the beneficiary to make an informed decision on whether or not to receive the service or item in question and accept potential financial liability.	Yes. It is recommended, but not necessary to transfer liability, for SNFs to issue prior to furnishing a care item or service that is never covered by Medicare (i.e. not a Medicare benefit).

[3] This is an abbreviated reference tool and is not meant to replace or supersede any of the directives contained in Section 70.

70.1 - SNF ABN Standards

(Rev.: 12758; Issued: 08-01-24; Effective: 10-02-24; Implementation: 10-02-24)

Step by step instructions for notice completion are posted along with the online replicable copies of the CMS-Approved Model, Form CMS-10055 on the CMS website. SNFs should not add any customizations to the notice beyond what is permitted by the accompanying SNF ABN form instructions and the guidelines published in this section. SNFs should follow the same standards when completing the SNF ABN as the ABN, Form CMS-R- 131 in §50.6 of this chapter, as applicable.

70.2 - Situations in Which a SNF ABN Should Be Given

(Rev. 4198; Issued: 01-11-19; Effective: 04-30-18; Implementation: 04-30-18)

A. Triggering Events

A SNF ABN is evidence of beneficiary knowledge about the likelihood of a 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. If Medicare is expected to deny payment (entirely or in part) on the basis of one of the exclusions listed in §70 of this chapter for extended care items or services that the SNF furnishes to a beneficiary, a SNF ABN must be given to the beneficiary in order to transfer financial liability for the item or service to the beneficiary. The initiation, reduction and termination of such extended care items or services, that Medicare may not pay, are considered triggering events. The following describe the three triggering events for a SNF ABN:

EVENT	DESCRIPTION
Initiation	In the situation in which a SNF believes Medicare will not pay for extended care items or services that a physician has ordered, the SNF must provide a SNF ABN to the beneficiary before it furnishes those non-covered extended care items or services to the beneficiary.
Reduction	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 SNF ABN to the beneficiary before it reduces items or services to the beneficiary.
Termination	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 and the beneficiary would like to continue receiving the care, the SNF must provide a SNF ABN to the beneficiary before it terminates such extended care items or services.

B. Effect of Other Insurers/Payers

Some States have specific rules established regarding completion of liability notices in situations where dual-eligibles need to accept liability for Medicare non-covered care that will be covered by Medicaid. 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. If the patient is a Medicare-Medicaid dual-eligible and a triggering event occurs, the SNF needs to give the beneficiary a SNF ABN.

On a practical basis, physician-prescribed 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." In these instances, a SNF ABN must be issued to transfer financial liability to the beneficiary.

70.3 - Situations in Which a SNF ABN Is Not Needed to Transfer Financial Liability to the Beneficiary

(Rev.: 4198; Issued: 01-11-19; Effective: 04-30-18; Implementation: 04-30-18)

SNFs need not issue a SNF ABN to transfer financial liability to the beneficiary:

- If the extended care item or service is not a Medicare benefit (e.g., personal comfort items excluded under §1862(a)(6)).

- If a beneficiary is being furnished post-hospital extended care services while a resident in a SNF and payment is expected to be denied for an otherwise Medicare covered benefit because it does not meet a technical benefit requirement (e.g., SNF stay not preceded by the required prior three-day hospital stay or the beneficiary is exhausting his/her 100 benefit days).

- 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 non-covered level of care).

- If the SNF will not furnish the extended care items or services. A SNF must not give a beneficiary a SNF ABN 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, as this is equivalent to the prohibited practice of the SNF pre-selecting Option 2 (not to receive items or services) on a SNF ABN. This rule also applies when the beneficiary agrees with the triggering event (i.e., terminating therapy) and the beneficiary will not be receiving the extended care items or services.

  NOTE: This rule is not applicable in the situation where the beneficiary elects to receive extended care items or services but refuses to sign the SNF ABN attesting to being personally and fully responsible for payment, in which

case, the SNF may then consider not furnishing the specified items or services.

- For Medicare Advantage (Part C) enrollees nor for non-Medicare patients because it is to be used solely for individuals enrolled in the Medicare FFS program (Parts A and B).

- 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.

- For swing-bed determinations. The Preadmission/Admission HINN (HINN 1) should be given.

NOTE: 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. See Section 50 of this manual, as applicable.

70.4 - SNF ABN Specific Delivery Issues

(Rev.: 12758; Issued: 08-01-24; Effective: 10-02-24; Implementation: 10-02-24)

When completing and delivering the SNF ABN, SNFs must meet the written notice standards in §50.6, 50.7 and 50.8 of this chapter, unless otherwise specified. Failure to provide a proper SNF ABN in situations where a physician has ordered the extended care item or service may result in the SNF being held financially liable under the LOL provisions, where such provisions apply. SNFs may also be sanctioned for violating the conditions of participation (42 CFR 483.10) regarding resident (beneficiary) rights.

NOTE: The SNF ABN is not a replacement for, but is in addition to, the required UR entity notices**.** The SNF ABN protects the SNF from liability in the event the beneficiary, for some reason, does not receive the UR entity notice.

70.5 - Special Rules for SNF ABNs

(Rev.: 4198; Issued: 01-11-19; Effective: 04-30-18; Implementation: 04-30-18)

A. Collection from Beneficiary

When a SNF ABN 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 Medicare Summary Notice (MSN) 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 some other Federal or non-Federal payment source.

NOTE: The beneficiary may request a demand bill at any point in her or his care.

B. Unbundling Prohibition

The SNF ABNs 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 SNF ABN to collect from a beneficiary where full payment is made on a bundled basis would constitute double billing. A SNF ABN 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.

C. Acceptance or Rejection of SNF ABN

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 should:

- Answer inquiries from a beneficiary 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, the SNF must give the beneficiary access to medical record information or other documents upon which these entities based their assessment, to the extent permissible or required under applicable state law.

  NOTE: Where state law prohibits such direct disclosure, the SNF should advise a beneficiary who has requested access to such information how to obtain that information from the SNF once a demand bill has been submitted.

- Respond timely, accurately, and completely to a beneficiary who requests information about the extent of the beneficiary's personal financial liability.

- Timely submit additional information to the Medicare contractor, if a beneficiary or a physician provides that additional information with respect to Medicare coverage of the subject extended care items or services.

70.6 - Establishing When Beneficiary Is On Notice of Non-coverage
(Rev.: 4198; Issued: 01-11-19; Effective: 04-30-18; Implementation: 04-30-18)

If the beneficiary has previously been informed in writing that similar or reasonably comparable extended care items or services were non-covered and it was clear that the beneficiary knew that the circumstances were the same, the beneficiary is liable. 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, s/he receives notification from an appropriate source.

70.6.1 - Source of Beneficiary Notification
(Rev.: 4198; Issued: 01-11-19; Effective: 04-30-18; Implementation: 04-30-18)

Written Notification must be given by one of the following sources:

A. The SNF that is furnishing non-covered extended care items or services.

Examples:

- On or before the day of admission, the SNF furnishes to the beneficiary a SNF ABN notifying the beneficiary that the extended care item(s) or service(s) is non-covered; or

- During the inpatient stay, the SNF timely furnishes to the beneficiary a SNF ABN notifying the beneficiary that the covered extended care item(s) or service(s) will no longer be covered.

B. The UR entity of the SNF that is furnishing non-covered extended care items or services.

Example:

- The UR entity timely furnishes to the beneficiary a SNF ABN notifying the beneficiary that the extended care item(s) or service(s) is no longer covered.

C. The QIO or Medicare contractor.

Example:

- The QIO, where a beneficiary is in a swing bed, timely furnishes to the beneficiary, a SNF ABN 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.

  NOTE: This occurs after the beneficiary receives a HINN 1 (Preadmission/Admission HINN) and after the QIO's decision of the non-coverage.

- The Medicare contractor sends the beneficiary her or his first notification of non-coverage (e.g., the MSN).

70.7 – 70.13 New sections to be added

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)

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)

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:

  - The month in which payment was made to the provider, practitioner or supplier; or

  - 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)

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)

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)

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)

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 l.) 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)

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)

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)

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 A/B MAC (A) or (HHH) determines that additional time is needed to arrange for post-discharge care, also for a "grace period" of l 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 A/B MAC (A) or (HHH) 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 A/B MAC (A)'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 A/B MAC (A)'s notice on February 15 but failed to give the beneficiary notice until the next day - February 16 - the beneficiary and provider, if the A/B MAC (A) 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 A/B MAC (A) or (HHH) 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 1879 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 §§1814(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 §1861(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. 3560, Issued: 07-15-16, Effective: 10-17-16, Implementation: 10-17-16)

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 §1814(a)(2)(C) or §1835(a)(2)(A) of the Act, or in the case of hospice services, are denied for technical reasons under §1861(dd)(3)(A) of the Act:

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., Remittance Advice Remark Codes) conveyed via the 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. 3187, Issued: 02-06-15, Effective: 03-06-15, Implementation: 03-06-15)

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 A/B MAC (A) 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 by institutional providers, 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. 12758; Issued: 08-01-24; Effective: 10-02-24; Implementation: 10-02-24)

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): (l) 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. 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 have determined that you knew Medicare would not pay for this service, you are liable for the charges. (See, Section 1879 of the Social Security Act; 42 CFR 405.411)

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 - A/B MAC (A) and (HHH) 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. 3187, Issued: 02-06-15, Effective: 03-06-15, Implementation: 03-06-15)

The following sections discuss how the limitation on liability provision is applied to claims involving ancillary, outpatient and rural health clinic services billed to the A/B MAC (A), where reimbursement is sought under Part B. The A/B MAC (A) 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)

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)

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 A/B MAC (A) considers the covered portion of the stay in determining whether the SNF prior hospitalization requirement is met.

B. Transfer Requirements

1. Transfer Period

The A/B MAC (A) 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 A/B MAC (A) 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 A/B MAC (A) 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 A/B MAC (A) 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 A/B MAC (A) determines that additional time is needed to arrange for post-discharge care, for a "grace period" of l day thereafter. If the A/B MAC (A) 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 A/B MAC (A) 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. 4001, Issued: 03-16-18, Effective: 06-19-18, Implementation: 06-19-18)

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 portion of the same institution that also includes a participating SNF or hospital. When requested by the beneficiary or his/her authorized representative, a provider must submit a claim to the A/B MAC (A) for services rendered in a non-certified bed. When the A/B MAC (A) 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 A/B MAC (A) 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 A/B MAC (A) 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 the institution 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 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 the institution 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 A/B MAC (A) (contemplated only at an appeal level of claim processing), submit a copy of the ABN signed by the beneficiary to the A/B MAC (A), 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 A/B MAC (A) automatically determines the ABN is defective.

When the A/B MAC (A) receives a claim with an indication that the provider has provided the beneficiary or his/her authorized representative, with an ABN, the A/B MAC (A) 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 A/B MAC (A) determines that the ABN is not valid, the A/B MAC (A) processes the claim in accordance with §130.4.

If the beneficiary appeals the initial denial, the A/B MAC (A) obtains the ABN from the provider and determines whether it is valid. If the A/B MAC (A) 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 A/B MAC (A) 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 A/B MAC (A) 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 .4001, Issued: 03-16-18, Effective: 06-19-18, Implementation: 06-19-18)

The A/B MAC (A) 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 A/B MAC (A)'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 A/B MAC (A) determines that the beneficiary did not consent to placement in a noncertified portion of the same institution that also includes 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 A/B MAC (A) 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 A/B MAC (A), 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);

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

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(l) 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(l) 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(l) 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(l) 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:

1. 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

2. 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. 4250; Issued: 03-08-10; Effective: 04-08-19; Implementation: 04-08-19)

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

Include in the notice to the physician the following:

- The patient's name and Medicare beneficiary identifier;
- 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. 4250; Issued: 03-08-10; Effective: 04-08-19; Implementation: 04-08-19)

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

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, Medicare beneficiary identifier, 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 §140.4. In the absence of acceptable evidence of advance notice, the contractor will go on to §140.8.3.

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(l) 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 §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.

150.1.4 - 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
(Rev. 1, 10-01-03)

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. 4250; Issued: 03-08-10; Effective: 04-08-19; Implementation: 04-08-19)

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

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 claim 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 claim 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 knew that Medicare wouldn't pay and you paid, you might get a refund unless you signed a notice in advance. Refunds may be delayed if the provider appeals. Call your supplier if you don't hear anything within 30 days.

(MSN 8.54) - In Spanish

> Si pagó por un servicio que su proveedor sabía Medicare no iba a pagar, usted tiene derecho a un reembolso, a menos de que haya firmado un aviso por adelantado. Los reembolsos se pueden demorar si el proveedor apela la decisión. Llame a su proveedor si no escucha nada en 30 días.

B. Initial Supplier Notice

Include in the notice to the supplier the following;

- The patient's name Medicare beneficiary identifier;
- 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

(Remittance Advice 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.
>
> Remittance Advice Remark Codes cannot be reported without a Claim Adjustment Reason Code and a Group Code. For Notice 1 where ABN has been obtained, use CARC 96 - Non-covered charge(s), and Group Code – PR (Patient Responsibility).

Or

Notice 2. – Signed Advance Beneficiary Notice Not Obtained

(Remittance Advice 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.

Remittance Advice Remark Codes cannot be reported without a Claim Adjustment Reason Code and a Group Code. For Notice 2 where ABN has NOT been obtained, use CARC 96 - Non-covered charge(s), and Group Code – CO (Contractual obligation).

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 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. 4250; Issued: 03-08-10; Effective: 04-08-19; Implementation: 04-08-19)

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

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, Medicare beneficiary identifier, 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 §150.7 . 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 Pay

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

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

150.10.3 - Supplier Knowledge

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

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

150.11 - Guide Paragraphs for Inclusion in Appeal Determination

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

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

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

> Under §1834(a)(18) and under §1834(j)(4) of the Social Security Act, a supplier which does not accept assignment and collects any amounts from a Medicare beneficiary for medical equipment and supplies for which Medicare does not pay on the basis of §1834(a)(17)(B), §1862(a)(1), §1834(j)(1), or §1834(a)(15) of the Social Security Act, must refund these amounts to the beneficiary. However, a refund is not required if, prior to furnishing the items or services, the supplier notified the beneficiary in writing that Medicare would not pay for the items or services and the beneficiary signed a statement agreeing to pay for them. After reviewing

this claim, we have determined that you informed the beneficiary in advance that Medicare does not pay for the above items or services and the beneficiary agreed to pay for them. Therefore, you are not required to make a refund in this case. The beneficiary has been sent a copy of this notice.

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

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

Paragraph 3. Adverse Action on Denial - Refund Required

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

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

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

150.12 - Supplier Fails to Make Refund

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

Under §1834(a)(18)(B) of the Act, a supplier which knowingly and willfully fails to make refund within the time limits in §150.4 may be subject to sanctions under §1128A the Act (i.e., civil money penalties (up to $10,000 per item or service), assessments (three times the amount of the claim), and exclusion from the Medicare program).

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

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

150.13 - CMS Regional Office (RO) Referral Procedures

(Rev. 4250; Issued: 03-08-10; Effective: 04-08-19; Implementation: 04-08-19)

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

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 beneficiary identifier, 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 Medicare beneficiary identifier;
- 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 Determinations of Inpatient Hospital Discharges

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

Medicare beneficiaries who are hospital inpatients have a statutory right to appeal to a BFCC-QIO for an expedited review when a hospital, with physician concurrence, determines that inpatient care is no longer necessary.

200.1 - Statutory Authority

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

- Sections 1866(a)(1)(M),
- 1869(c)(3)(C)(iii)(III), and
- 1154(e) of the Act.

This process was implemented through a final rule with comment period, CMS-1655-F (81 FR 56761, 57037 through 57052, August 22, 2016), effective October 1, 2016. The resulting regulations are located at 42 CFR Part 405.1205 and 405.1206).

There is a parallel process for beneficiaries enrolled in Medicare health plans. (See 42 CFR 422.620 - 422.622 and §100.1 in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.) Please see the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for Medicare Advantage instructions.

200.2 - Scope

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The expedited determination process is available to beneficiaries in Original Medicare who are being discharged from a Medicare covered inpatient hospital stay. All beneficiaries receiving covered inpatient hospital care must receive an Important Message from Medicare (IM). This includes, but is not limited to, beneficiaries in the following circumstances:

- Beneficiaries for whom Medicare is either the primary or secondary payer.

- Beneficiaries with brief inpatient hospital stays.
- Beneficiaries physically discharged from the hospital or discharged to a lower level of care (such as a Swing Bed) in the same hospital.

NOTE:

For purposes of these instructions, the term "beneficiary" means either beneficiary or representative, when a representative is acting for a beneficiary.

Hospitals Affected by these Instructions. These instructions apply to hospitals as well as Critical Access Hospitals (CAHs) per section 1861(e) and section 1861(mm) of the Social Security Act. CAHs, as well as psychiatric hospitals, are included in the scope of these instructions.

200.2.1 - Exceptions

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The following situations are not eligible for an expedited determination. Hospitals should not deliver an IM in these instances.

- When a beneficiary transfers to another hospital at the same level of care (e.g., a beneficiary transfers from one hospital to another while remaining a hospital inpatient).

- When beneficiaries exhaust their benefits (e.g., a beneficiary reaches the number of lifetime reserve days of the Medicare inpatient hospital benefit.)

- When beneficiaries end care on their own initiative (e.g., a beneficiary elects the hospice benefit).

- Condition Code 44 (CC44) (See Section 50.3 of Chapter 1 of the Medicare Claims Processing Manual)

- Physician does not concur with discharge. (See Section 220 of this chapter.)

NOTE:

The IM should only be given when an inpatient admission is pending or has occurred. It should not be given 'just in case', such as a hospital delivering to all Medicare patients being treated in a hospital emergency room.

200.3 - Important Message from Medicare (IM)

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The IM is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB). The IM may only be modified as per the accompanying instructions, as well as per guidance in this section. Unapproved modifications cannot be made to the OMB-approved, standardized IM. The notice and accompanying instructions may be found online at Hospital Discharge Appeal Notices.

200.3.1 - Alterations to the IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

- The IM must remain two pages. The notice can be two sides of one page or one side of two separate pages, but **must not** be condensed to one page.
- Hospitals may include their business logo and contact information on the top of the IM. Text may not be shifted from page 1 to page 2 to accommodate large logos, address headers, etc.
- Hospitals may include information in the optional "Additional Information" section relevant to the beneficiary's situation.

NOTE:
Including information normally included in the Detailed Notice of Discharge (DND) in the "Additional Information" section does not satisfy a hospital's responsibility to deliver the DND, if otherwise required. See §200.4.5 'The Detailed Notice of Discharge (DND)'.

200.3.2 - Completing the IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

Hospitals must use the OMB-approved IM (CMS-10065). Hospitals must add the following information in the corresponding blanks of the IM:

1. Patient name
2. Patient number
3. BFCC-QIO contact information

NOTE:

The Patient number may be a unique medical record or other provider-issued identification number. It may not be the Social Security Number, HICN or any other Medicare number issued to the beneficiary such as the MBI (Medicare Beneficiary Identifier).

200.3.3 - Hospital Delivery of the IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

Hospitals must deliver the IM to all beneficiaries eligible for the expedited determination process per §200.2. An IM must be delivered even if the beneficiary agrees with the discharge.

- The hospital must ensure that the beneficiary or representative signs and dates the IM to demonstrate that the beneficiary or representative received the notice and understands its contents. See 200.3.7 'Ensuring Beneficiary Comprehension'.

- Use of assistive devices may be used to obtain a signature.

- Electronic issuance of the IM is permitted.

If a hospital elects to issue an IM viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper issuance over electronic issuance if that is what the beneficiary prefers. Regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the IM, as specified in 200.3.9, and the required beneficiary specific information must be inserted, at the time of notice delivery.

200.3.4- Required Delivery Timeframes

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

200.3.4.1- First IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

Hospitals must deliver the first 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 first copy of the notice if the beneficiary is seen during a preadmission visit, but not more than 7 calendar days in advance of admission.

A hospital must deliver the IM to all inpatients, including those in the hospital for a short stay.

- Once the discharge date is planned, a hospital does not need discharge orders in advance of delivering the IM.

Timing of First IM Delivery

Pre-Admission	Up to 7 days before admission
At Admission	At admission
After Admission	Up to 2 days following admission

200.3.4.2 - Follow-Up Copy of the IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

Hospitals must deliver the follow up copy of the IM within 2 days of discharge. It may be given as late as four hours prior to discharge.

However, if delivery of the first 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.

- A hospital may 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, or

- A hospital may deliver a copy of the signed, first IM with the date of delivery of the follow up copy indicated on the IM.

Timing of Follow-Up IM Delivery

No sooner than:	Two days before discharge
No later than:	Four hours prior to discharge

Notes:

- If two or fewer days have passed since delivery of the first IM, no follow-up IM is required.

- The follow-up IM may be copy of signed first IM and does not need to be re-signed.

200.3.5 - Refusal to Sign the IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

If the beneficiary refuses to sign the IM the provider should annotate the notice to that effect, and indicate the date of refusal on the notice. The date of refusal is considered to be the date of notice receipt. Beneficiaries who refuse to sign the IM remain entitled to an expedited determination.

200.3.6 - Ensuring Beneficiary Comprehension

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The OMB-approved standardized IM is available in English and Spanish. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, hospitals and CAHs must employ their usual procedures to ensure notice comprehension. Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies. Hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with limited English proficiency (LEP) consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, consistent with section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

200.3.7 - IM Delivery to Representatives

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation:04-21-2022)

The IM may be delivered to a beneficiary's appointed or authorized representative.

Types of Representative

Appointed Representative	Authorized Representative
Appointed representatives are individuals designated by beneficiaries to act on their behalf. A beneficiary may designate an appointed representative via the "Appointment of Representative" form, the CMS-1696. See Chapter 29 of the Medicare Claims Processing Manual, section 270.1, for more information on appointed representatives.	An authorized 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).

Notes:

- However, if a beneficiary is temporarily incapacitated and there is no representative, a person (typically, a family member or close friend) whom the hospital has determined could reasonably represent the beneficiary, but who has not been named in any legally binding document, may be a representative for the purpose of receiving the IM. Such a representative should act in the beneficiary's best interests and 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.

- In instances where the notice is delivered to a representative who has not been named in a legally binding document, the hospital must annotate the IM with the name of the staff person initiating the contact, the name of the person contacted, and the date, time, and method (in person or telephone) of the contact.

Delivery to off-site representatives

If the IM must be delivered to a representative who is not physically present, the hospital is not required to personally deliver the IM or have the IM delivered via courier to the representative. The hospital must complete the IM as required and may instead telephone the representativeand then mail the IM. The date and time of the telephone call is considered the receipt date of the IM.

The hospital must complete <u>all</u> of the following actions.

1. Verbally convey all contents of the IM;

2. Note the date and time this information is communicated verbally;

3. Annotate the "Additional Information" section to reflect that IM was communicated verbally to the representative; and

4. Annotate the "Additional Information" section with 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.

5. Mail a copy of the annotated IM to the representative the day telephone contact is made.

A hard copy of the IM must be sent to the representative by certified mail, return receipt requested, or any other delivery method that can provide signed verification of delivery (e.g., FedEx, UPS). The burden is on the hospital to demonstrate that timely contact was attempted with the representative and that the notice was delivered.

If the hospital and the representative both agree, the hospital may send the notice by fax or e-mail; however, the hospital or CAH's fax and e-mail systems must meet the Health

Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security requirements.

200.3.8- Notice Retention for the IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The hospital or CAH must retain the signed IM in the beneficiary's medical record. The beneficiary receives a paper copy of the IM that includes all of the required information described in this section. Electronic notice retention is permitted.

Hospitals must also document delivery of the follow-up copy of the IM in the patient records, when applicable. For example, hospitals may use the "Additional Information" section of the IM to document delivery of the follow-up copy by adding a line for the beneficiary's or representative's initials and date.

200.4 - Expedited Determination Process

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

200.4.1 - Expedited Determination Process

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

200.4.1.1 - Timeframe for Requesting an Expedited Determination

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

A beneficiary who receives an IM and disagrees with the discharge may request an expedited determination by the appropriate BFCC-QIO for the state where the services were provided. The beneficiary must contact the BFCC-QIO by midnight of the day of discharge, before leaving the hospital. The beneficiary may contact the BFCC-QIO by telephone or in writing.

200.4.1.2 - Provide Information to BFCC-QIO

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The beneficiary must be available to answer questions or supply information requested by the BFCC-QIO. The beneficiary may, but is not required to, supply additional information to the BFCC-QIO that he or she believes is pertinent to the case.

200.4.2 - Beneficiary Liability During BFCC-QIO Review

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

When the beneficiary makes a timely request for a BFCC-QIO expedited determination per §200.4.1.1, 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 BFCC-QIO. Please see §200.5.6 for QIO notification requirements.

When Liability Begins

BFCC-QIO determination	Liability begins
Unfavorable to the beneficiary	Noon of the day after the BFCC-QIO notifies the beneficiary of the decision.
Favorable to the beneficiary	Once the hospital again determines that the beneficiary no longer requires inpatient care, determines a new last date of coverage and notifies the beneficiary with a follow-up copy of the IM.

200.4.3 - Untimely Requests for Review

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

Untimely request timeframes

Beneficiary location	BFCC-QIO determination
Beneficiary in hospital [may request expedited review anytime while in hospital]	BFCC-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 information.
Beneficiary left hospital [may request expedited review within 30 days of discharge]	BFCC-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 information.

The coverage protections discussed in §200.4.2 do not apply to a beneficiary who makes an untimely request to the BFCC-QIO.

200.4.4 - Hospital Responsibilities

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

When a hospital is notified by a BFCC-QIO of a beneficiary request for an expedited determination, the provider must perform all of the following actions.

1. Deliver the beneficiary a DNC (see §200.4.5) as soon as possible, but no later than noon of the day after BFCC-QIO notification;

2. Supply the BFCC-QIO with copies of the IM and DNC as soon as possible, but no later than noon of the day after BFCC-QIO notification;

3. Supply all information, including medical records, requested by the BFCC-QIO. The BFCC-QIO may allow this required information to be supplied via phone, writing, or electronically. If supplied via phone, the provider must keep a written record of the information it provides within the patient record; and

4. Furnish the beneficiary, at their request, with access to or copies of any documentation it provides to the BFCC-QIO. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating and delivering the documentation. This documentation must be provided to the beneficiary by close of business of the first day after the material is requested.

200.4.5 - The Detailed Notice of Discharge (DND)

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The Detailed Notice of Discharge (DND) is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB). The DND may only be modified as per the accompanying instructions, as well as per guidance in this section. Unapproved modifications cannot be made to the OMB-approved, standardized DND. The notice and accompanying instructions may be found online at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/HospitalDischargeAppealNotices

Hospitals are responsible for the delivery of the DND to beneficiaries who request an expedited determination by the BFCC-QIO.

The DND must contain all the following information:

1. The facts specific to the beneficiary's discharge and provider's determination that coverage should end.

2. A specific and detailed explanation of why services are either no longer reasonable or necessary or no longer covered.
3. A description of, and citations to, the Medicare coverage rule, instruction, or other policies applicable to the review.

The delivery must occur in person by noon of the day after the BFCC-QIO notifies the provider that the beneficiary has requested an expedited determination.

The DND does not require a signature but should be annotated in the event of a beneficiary's refusal to accept the notice upon delivery.

200.5 – BFCC-QIO Responsibilities

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

200.5.1 - Receive Beneficiary Requests for Expedited Review

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

BFCC-QIOs must be available to receive beneficiary requests for review 24 hours a day, 7 days a week.

200.5.2 - Notify Hospitals and Allow Explanation of Why Covered Services Should End

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

When the BFCC-QIO receives a request from a beneficiary, the BFCC-QIO must immediately notify the provider of services that a request for an expedited determination was made. If the request is received after normal working hours, the BFCC-QIO should notify the provider as soon as possible on the morning after the request was made.

200.5.3 - Validate Delivery of the IM

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The BFCC-QIO should determine that IM delivery was valid if all of the following criteria are met:

- The notice used is the OMB approved IM published by CMS.

- The notice was delivered timely per 200.3.4.
- The notice was signed and dated by the beneficiary.

If the BFCC-QIO determines that the hospital did not deliver a valid notice, the BFCC-QIO will provide education to the hospital on valid notice requirements.

200.5.4 - Solicit the Views of the Beneficiary

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The BFCC-QIO must solicit views of the beneficiary who requested the expedited determination.

200.5.5 - Solicit the Views of the Hospital

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

The BFCC-QIO must afford the provider an opportunity to explain why the discharge is appropriate.

200.5.6 - Make Determination and Notify Required Parties

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

No later than one calendar day after it receives all requested information, the BFCC-QIO must make its determination on whether the discharge is appropriate based on medical necessity or other Medicare coverage policies.
The BFCC-QIO must perform the following actions.

1. Notify the beneficiary, the beneficiary's physician, and the provider of services of its determination. This notification must include the rationale for the determination and an explanation of Medicare payment consequences and beneficiary liability.

2. Inform the beneficiary of the right to an expedited reconsideration by the BFCC-QIO and how to request a timely expedited reconsideration.

3. Make its initial notification via telephone and follow up with a written determination letter.

NOTE:

If the BFCC-QIO does not receive supporting information from the hospital, it may make its determination based on the evidence at hand, or defer a decision until it receives the necessary information. If this delay results in continued services for the beneficiary, the

provider may be held financially liable for these services as determined by the BFCC-QIO.

200.6 - Effect of a BFCC-QIO Expedited Determination

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation:0 4-21-2022)

The BFCC-QIO determination is binding unless the beneficiary pursues an expedited reconsideration per section 300 of this chapter.

200.6.1 - Right to Pursue an Expedited Reconsideration

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

If dissatisfied with the expedited determination, the beneficiary may request an expedited reconsideration according to the procedures described in section 300 of this chapter.

200.6.2 - Effect of a BFCC-QIO Determination on Continuation of Care

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

A beneficiary may choose to remain in the hospital beyond the last day of coverage, but may be liable for services after that day. The hospital should issue a Hospital-Issued Notice of Non-coverage (HINN 12) to inform the beneficiary of potential liability. Please see (https://www.cms.gov/Medicare/Medicare-General-Information/BNI/HINNs) for HINN delivery instructions.

200.6.3 - Right to Pursue the Standard Claims Appeal Process

(Rev. 11210; Issued: 01-21-2022; Effective: 04-21-2022; Implementation: 04-21-2022)

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.).

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 http://www.cms.gov/Medicare/Medicare-General-Information/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 Physician:_____
Patient ID Number: _____Date Issued:_____

We believe that Medicare will not continue to cover your hospital care because these services are no longer considered medically necessary in your case. Because your doctor disagreed with our finding, the hospital is asking the quality improvement organization (QIO) to review your case. The QIO is an outside reviewer hired by

Medicare to look at your case to decide if you are ready to leave the hospital. The name of the QIO is **_____(insert the name of the QIO)_____.**

- The QIO will contact you to solicit your views about your case and the care you need.
- You do not need to take any action until you hear from the QIO.

For more information about this notice, call 1-800-MEDICARE (1-800-633-4227), or TTY: 1-877-486-2048.

Please sign your name, the date and time. Your signature does not mean that you agree with this notice, just that you received the notice and understand it.

_____	_____	_____
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: _____

We believe that Medicare is not likely to pay for your admission for
_____(specify service or condition)_____ because:

____it is not considered to be medically necessary

____it could be furnished safely in another setting

____other_____.

However, this notice is not an official Medicare decision.

If you disagree with our finding:

- You should talk to your doctor about this notice and any further health care you may need.
- 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 ahead with the hospitalization, you will have to pay for:** _____[1]
-

CONTINUED ON PAGE 2

[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."

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 immediate 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.

    - 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.

- IF THE QIO FINDS THAT YOUR HOSPITAL CARE IS NOT COVERED, you are responsible for payment for all services beginning on _____(specify date)____. (see footnote[1] on page 1).

For more information, call 1-800-MEDICARE (1-800-633-4227), or TTY: 1-877-486-2048.

Please sign your name, the date and time. Your signature does not mean that you agree with this notice, just that you received the notice and understand it.

_____ _____ _____

Signature of Patient or Representative Date
Time

260 - Expedited Determinations of Provider Service Terminations
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

260.1 - Statutory Authority
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

Section 1869(b)(1)(F) of the Social Security Act (the Act), as amended by section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) granted beneficiaries in Original Medicare the right to an expedited determination process to dispute the end of their Medicare covered care in certain provider settings.

This process was implemented though a final rule with comment period, CMS-4004-FC (69 FR 69252, November 26, 2004), effective July 1, 2005. The resulting regulations are located at 42 CFR Part 405, §§405.1200 - 405.1204. There is a parallel process for beneficiaries enrolled in Medicare health plans. (See §§90.2-90.8 in Chapter 13 of the Medicare Managed Care Manual (CMS Pub. 100-16.)

260.2 - Scope
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The expedited determination process is available to beneficiaries in Original Medicare whose Medicare covered services are being terminated in the following settings. All beneficiaries receiving services in these settings must receive a Notice of Medicare Non-Coverage (NOMNC) before their services end: For purposes of this instruction, the term "beneficiary" means either beneficiary or representative, when a representative is acting for a beneficiary.

- Home Health Agencies (HHAs)
- Comprehensive Outpatient Rehabilitation Services (CORFs)
- Hospice
- Skilled Nursing Facilities (SNFs)-- Includes services covered under a Part A stay, as well as Part B services provided under consolidated billing (i.e. physical therapy, occupational therapy, and speech therapy). A NOMNC must be delivered by the SNF at the end of a Part A stay or when all of Part B therapies are ending. For example, a beneficiary exhausts the SNF Part A 100-day benefit, but remains in the facility under a private pay stay and receives physical and occupational therapy covered under Medicare Part B. A NOMNC must be delivered by the SNF when both Part B therapies are ending.

Skilled Nursing Facilities includes beneficiaries receiving Part A and B services in Swing Beds.

260.2.1 - Exceptions
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The following service terminations, reductions, or changes in care are not eligible for an expedited review. Providers should not deliver a NOMNC in these instances.

When beneficiaries never received Medicare covered care in one of the covered settings (e.g., an admission to a SNF will not be covered due to the lack of a qualifying hospital stay or a face-to-face visit was not conducted for the initial episode of home health care).

When services are being reduced (e.g., an HHA providing physical therapy and occupational therapy discontinues the occupational therapy).

When beneficiaries are moving to a higher level of care (e.g., home health care ends because a beneficiary is admitted to a SNF).

When beneficiaries exhaust their benefits (e.g., a beneficiary reaches 100 days of coverage in a SNF, thus exhausting their Medicare Part A SNF benefit).

When beneficiaries end care on their own initiative (e.g., a beneficiary decides to revoke the hospice benefit and return to standard Medicare coverage).

When a beneficiary transfers to another provider at the same level of care (e.g., a beneficiary transfers from one SNF to another while remaining in a Medicare-covered SNF stay).

When a provider discontinues care for business reasons (e.g., an HHA refuses to continue care at a home with a dangerous animal or because the beneficiary was receiving physical therapy and the provider's physical therapist leaves the HHA for another job).

260.3 - Notice of Medicare Non-Coverage
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The notice is subject to the Paperwork Reduction Act Process and approval by the Office of Management and Budget. OMB-approved notices may only be modified as per their accompanying instructions. Unapproved modifications may invalidate the NOMNC. The notice and accompanying instructions may be found online at http://www.cms.gov/Medicare/Medicare-General-Information/BNI

260.3.1 - Alterations to the NOMNC
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The NOMNC must remain two pages. The notice can be two sides of one page or one side of two separate pages, but **must not** be condensed to one page.

Providers may include their business logo and contact information on the top of the NOMNC. Text may not be shifted from page 1 to page 2 to accommodate large logos, address headers, etc.

Providers may include information in the optional "Additional Information" section relevant to the beneficiary's situation.

Note: Including information normally included in the Detailed Explanation of Non-Coverage (DENC) in the "Additional Information" section does not satisfy a provider's responsibility to deliver the DENC, if otherwise required.

260.3.2 - Completing the NOMNC

(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

Providers must use the OMB-approved NOMNC (CMS-10123). Providers must type or write the following information in the corresponding blanks of the NOMNC:

- Patient name
- Medicare patient number
- Type of coverage (SNF, Home Health, CORF, or Hospice)
- Effective date (last day of coverage)

Note: The effective date is always the last day beneficiaries will receive coverage for their services. Beneficiaries have no liability for services received on this date, but may face charges for services received the day following the effective date of the NOMNC for home health, hospice, and CORF services. Because SNFs cannot bill the beneficiary for services furnished on the day of (but before the actual moment of) discharge, beneficiaries may leave a SNF the day after the effective date and not face liability for such services.

260.3.3 – Provider Delivery of the NOMNC

(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

Providers must deliver the NOMNC to all beneficiaries eligible for the expedited determination process per §260.2. A NOMNC must be delivered even if the beneficiary agrees with the termination of services.

Medicare providers are responsible for the delivery of the NOMNC. Providers may formally delegate the delivery of the notices to a designated agent such as a courier service; however, all of the requirements of valid notice delivery apply to designated agents.

The provider must ensure that the beneficiary or representative signs and dates the NOMNC to demonstrate that the beneficiary or representative received the notice and understands that the termination decision can be disputed. Use of assistive devices may be used to obtain a signature.

Electronic issuance of NOMNCs is not prohibited. If a provider elects to issue a NOMNC that is viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper issuance over electronic if that is what is preferred. Regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the NOMNC, with the required beneficiary-specific information inserted, at the time of notice delivery.

260.3.4 - Required Delivery Timeframes

(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The NOMNC should be delivered to the beneficiary at least two calendar days before Medicare covered services end or the second to last day of service if care is not being provided daily. For example, if the last day of covered SNF care is a Friday, the NOMNC should be delivered no later than the preceding Wednesday.

Note: The two day advance requirement is NOT a 48 hour requirement. For example, if a patient's last covered home health service is at 10AM on Wednesday and the notice is delivered at 4PM on the prior Monday, it is considered timely.

If home health services are being provided less frequently than daily, the notice must be delivered no later than the next to last visit before Medicare covered services end. For example, if home health care is provided on Tuesdays and Thursdays, and Tuesday is the last day of Medicare covered services, the notice must be delivered no later than the preceding Thursday.

The NOMNC may be delivered earlier than two days preceding the end of covered services. However, delivery of the notice should be closely tied to the impending end of coverage so a beneficiary will more likely understand and retain the information regarding the right to an expedited determination.

The notice may not be routinely given at the time services begin. An exception is when the services are expected to last fewer than two days. In these instances, the notice may be given by the provider when services begin.

There is an accepted circumstance when the NOMNC may be delivered sooner than two days or the next to last visit before coverage ends. This exception is limited to cases where a beneficiary receiving home health services is found to no longer be homebound, and thus ineligible for covered home health care. In this circumstance, the NOMNC should be immediately delivered to the beneficiary upon discovery of the loss of homebound status. We expect that in the vast majority of cases, in all settings, the decision of a physician to end care will be based on medical necessity, and thus, foreseeable by the provider within the required time frames for notice delivery.

260.3.5 - Refusal to Sign the NOMNC

(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

If the beneficiary refuses to sign the NOMNC the provider should annotate the notice to that effect, and indicate the date of refusal on the notice. The date of refusal is considered to be the date of notice receipt. Beneficiaries who refuse to sign the NOMNC remain entitled to an expedited determination.

260.3.6 - Financial Liability for Failure to Deliver a Valid NOMNC
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

If a Qualified Independent Contractor (QIO) determines that a provider did not deliver a valid NOMNC to a beneficiary, the provider is financially liable for continued services until two days after the beneficiary receives valid notice, or until the effective date of the valid notice, whichever is later.

260.3.7 - Amending the Date of the NOMNC
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

If the initial NOMNC was delivered to a beneficiary and the effective date was changed, the provider may amend the notice to reflect the new date. The newer effective date may not be earlier than the effective date of the original notice except in those cases involving the abrupt end of services, as discussed in §260.3.4.

The beneficiary must be verbally notified as soon as possible after the provider is aware of the change. The amended NOMNC must be delivered or mailed to the beneficiary and a copy retained in the beneficiary's file.

If an expedited determination is already in progress, the provider must immediately notify the QIO of the change and provide an amended notice to the QIO.

260.3.8 – NOMNC Delivery to Representatives
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The NOMNC may be delivered to a beneficiary's appointed or authorized representative. Appointed representatives are individuals designated by beneficiaries to act on their behalf during the appeal process. A beneficiary may designate an appointed representative via the "Appointment of Representative" form, the CMS-1696. http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1696.pdf See Chapter 29 of the Medicare Claims Processing Manual, section 270.1, for more information on appointed representatives.

CMS usually requires that notification to a beneficiary who has been deemed legally incompetent be made to an authorized representative of the beneficiary. Generally, an authorized 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).

However, if a beneficiary is temporarily incapacitated a person (typically, a family member or close friend) whom the provider has determined could reasonable represent the beneficiary, but who has not been named in any legally binding document, may be a representative for the purpose of receiving the notices described in this section. Such a representative 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.

In these instances of delivering a notice to an unnamed representative, the provider should annotate the NOMNC with the name of the staff person initiating the contact, the name of the person contacted, and the date, time, and method (in person or telephone) of the contact. A copy of the NOMNC with this information should be retained in the beneficiary's record.

Note - Exceptions to in person notice delivery. If the NOMNC must be delivered to a representative not living with the beneficiary, the provider is not required to make off-site in- person notice delivery to the representative. The provider must complete the NOMNC as required and telephone the representative at least two days prior to the end of covered services. The provider should inform the representative of the beneficiary's right to appeal a coverage termination decision.

The information provided should include the following:

- The beneficiary's last day of covered services, and the date when the beneficiary's liability is expected to begin.
- The beneficiary's right to appeal a coverage termination decision.
- A description of how to request an appeal by a QIO.
- The deadline to request a review as well as what to do if the deadline is missed.
- The telephone number of the QIO to request the appeal.

The date the provider communicates this information to the representative, whether by telephone or in writing, is considered the receipt date of the NOMNC.

The NOMNC must be annotated with the following information on the day that the provider makes telephone contact:

Reflect that all of the information indicated above was communicated to the representative;

Note 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.

A copy of the annotated NOMNC should be mailed to the representative the day telephone contact is made and a dated copy should be placed in the beneficiary's medical file.

If the provider chooses to communicate the information in writing, a hard copy of the NOMNC must be sent to the representative by certified mail, return receipt requested, or any other delivery method that can provide signed verification of delivery (e.g. FedEx, UPS) The burden is on the provider to demonstrate that timely contact was attempted with the representative and that the notice was delivered.

The date that someone at the representative's address signs (or refuses to sign) the receipt is considered the date received. Place a copy of the annotated NOMNC in the beneficiary's medical file.

If both the provider and the representative agree, providers may send the notice by fax or e-mail, however, providers fax and e-mail systems must meet the **The Health Insurance Portability and Accountability Act of 1996 (**HIPAA) privacy and security requirements.

260.3.9 - Notice Retention for the NOMNC
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The provider must retain the original signed NOMNC in the beneficiary's file. The beneficiary should receive a paper copy of the NOMNC that includes all of the required information such as the effective date and covered service at issue. Electronic notice retention is permitted if the NOMNC was delivered electronically.

260.3.10 - Hours of NOMNC Delivery
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

Notice delivery should occur within the normal operating hours of the provider. Providers are not expected to extend their hours or days of business solely to meet the requirements of the expedited determination process. However, it is expected that all notices be provided as timely as possible within these constraints.

260.4 - Expedited Determination Process
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

260.4.1 - Beneficiary Responsibilities
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

260.4.1.1 - Timeframe for Requesting an Expedited Determination
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

A beneficiary who receives a NOMNC and disagrees with the termination of services may request an expedited determination by the appropriate QIO for the state where the services were provided. The beneficiary must contact the QIO by noon of the day before the effective date on the NOMNC. The beneficiary may contact the QIO by telephone or in writing. If the QIO is unable to accept the request, the beneficiary must submit the request by noon of the next day the QIO is available.

260.4.1.2 - Provide Information to QIO
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The beneficiary must be available to answer questions or supply information requested by the QIO. The beneficiary may, but is not required to, supply additional information to the QIO that he or she believes is pertinent to the case.

260.4.1.3 - Obtain Physician Certification of Risk (Home Health and CORF services only)
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

A beneficiary must obtain a physician certification stating that failure to continue home health or CORF services is likely to place the beneficiary's health at significant risk. Without such a certification statement a QIO may not make a determination for service terminations in these settings.

The physician certification is a written statement from any licensed physician contacted by a beneficiary. This is a special certification required only in this expedited determination process for expedited determinations in home health and CORF settings.

A beneficiary may request an expedited determination from a QIO before obtaining this certification of risk. Once the QIO is aware of a review request, it will instruct the beneficiary on how to obtain the necessary certification from a physician.

260.4.2 - Beneficiary Liability During QIO Review
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

A provider may not bill a beneficiary who has timely filed an expedited determination for disputed services until the review process, including a reconsideration by a Qualified Independent Contractor (QIC), if applicable, is complete.

260.4.3 - Untimely Requests for Review
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

If the beneficiary makes an untimely request to the QIO, the QIO will accept the request for review, but is not required to complete the review within its usual 72-hour deadline. The QIO will make a determination as soon as possible upon receipt of the request.

Beneficiaries have up to 60 days from the effective date of the NOMNC to make an untimely request to a QIO. When the beneficiary is still receiving services, the QIO must make a determination and notify the parties within 7 days of receipt of the request. When the beneficiary is no longer receiving services, the QIO will make a determination within 30 days of the request.

The coverage protections discussed in 260.4.2 do not apply to a beneficiary who makes an untimely request to the QIO.

260.4.4 - Provider Responsibilities

(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

When a provider is notified by a QIO of a beneficiary request for an expedited determination, the provider must:

- Deliver the beneficiary a DENC (see §260.4.5) by close of business the day they are notified;
- Supply the QIO with copies of the NOMNC and DENCs by close of business of the day of the QIO notification;
- Supply all information, including medical records, requested by the QIO. The QIO may allow this required information to be supplied via phone, writing, or electronically. If supplied via phone, the provider must keep a written record of the information it provides within the patient record; and

Furnish the beneficiary, at their request, with access to or copies of any documentation it provides to the QIO. The provider may charge the beneficiary a reasonable amount to cover the costs of duplicating and delivering the documentation. This documentation must be provided to the beneficiary by close of business of the first day after the material is requested.

260.4.5 - The Detailed Explanation of Non-Coverage

(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The DENC is subject to the Paperwork Reduction Act Process and approval by the Office of Management and Budget. OMB-approved notices may only be modified as per their accompanying instructions. Unapproved modifications may invalidate the DENC. The notice and accompanying instructions may be found online at http://www.cms.gov/Medicare/Medicare-General-Information/BNI. Medicare providers are responsible for the delivery of the DENC to beneficiaries who request an expedited determination by the QIO.

The DENC must contain the following information:

- The facts specific to the beneficiary's discharge and provider's determination that coverage should end.

- A specific and detailed explanation of why services are either no longer reasonable and necessary or no longer covered.

- A description of, and citations to, the Medicare coverage rule, instruction, or other policies applicable to the review.

The provider should make insertions on the notice in Spanish, if necessary. If this is impossible, additional steps should be taken to ensure that the beneficiary comprehends the content of the notice. Providers may resource CMS multilingual services provided through the 1-800-MEDICARE help line if needed.

The delivery must occur in person by close of business of the day the QIO notifies the provider that the beneficiary has requested an expedited determination. A provider may also choose to deliver the DENC with the NOMNC.

The DENC does not require a signature but should be annotated in the event of a beneficiary's refusal to accept the notice upon delivery.

Note: An HHA is not required to make a separate trip to the beneficiary's residence solely to deliver a DENC. Upon notification from the QIO of a beneficiary's request for an expedited determination, an HHA may telephone the beneficiary to provide the information contained on the DENC, annotate the DENC with the date and time of telephone contact and file with the beneficiary's records. A hard copy of the DENC should be sent to the beneficiary via tracked mail or other personal courier method by close of business of the day the QIO notifies the provider that the beneficiary has requested an expedited determination. The burden is on the provider to demonstrate that timely contact was attempted with the beneficiary and that the notice was delivered.

DENC delivery to representatives, DENC hours of delivery, and DENC retention requirements are the same as the NOMNC requirements outlined in §260.3.

Expedited Determination Scenario in a Skilled Nursing Facility - Example

On June 2nd, the SNF delivers a NOMNC to Bob Mills notifying him that his Medicare covered stay will end on June 4th. Bob decides to request an expedited determination.

June 2nd	June 3nd	June 4rd	June 5th	June 6th
NOMNC Delivered Bob receives a NOMNC indicating that his coverage is ending June 4th.	**Bob must** request an expedited determination by noon today**.**	**NOMNC Effective Date** This is the last day of coverage, as stated on the NOMNC.	**If Bob made his request on June 2nd:** The QIO makes its decision and notifies Bob and the SNF by COB.	**If Bob made his request on June 3rd:** The QIO makes its decision and notifies Bob and the SNF by COB.
	The QIO must notify the SNF of Bob's request for an expedited determination. **The SNF must deliver the DENC to Bob by COB today.** **The SNF must provide relevant medical records to the QIO by COB today.**	**The beneficiary has no liability for this day as this is the last day of coverage in the SNF.**	**If QIO decision is unfavorable:** Beginning today Bob is liable for his stay if he does not leave the SNF.	

260.5 - QIO Responsibilities
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

260.5.1 - Receive Beneficiary Requests for Expedited Review
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

QIOs must be available to receive beneficiary requests for review 24 hours a day, 7 days a week.

260.5.2 - Notify Providers and Allow Explanation of Why Covered Services Should End
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

When the QIO receives a request from a beneficiary, the QIO must immediately notify the provider of services that a request for an expedited determination was made. If the request is received after normal working hours, the QIO should notify the provider as soon as possible on the morning after the request was made.

260.5.3 - Validate Delivery of NOMNC
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The QIO must validate that the NOMNC included the required elements outlined below:

- Date that coverage of services ends.
- Date that beneficiary's financial liability begins.
- Description of right to an expedited determination (and how to request an expedited determination) and the right to submit relevant information to the QIO.
- Right to detailed information on why the provider believes Medicare will no longer cover services.
- Contact information for QIO in the state where services were delivered.

The QIO should determine that NOMNC delivery was valid if all of the following criteria are met:

- All elements stated above are included.
- The beneficiary signed and dated the notice. If the NOMNC was annotated because the beneficiary refused to sign the notice upon delivery, the QIO may still conduct an expedited determination in these instances.

- Notice was delivered at least two days before services terminate. For a non-residential provider, the notice may be delivered at the next to last visit before services terminate.

Invalidating a NOMNC should be a rare occurrence. The only reasons to invalidate are the lack of one of the criteria stated above or a pattern of minor errors as established by the provider.

If a QIO invalidates a NOMNC, a new NOMNC must be issued to the beneficiary with an effective date at least two days after the beneficiary receives valid notice. If the beneficiary again disagrees with the termination of care, a new request to the QIO must be made.

260.5.4 - Solicit the Views of the Beneficiary
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The QIO must solicit the views of the beneficiary who requested the expedited determination.

260.5.5 - Solicit the Views of the Provider
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The QIO must afford the provider an opportunity to explain why the discharge is appropriate.

260.5.6 - Make Determination and Notify Required Parties
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

No later than 72 hours after receipt of the request for an expedited determination, the QIO must make its determination on whether the discharge is appropriate based on medical necessity or other Medicare coverage policies.

Note: If the QIO does not receive supporting information from the provider, it may make its determination based on the evidence at hand, or defer a decision until it receives the necessary information. If this delay results in continued services for the beneficiary, the provider may be held financially liable for these services as determined by the QIO.

The QIO must notify the beneficiary, the beneficiary's physician, and the provider of services of its determination. This notification must include the rationale for the determination and an explanation of Medicare payment consequences and beneficiary liability. QIOs must also inform the beneficiary of the right to an expedited reconsideration by the Qualified Independent Contractor (QIC) and how to request a timely expedited reconsideration. The QIO will make its initial notification via telephone and will follow up with a written determination letter.

260.6 - Effect of a QIO Expedited Determination
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

The QIO determination is binding unless the beneficiary pursues an expedited reconsideration per section 270 of this chapter.

260.6.1 - Right to Pursue an Expedited Reconsideration
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

If dissatisfied with the expedited determination, the beneficiary may request an expedited reconsideration according to the procedures described in section 270 of this chapter.

260.6.2 - Effect of QIO Determination on Continuation of Care
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

If the QIO decision extends coverage to a period where a physician's orders do not exist, either because of the duration of the expedited determination process, or because the physician has already concurred with the termination of care, providers cannot deliver care. In the event of a QIO decision favorable to a beneficiary without physician orders, the ordering physician should be made aware the QIO has ruled coverage should continue, and be given the opportunity to reinstate orders. The beneficiary may also seek other personal physicians to write orders for care as well as find another service provider. The expedited determination process does not override regulatory or State requirements that physician orders are required for a provider to deliver care.

If a QIO decision is favorable to the beneficiary and the beneficiary resumes covered services, a new NOMNC should be delivered if that care is later terminated, per the requirements of this section. If the beneficiary again disagrees with the termination of care, a new request to the QIO must be made.

The QIO decision will affect the necessity of subsequent Advance Beneficiary Notice of Noncoverage (ABN) deliveries.

Example: If covered home health care continues following a favorable QIO decision for the beneficiary, the HHA would resume issuance of Home Health Advanced Beneficiary Notices (HHABNs) as warranted for the remainder of this home health episode. If the QIO decides that Medicare covered care should end and the patient wishes to continue receiving care from the HHA, even though Medicare will not pay, an HHABN with Option Box 1 must be issued to the beneficiary since this would be an initiation of non-covered care.

Example: If covered Skilled Nursing Facility (SNF) care continues following a favorable QIO decision for the beneficiary but later ends due to the end of Medicare coverage, and the patient wishes to continue receiving uncovered care at the SNF, a SNFABN must be issued to the beneficiary.

260.6.3 - Right to Pursue the Standard Claims Appeal Process
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

If a beneficiary receives services of the type at issue in the expedited determination after the coverage end date, and coverage is denied, the beneficiary may appeal the denial within the standard claims appeal process (See Chapter 29 of this manual.)

261 - Expedited Determination Notice Association with Advance Beneficiary Notices
(Rev. 2711, Issued: 05-24-13, Effective: 08-26-13, Implementation: 08-26-13)

Delivery of the NOMNC does not replace the required delivery of other mandatory notices, including ABNs. Notice delivery must be determined by the individual NOMNC requirements per this section and ABN delivery requirements per §1879 of the Act and per guidance in this chapter. Both the NOMNC and an ABN may be required in certain instances.

Only one notice may be required when Medicare covered care is ending.

Example: A beneficiary is receiving CORF services and all covered CORF care is ending. A NOMNC must be delivered at least two days, or two visits, prior to the end of coverage. If the beneficiary does not continue the CORF services, an ABN should not be issued.

Some situations may require two notices at the end of Medicare covered care.

Example: A beneficiary's Part A stay is ending because skilled level care is no longer medically necessary and the beneficiary wishes to remain in the SNF receiving custodial care. The beneficiary must receive the NOMNC two days prior to the end of coverage. A SNFABN must also be delivered before custodial care begins.

It is also possible that no notice is required when Medicare coverage is ending.

Example: A beneficiary exhausts the 100 day benefit in a SNF. In this instance, the NOMNC should not be delivered. The SNFABN is not required in this situation. However, it can be issued voluntarily, as a courtesy to the beneficiary.

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,

k

- 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.

400 - Part A Medicare Outpatient Observation Notice

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

The MOON informs all Medicare beneficiaries when they are an outpatient receiving observation services, and are not an inpatient of the hospital or critical access hospital (CAH).

400.1 - Statutory Authority

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

On August 6, 2015, Congress enacted the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) Public Law 114-42, amending Section 1866(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395cc(a)(1)), by adding a new subparagraph (Y). The NOTICE Act requires hospitals and CAHs to provide written and oral explanation of such written notification to individuals who receive observation services as outpatients for more than 24 hours.

The process for delivery of this notice, the Medicare Outpatient Observation Notice (MOON), was addressed in rulemaking, including a final rule, CMS-1655-F (81 FR 56761, 57037 through 57052, August 22, 2016), effective October 1, 2016. The resulting regulations are located at 42 CFR Part 489.20(y).

400.2 - Scope

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

The MOON must be delivered to beneficiaries in Original Medicare (fee-for-service) and Medicare Advantage enrollees who receive observation services as outpatients for more than 24 hours. The hospital or CAH must provide the MOON no later than 36 hours after observation services as an outpatient begin. This also includes beneficiaries in the following circumstances:

- Beneficiaries who do not have Part B coverage (as noted on the MOON, observation stays are covered under Medicare Part B).
- Beneficiaries who are subsequently admitted as an inpatient prior to the required delivery of the MOON.
- Beneficiaries for whom Medicare is either the primary or secondary payer.

NOTES:

- For purposes of these instructions, the term “beneficiary” means either beneficiary or representative, when a representative is acting for a beneficiary.
- Please see Chapter 13 of the Medicare Managed Care Manual for Medicare Advantage instructions.

The statute expressly provides that the MOON be delivered to beneficiaries who receive observation services as an outpatient for more than 24 hours. In other words, the statute does not require hospitals to deliver the MOON to all beneficiaries receiving outpatient services. The MOON is intended to inform beneficiaries who receive observation services for more than 24 hours that they are outpatients receiving observation services and not inpatients, and the reasons for such status, and must be delivered no later than 36 hours after observation services begin. However, hospitals and CAHs may deliver the MOON to an individual receiving observation services as an outpatient before such individual has received more than 24 hours of observation services. Allowing delivery of the MOON before an individual has received 24 hours of observation services affords

hospitals and CAHs the flexibility to deliver the MOON consistent with any applicable State law that requires notice to outpatients receiving observation services within 24 hours after observation services begin. The flexibility to deliver the MOON any time up to, but no later than, 36 hours after observation services begin also allows hospitals and CAHs to spread out the delivery of the notice and other hospital paperwork in an effort to avoid overwhelming and confusing beneficiaries.

Hospitals Affected by these Instructions. These instructions apply to hospitals as well as CAHs per section 1861(e) and section 1861(mm) of the Social Security Act.

400.3 - Medicare Outpatient Observation Notice

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

The MOON is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB). The MOON may only be modified as per their accompanying instructions, as well as per guidance in this section. Unapproved modifications cannot be made to the OMB-approved, standardized MOON. The notice and accompanying instructions may be found online at http://www.cms.gov/Medicare/Medicare-General-Information/BNI

400.3.1 - Alterations to the MOON

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

In general, the MOON must remain two pages, unless inclusion of additional information per section 400.3.8 or State-specific information per section 400.5 below results in additional page(s). Hospitals and CAHs subject to State law observation notice requirements may attach an additional page to the MOON to supplement the "Additional Information" section in order to communicate additional content required under State law, or may attach the notice required under State law to the MOON. The pages of the notice can be two sides of one page or one side of separate pages, but must not be condensed to one page.

Hospitals may include their business logo and contact information on the top of the MOON. Text may not be shifted from page 1 to page 2 to accommodate large logos, address headers, or any other information.

400.3.2 - Completing the MOON

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

Hospitals must use the OMB-approved MOON (CMS-10611). Hospitals must type or write the following information in the corresponding blanks of the MOON:

- Patient name;
- Patient number; and
- Reason patient is an outpatient.

400.3.3 - Hospital Delivery of the MOON
(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

Hospitals and CAHs must deliver the MOON to beneficiaries in accordance with section 400.2 above. Hospitals and CAHs must provide both the standardized written MOON, as well as oral notification.

Oral notification must consist of an explanation of the standardized written MOON. The format of such oral notification is at the discretion of the hospital or CAH, and may include, but is not limited to, a video format. However, a staff person must always be available to answer questions related to the MOON, both in its written and oral delivery formats.

The hospital or CAH must ensure that the beneficiary or representative signs and dates the MOON to demonstrate that the beneficiary or representative received the notice and understands its contents. Use of assistive devices may be used to obtain a signature.

Electronic issuance of the MOON is permitted. If a hospital or CAH elects to issue a MOON viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper issuance over electronic issuance if that is what the beneficiary prefers. Regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the MOON, as specified in 400.3.9, and the required beneficiary specific information inserted, at the time of notice delivery.

400.3.4 - Required Delivery Timeframes
(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

The MOON must be delivered to a beneficiary who receives observation services as an outpatient for more than 24 hours, and must be delivered not later than 36 hours after observation services begin. The MOON must be delivered before 36 hours following initiation of observation services if the beneficiary is transferred, discharged, or admitted. The MOON may be delivered before a beneficiary receives 24 hours of observation services as an outpatient.

The start time of observation services, for purposes of determining when more than 24 hours of observation services have been received, is the clock time observation services are initiated (furnished to the patient), as documented in the patient's medical record, in accordance with a physician's order. This follows the elapsed clock time, rather than the billed time, associated with the observation services.

400.3.5 - Refusal to Sign the MOON
(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

If the beneficiary refuses to sign the MOON, and there is no representative to sign on behalf of the beneficiary, the notice must be signed by the staff member of the hospital or CAH who presented the written notification. The staff member's signature must include

the name and title of the staff member, a certification that the notification was presented, and the date and time the notification was presented. The staff member annotates the "Additional Information" section of the MOON to include the staff member's signature and certification of delivery. The date and time of refusal is considered to be the date of notice receipt.

400.3.6 - MOON Delivery to Representatives

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

The MOON may be delivered to a beneficiary's appointed representative. Appointed representatives are individuals designated by beneficiaries to act on their behalf. A beneficiary may designate an appointed representative via the "Appointment of Representative" form, the CMS-1696. http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1696.pdf. See Chapter 29 of the Medicare Claims Processing Manual, section 270.1, for more information on appointed representatives.

The MOON may also be delivered to an authorized representative. Generally, an authorized 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).

Notification to a beneficiary who has been deemed legally incompetent is typically made to an authorized representative of the beneficiary. However, if a beneficiary is temporarily incapacitated, a person (typically, a family member or close friend) whom the hospital or CAH has determined could reasonably represent the beneficiary, but who has not been named in any legally binding document, may be a representative for the purpose of receiving the MOON. Such a representative should act in the beneficiary's best interests and 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.

In instances where the notice is delivered to a representative who has not been named in a legally binding document, the hospital or CAH annotates the MOON with the name of the staff person initiating the contact, the name of the person contacted, and the date, time, and method (in person or telephone) of the contact.

NOTE: There is an exception to the in-person notice delivery requirement. If the MOON must be delivered to a representative who is not physically present to receive delivery of the notice, the hospital or CAH is not required to make an off-site delivery to the representative. The hospital or CAH must complete the MOON as required and telephone the representative.

- The information provided telephonically includes all contents of the MOON;

- Note the date and time the hospital or CAH communicates (or makes a good faith attempt to communicate) this information telephonically, per 400.2 above, to the representative is considered the receipt date of the MOON;

- Annotate the "Additional Information" section to reflect that all of the information indicated above was communicated to the representative; and

- Annotate the "Additional Information" section with 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.

Mail a copy of the annotated MOON to the representative the day telephone contact is made.

A hard copy of the MOON must be sent to the representative by certified mail, return receipt requested, or any other delivery method that can provide signed verification of delivery (e.g., FedEx, UPS). The burden is on the hospital or CAH to demonstrate that timely contact was attempted with the representative and that the notice was delivered.

If the hospital or CAH and the representative both agree, the hospital or CAH may send the notice by fax or e-mail; however, the hospital or CAH's fax and e-mail systems must meet the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security requirements.

400.3.7 - Ensuring Beneficiary Comprehension

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

The OMB-approved standardized MOON is available in English and Spanish. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, hospitals and CAHs must employ their usual procedures to ensure notice comprehension. Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies. Hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with limited English proficiency (LEP) consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, consistent with section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

400.3.8 - Completing the Additional Information Field of the MOON

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

This section may be populated with any additional information a hospital wishes to convey to a beneficiary.

Such information may include, but is not limited to:

- Contact information for specific hospital departments or staff members.

- Additional content required under applicable State law related to notice of observation services.
- Part A cost-sharing responsibilities if a beneficiary is admitted as an inpatient before 36 hours following initiation of observation services.

- The date and time of the inpatient admission if a patient is admitted as an inpatient prior to delivery of the MOON.

- Medicare Accountable Care Organization information.

- Hospital waivers of the beneficiary's responsibility for the cost of self-administered drugs.

- Any other information pertaining to the unique circumstances regarding the particular beneficiary.

If a hospital or CAH wishes to add information that cannot be fully included in the "Additional Information" section, an additional page may be attached to supplement the MOON.

400.3.9 - Notice Retention for the MOON

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

The hospital or CAH must retain the original signed MOON in the beneficiary's medical record. The beneficiary receives a paper copy of the MOON that includes all of the required information described in section 400.3.2 and, as applicable, sections 400.3.5, 400.3.6 and 400.3.8. Electronic notice retention is permitted.

400.4 - Intersection with State Observation Notices

(Rev. 3698, Issued: 01-27-17, Effective: 02-21-17; Implementation: 02-21-17)

As noted in sections 400.3.1 and 400.3.8 above, hospitals and CAHs in States that have State-specific observation notice requirements may add State-required information to the "Additional Information" field, attach an additional page, or attach the notice required under State law to the MOON.

450 - Expedited Determinations When a Beneficiary is Reclassified from an Inpatient to an Outpatient Receiving Observation Services

(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

Medicare beneficiaries with Original Medicare who have been reclassified by a hospital from an inpatient to an outpatient receiving observation services and meet additional criteria (See 450.2 of this section) have a right to appeal their status change to a

Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIO).

450.1 –Authority

(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

This process was implemented through a final rule, CMS-4204-F, effective November 15, 2024. The resulting regulations are located at 42 CFR Part 405.1210 through 405.1212.

450.2 - Scope

(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The expedited determination process is available to beneficiaries in Original Medicare who, after formally being admitted as an inpatient, have subsequently been reclassified by the hospital as an outpatient receiving observation services. The reclassification must have happened while the beneficiary was still in the hospital, and also met one of the following criteria:

- *For beneficiaries with Medicare Part B, their stay in the hospital must last at least three days.*
- *For beneficiaries that do not have Medicare Part B, no three day stay is required to qualify for this expedited appeals process.*

NOTE: For purposes of these instructions, the term "beneficiary" means either beneficiary or representative, when a representative is acting on a beneficiary's behalf.

Hospitals Affected by these Instructions. *These instructions apply to 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 (CAHs).*

450.3 – Medicare Change of Status Notice (MCSN)

(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The Medicare Change of Status Notice (MCSN) is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB). The MCSN may only be modified as per the accompanying instructions, as well as per guidance in this section. Unapproved modifications cannot be made to the OMB-approved, standardized MCSN. The notice and accompanying instructions may be found online at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/HospitalDischargeAppealNotices

450.3.1 Alterations to the MCSN

(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

- *The MCSN must remain two pages. The notice can be two sides of one page or one side of two separate pages but **must not** be condensed to one page.*

- *Hospitals may include their business logo and contact information on the top of the MCSN. Text may not be shifted from page one to page two to accommodate large logos, address headers, etc.*

- *Hospitals may include information in the optional "Additional Information" section relevant to the beneficiary's situation.*

450.3.2 - Hospital Delivery of the MCSN

(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

Hospitals must deliver the MCSN to all beneficiaries eligible for the expedited determination process per §450.2.

- *The hospital must ensure that the beneficiary or representative signs and dates the MCSN to demonstrate that the beneficiary or representative received the notice and understands its contents. See §450.3.6 'Ensuring Beneficiary Comprehension'.*

- *Use of assistive devices may be used to obtain a signature.*

- *Electronic issuance of the MCSN is permitted.*

If a hospital elects to issue an MCSN viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper issuance over electronic issuance if that is what the beneficiary prefers. Regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the required beneficiary specific information must be inserted, and the beneficiary must be given a paper copy of the MCSN at the time of notice delivery.

450.3.3- Required Delivery Timeframes of the MCSN

(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

Hospitals must deliver the MCSN as soon as possible after a beneficiary is eligible for this process per §450.2, but no later than four hours prior to discharge.

For beneficiaries with Part B, the notice must be delivered as soon as possible after the hospital reclassifies the beneficiary from inpatient to outpatient receiving observation services and the third day in the hospital is reached.

For beneficiaries without Medicare Part B coverage, hospitals must deliver the notice as soon as possible after the change in status from inpatient to outpatient receiving

observation services because a three day hospital stay is not required for these beneficiaries to be eligible for this expedited appeals process.

450.3.4 - Refusal to Sign the MCSN
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

If the beneficiary refuses to sign the MCSN, the hospital should annotate the notice to that effect and indicate the date of refusal on the notice. The date of refusal is considered to be the date of notice receipt. Beneficiaries who refuse to sign the MCSN remain entitled to an expedited determination.

450.3.5 - Ensuring Beneficiary Comprehension
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The OMB-approved standardized MCSN is available in English, Spanish, and additional languages as they become available. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, hospitals and CAHs must employ their usual procedures to ensure notice comprehension. Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies. Hospitals and CAHs are reminded that recipients of federal financial assistance have an independent obligation to provide language assistance services to individuals with limited English proficiency (LEP) consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, consistent with section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

450.3.6 - MCSN Delivery to Representatives
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The MCSN may be delivered to a beneficiary's appointed or authorized representative.

Type Of Representative

Appointed Representative	*Authorized Representative*

An appointed representative is an individual designated by a beneficiary to act on the beneficiary's behalf. A beneficiary may designate an appointed representative via the "Appointment of Representative" form CMS-1696 (or a similar written instrument containing the required elements under 42 CFR 405.910). See Chapter 29 of the Medicare Claims Processing Manual, section 270.1, for more information on appointed representatives.	*An authorized 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).*

Notes:

- *If a beneficiary is temporarily incapacitated and there is no appointed or authorized representative, a person (typically, a family member or close friend) whom the hospital has determined could reasonably represent the beneficiary, but who has not been named in any legally binding document, may be a representative for the purpose of receiving the MCSN. Such a representative should act in the beneficiary's best interests and in a manner that is protective of the beneficiary and the beneficiary's rights. There should be no relevant conflict between the representative's and the beneficiary's interests.*

- *In instances where the notice is delivered to a representative who has not been named in a legally binding document, the hospital must annotate the MCSN with the name of the staff person initiating the contact, the name of the person contacted, and the date, time, and method (in person or telephone) of the contact.*

Delivery to off-site representatives

If the MCSN must be delivered to a representative who is not physically present, the hospital is not required to personally deliver the MCSN or have the MCSN delivered via courier to the representative. The hospital must complete the MCSN as required and may telephone the representative instead, and then also mail the MCSN. The date and time of the telephone call is considered the receipt date of the MCSN.

The hospital must complete all of the following actions under this delivery method:

6. *Verbally convey all contents of the MCSN.*
7. *Note the date and time this information is communicated verbally.*
8. *Annotate the "Additional Information" section to reflect that the MCSN was communicated verbally to the representative.*

9. *Annotate the "Additional Information" section with 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.*
10. *Mail a copy of the annotated MCSN to the representative the day telephone contact is made.*

The burden is on the hospital to demonstrate that timely contact was attempted with the representative and that the notice was delivered.

If the hospital and the representative both agree, the hospital may send the notice by fax or e-mail; however, the hospital or CAH's fax and e-mail systems must meet the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security requirements.

450.3.7- Notice Retention for the MCSN
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The hospital or CAH must retain the signed MCSN in the beneficiary's medical record. The beneficiary or their representative receives a paper copy of the MCSN that includes all of the required information described in this section. Electronic notice retention is permitted.

450.4 Expedited Determination Process
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

450.4.1 - Beneficiary Responsibilities
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

450.4.1.1 - Timeframes for Requesting an Expedited Determination
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

A beneficiary who receives an MCSN and disagrees with the status change may request an expedited determination by the appropriate BFCC-QIO for the state where the services were provided. The beneficiary may contact the BFCC-QIO by telephone or in writing.

For timely requests:
The beneficiary must contact the BFCC-QIO before leaving the hospital for a timely request.

For untimely requests:

The beneficiary may contact the BFCC-QIO at any time, including after a related claim has been filed with the Medicare Administrative Contractor (MAC).

450.4.1.2 - Provide Information to BFCC-QIO
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The beneficiary must be available to answer questions or supply information requested by the BFCC-QIO. The beneficiary may, but is not required to, supply additional information to the BFCC-QIO that he or she believes is pertinent to the case.

450.4.2 - Beneficiary Liability During BFCC-QIO Review
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

A hospital may not bill a beneficiary who has timely filed an expedited determination until the review process is complete.

450.4.3 - Hospital Responsibilities
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

When a hospital is notified by a BFCC-QIO of a beneficiary request for an expedited determination, the hospital must perform all of the following actions.

5. *Supply the BFCC-QIO with a copy of the MCSN as soon as possible, but no later than noon of the day after BFCC-QIO notification.*

6. *Supply all information, including medical records, requested by the BFCC-QIO. The BFCC-QIO may allow this required information to be supplied via phone, writing, or electronically. If supplied via phone, the provider must keep a written record of the information it provides within the patient record.*

7. *Furnish the beneficiary, at their request, with access to or copies of any documentation it provides to the BFCC-QIO. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating and delivering the documentation. This documentation must be provided to the beneficiary by close of business of the first day after the material is requested.*

450.5 – BFCC-QIO Responsibilities
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

450.5.1 – Receive Beneficiary Requests for Expedited Review
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

BFCC-QIOs must be available to receive beneficiary requests for review 24 hours a day, seven days a week.

450.5.2 – Notify Hospitals
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

When the BFCC-QIO receives a request from a beneficiary, the BFCC-QIO must immediately notify the hospital that a request for an expedited determination was made. If the request is received after normal working hours, the BFCC-QIO should notify the hospital as soon as possible on the morning after the request was made.

450.5.3 – Validate Delivery of the MCSN
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The BFCC-QIO should determine that MCSN delivery was valid if all of the following criteria are met:

- *The notice used is the OMB approved MCSN published by CMS.*
- *The notice was delivered timely per §450.3.3.*
- *The notice was signed and dated by the beneficiary.*

If the BFCC-QIO determines that the hospital did not deliver a valid notice, the BFCC-QIO will instruct the hospital to reissue the notice.

450.5.4 - Solicit the Views of the Beneficiary
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The BFCC-QIO must solicit the views of the beneficiary who requested the expedited determination.

450.5.5 - Solicit the Views of the Hospital
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The BFCC-QIO must provide the hospital an opportunity to explain why the reclassification of the beneficiary from an inpatient to an outpatient receiving observation services was appropriate.

450.5.6 – Make Determination and Notify Required Parties
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

For timely requests *(received before the beneficiary leaves the hospital):*
The BFCC-QIO must make its determination no later than one calendar day after it receives all requested pertinent information from the hospital.

For untimely requests *(received after the beneficiary leaves the hospital):*
The BFCC-QIO must make its determination no later than two calendar days after it receives all requested pertinent information from the hospital.

The BFCC-QIO must perform the following actions for timely and untimely requests.

4. *Notify the beneficiary, the hospital, and SNF (if applicable) of its determination. This notification must include the rationale for the determination and an explanation of Medicare payment consequences and beneficiary liability.*
5. *Inform the beneficiary of the right to an expedited reconsideration by the BFCC-QIO and how to request a timely expedited reconsideration.*
6. *Make its initial notification via telephone and follow up with a written determination letter.*

NOTE: *If the BFCC-QIO does not receive supporting information from the hospital, it may make its determination based on the evidence at hand or defer a decision until it receives the necessary information.*

450.6 - Effect of a BFCC-QIO Expedited Determination
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The BFCC-QIO determination is binding for payment purposes on the beneficiary, hospital, and MAC, unless the beneficiary pursues an expedited reconsideration per section 460 of this chapter.

460- Expedited Reconsiderations
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

A beneficiary who is dissatisfied with a QIO determination may request an expedited reconsideration by the BFCC-QIO.

460.1- Beneficiary Responsibilities
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

460.1.1- Timeframe for Requesting an Expedited Reconsideration
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

A beneficiary who is dissatisfied with a BFCC-QIO's expedited determination may request an expedited reconsideration. The beneficiary may contact the BFCC-QIO by telephone or in writing.

- ***For timely requests****: The beneficiary must contact the BFCC-QIO no later than noon of the calendar day following receipt of the initial notification (whether by telephone or in writing).*

- ***For untimely requests****: The beneficiary may contact the BFCC-QIO anytime, including after a related claim has been filed with the MAC.*

460.1.2- Provide Information to the BFCC-QIO
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The beneficiary must be available to answer questions or supply information requested by the BFCC-QIO. The beneficiary may, but is not required to, supply additional information to the BFCC-QIO that he or she believes is pertinent to the case.

460.1.3- Beneficiary Liability During BFCC-QIO
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

A hospital may not bill a beneficiary who has timely filed an expedited reconsideration until the review process is complete.

460.2- Hospital Responsibilities
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

A hospital is required to submit any and all documentation requested by the BFCC-QIO during the expedited determination process, as described in §450.4.3. The hospital may, but is not required to, submit evidence to the BFCC-QIO to be considered in the reconsideration decision. If a hospital fails to comply with a QIO's request for additional information, the BFCC-QIO makes its reconsideration decision based on the information available.

460.3- BFCC-QIO Responsibilities
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

460.3.1- Receive Beneficiary requests for Expedited Reconsiderations
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

BFCC-QIOs must be available to receive beneficiary requests for review 24 hours a day, seven days a week.

460.3.2- Notify Hospitals
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

When the BFCC-QIO receives a request from a beneficiary, the BFCC-QIO must immediately notify the hospital that a request for an expedited reconsideration was made. If the request is received after normal working hours, the BFCC-QIO should notify the hospital as soon as possible on the morning after the request was made.

460.3.3- Solicit the Views of the Beneficiary
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The BFCC-QIO must solicit the views of the beneficiary who requested the expedited reconsideration.

460.3.4- Solicit the Views of the Hospital
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The BFCC-QIO must provide the hospital an opportunity to provide information not submitted for the expedited redetermination.

460.3.5- Make Determination and Notify Required Parties
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

***For timely requests**:*
The BFCC-QIO must make its reconsideration determination no later than two calendar days after it receives all requested pertinent information from the hospital.

***For untimely requests**:*
The BFCC-QIO must make its reconsideration determination no later than three calendar days after it receives all requested pertinent information from the hospital.

460.4- Effect of a BFCC-QIO Expedited Reconsideration
(Rev. 12934; Issued: 10-31-24; Effective: 11-15-24; Implementation: 02-14-25)

The BFCC-QIO reconsideration determination is binding for payment purposes on the beneficiary, hospital, and MAC, unless the beneficiary requests a hearing by an ALJ in accordance with 42 CFR part 478 subpart B.

500 - Glossary
(Rev. 12423; Issued: 12-20-23; Effective: 01-01-24; Implementation: 01-02-24)

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

Advance notice of non-coverage– 42 CFR 418.408(d)(2) states that if Medicare would be likely to deny payment as not medically reasonable and necessary, before the service was provided, the physician informed the beneficiary, or someone acting on the beneficiary's behalf, in writing that the physician believed Medicare was likely to deny payment for the specific service and that the beneficiary signed a statement agreeing to pay for that service. This statement may appear as the notice of non-coverage (e.g.
Advance Beneficiary Notice of Non-coverage (ABN), Form CMS-R-131, Skilled
Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN), Form CMS10055, Home Health Change of Care Notice (HHCCN), Form CMS-10280), as defined in 42 CFR 411.404.)

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

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

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

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

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

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

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

Healthcare provider – Healthcare provider means a "provider of services" (or provider) (as defined under Section 1861(u) of the Social Security Act), a hospital, a critical access hospital (CAH), a skilled nursing facility (SNF), a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar

agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization or intensive outpatient services).

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

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

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

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

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

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

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

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

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

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

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

Refund Requirements (RR) for Assigned and Non-assigned Claims for Medical Equipment and Supplies – Under §132 of SSAA-1994 (Social Security Act Amendments of 1994, P.L. 103-432) which adds §1834(a)(18) to the Social Security Act, and under §133 of SSAA-1994 which adds §1834(j)(4) and §1879(h) to the Social Security Act, new liability protections for Medicare beneficiaries affect suppliers of medical equipment and supplies. All suppliers who sell or rent medical equipment and supplies to Medicare beneficiaries are subject to the refund provisions of §§1834(a)(18), 1834(j)(4) and 1879(h) of the Social Security Act.

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

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

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R12934CP	10/31/2024	Medicare Change of Status Notice (MCSN) Manual Instructions-	02/14/2025	13846
R12758CP	08/01/2024	Revisions to the Skilled Nursing Facility (SNF) Advance Beneficiary Notice of Non-Coverage (ABN)	10/02/2024	13621
R12423CP	12/20/2023	Enforcing Billing Requirements for Intensive Outpatient Program (IOP) Services with New Condition Code 92	01/02/2024	13222
R11210CP	01/21/2022	Expedited Review Process for Hospital Inpatients in Original Medicare	04/21/2022	12546
R10862CP	07/14/2021	Section 50 in Chapter 30 of Publication (Pub.) 100-04 Manual Updates	10/14/2021	12242
R4197CP	01/11/2019	Chapter 30 Revisions in Publication (Pub.) 100-04, Medicare Claims Processing Manual	04/15/2019	10848
R4250CP	03/08/2019	Update to Chapter 30 in Publication (Pub.) 100-04 to Provide Language-Only Changes for the New Medicare Card Project	04/08/2019	11165
R4198CP	01/11/2019	Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN)	04/30/2018	10567
R4001CP	03/16/2018	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF) (2018)	06/19/2018	10512
R4011CP	03/30/2018	Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN)- Rescinded and replaced by Transmittal 4198	04/30/2018	10567
R3698CP	01/27/2017	Medicare Outpatient Observation Notice (MOON) Instructions	02/21/2017	9935

Rev #	Issue Date	Subject	Impl Date	CR#
R3695CP	01/20/2017	Medicare Outpatient Observation Notice (MOON) Instructions – Rescinded and replaced by Transmittal 3698	02/10/2017	9935
R3560CP	07/15/2016	Correction of Remark Code Information	10/17/2016	9641
R3187CP	02/06/2015	Language Only Update to Pub 100-04, Chapter 30 for ASC X12 and Claim References	03/06/2015	8992
R2911CP	03/14/2014	Manual Updates to Clarify Skilled Nursing Facility Advanced Beneficiary Notice (SNF ABN) Requirements Pursuant to Jimmo vs. Sebelius	03/25/2014	8644
R2878CP	02/21/2014	Correction CR - Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131	05/15/2014	8597
R2782CP	09/06/2013	Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131	12/09/2013	8404
R2781CP	09/06/2013	Home Health Change of Care Notice (HHCCN), Form CMS-10280, Manual Instructions. This CR rescinds and fully replaces CR 7323.	12/09/2013	8403
R2711CP	05/24/2013	Expedited Determinations for Provider Service Terminations	08/26/2013	7903
R2480CP	06/01/2012	Advanced Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, Updated Manual Instructions	09/04/2012	7821
R2362CP	12/01/2011	Home Health Advance Beneficiary Notice, (HHABN), Form CMS-R-296	02/03/2012	7323
R1983CP	06/11/2010	Clarification on Use of the SNF ABN and Denial Letters	07/12/2010	6987

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
R577CP	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

Back to top of Chapter