

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4197	Date: January 11, 2019
	Change Request 10848

SUBJECT: Chapter 30 Revisions in Publication (Pub.) 100-04, Medicare Claims Processing Manual

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to revise Chapter 30 of Pub. 100-04, Medicare Processing Manual. The policy that is currently in Chapter 30 is not changing, but is being revised for formatting and readability. A glossary has been added to aid readers with common terminology within the chapter.

EFFECTIVE DATE: April 15, 2019

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

IMPLEMENTATION DATE: April 15, 2019

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	30/10/Financial Liability Protections (FLP) Provisions
R	30/20/Limitation On Liability (LOL) Under §1879 of the Act Where Medicare Claims Are Denied
R	30/20/20.1/LOL Coverage Denials
D	30/20/20.1/20.1.1/Statutory Basis
D	30/20/20.1/20.1.2/Dependent Services
D	30/20/20.1/20.1.3/Partial Denials Based on Reasonable and Necessary Levels of Care
R	30/20/20.2/Denials When the LOL Provision Does Not Apply
R	30/20/20.2/20.2.1/Categorical Denials
D	30/20/20.2/20.2.2/Technical Denials
R	30/30/Determining Liability for Disallowed Claims Under §1879
R	30/30/30.1/Beneficiary's Knowledge and Liability
R	30/30/30.1/30.1.1/Other Evidence of Knowledge
D	30/30/30.1/30.1.2/Beneficiary Determined to Be Without Liability
R	30/30/30.2/Healthcare Provider, Practitioner or Supplier Knowledge and Liability
R	30/30/30.2/30.2.1/Evidence of Healthcare Provider or Supplier Knowledge
R	30/30/30.2/30.2.2/Medical Record Evidence of Healthcare Provider or Supplier Knowledge
R	30/30/30.2/30.2.3/Acceptable Standards of Practice
N	30/30/30.3/The Right to Appeal
N	30/30/30.4/Fraud, Abuse, Patently Unnecessary Items and Services
R	30/40/Written Notice as Evidence of Knowledge
R	30/40/40.1/Sources of Written Notice
D	30/40/40.1/40.1.1/Criteria for Determining Practitioner and Other Supplier Knowledge
D	30/40/40.1/40.1.2/Criteria for Determining Provider Knowledge
D	30/40/40.1/40.1.3/Acceptable Standards of Practice
D	30/40/40.1/40.1.4/Fraud, Abuse, Patently Unnecessary Items and Services
R	30/40/40.2/Written Notice Standards
R	30/40/40.2/40.2.1/Other Written Notice Standards
R	30/40/40.2/40.2.2/Written Notice Special Considerations
D	30/40/40.2/40.2.3/Sources of Written Notice

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
D	30/40/40.2/40.2.4/Other Evidence of Knowledge
R	30/40/40.3/Medical Emergency or Otherwise Under Great Duress Situations
D	30/40/40.3/40.3.1/Proper Notice Documents
D	30/40/40.3/40.3.1/40.3.1.1/Readability Requirements
D	30/40/40.3/40.3.1/40.3.1.2/Specificity, Delivery, and Receipt
D	30/40/40.3/40.3.1/40.3.1.3/Defective Notice
D	30/40/40.3/40.3.2/Qualified Notifiers
D	30/40/40.3/40.3.3/Timeliness
D	30/40/40.3/40.3.4/Effective Delivery
D	30/40/40.3/40.3.4/40.3.4.1/Basic Delivery Requirements
D	30/40/40.3/40.3.4/40.3.4.2/Telephone Notice
D	30/40/40.3/40.3.4/40.3.4.3/Capable Recipient
D	30/40/40.3/40.3.4/40.3.4.4/Responsiveness to Inquiries
D	30/40/40.3/40.3.4/40.3.4.5/Identification of Notifier
D	30/40/40.3/40.3.4/40.3.4.6/Dealing With Beneficiary Refusals
D	30/40/40.3/40.3.5/Authorized Representatives
D	30/40/40.3/40.3.6/Routine Notice Prohibition
D	30/40/40.3/40.3.6/40.3.6.1/Generic ABNs
D	30/40/40.3/40.3.6/40.3.6.2/Blanket ABNs
D	30/40/40.3/40.3.6/40.3.6.3/Signed Blank ABNs
D	30/40/40.3/40.3.6/40.3.6.4/Routine ABN Prohibition Exceptions
D	30/40/40.3/40.3.7/Standards for Situations Where the Beneficiary is in a Medical Emergency or Is Otherwise Under Great Duress
D	30/40/40.3/40.3.7/40.3.7.1/Emergency Medical Treatment and Active Labor Act (EMTALA) Situations
D	30/40/40.3/40.3.7/40.3.7.2/Other Situations
D	30/40/40.3/40.3.8/Reason for Predicting Denial
N	30/40/40.4/Emergency Medical Treatment and Active Labor Act (EMTALA) Situations
N	30/500/Glossary

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is

not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4197	Date: January 11, 2019	Change Request: 10848
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SUBJECT: Chapter 30 Revisions in Publication (Pub.) 100-04, Medicare Claims Processing Manual

EFFECTIVE DATE: April 15, 2019

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IMPLEMENTATION DATE: April 15, 2019

I. GENERAL INFORMATION

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

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

In most cases, the FLP provisions apply only to beneficiaries enrolled in the Original Medicare Fee for Service program Parts A and B. The FLP provisions apply only when both of the following conditions are met:

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

The LOL provisions, §1879(a)-(g) of the Act, fall under the FLP provisions and provide financial relief and protection to beneficiaries, healthcare providers, and suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain items and/or services for which Medicare payment would otherwise be denied. When it is determined that a review falls under the LOL provisions, evidence must show that either a healthcare provider, supplier or the beneficiary knew or should have known that Medicare was going to deny payment on the item or service.

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

If the healthcare provider/supplier had actual knowledge of the non-coverage of item and/or service in a particular case, could reasonably have been expected to have such knowledge or the beneficiary was shown not to have knowledge (found not liable), the Medicare program shall not make a payment to the healthcare provider/supplier.

Generally, Medicare provides forms (i.e., the ABN, Form CMS-R-131, SNF ABN, Form CMS-10055, etc.) for healthcare providers and suppliers to use as a way to provide written notice to beneficiaries. The healthcare provider/supplier should issue the applicable written notice each time, and as soon as, it makes

the assessment that Medicare payment certainly or probably will not be made in order to transfer potential financial liability to the beneficiary. The written notice allows the beneficiary to:

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

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

For purposes of this CR, the only sections that are being revised are Sections 10-40 and adding Section 500, the glossary. All other sections within Ch. 30 of the Medicare Claims Processing Manual remain unchanged.

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10848.1	Contractors shall review the process associated with the revised language as indicated in Pub. 100-04, Chapter 30.	X	X	X	X					
10848.2	Contractors shall perform additional individual provider education if alerted that a notifier is not complying with these instructions.	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10848.3	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized	X	X	X	X	

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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

ATTACHMENTS: 0

Medicare Claims Processing Manual

Chapter 30 - Financial Liability Protections

Table of Contents
(Rev.4197, Issued: 01-11-19)

Transmittals for Chapter 30

- 10 - *Financial Liability Protections (FLP) Provisions*
- 20 - Limitation On Liability (LOL) Under §1879 of the Act Where Medicare Claims Are *Denied*
 - 20.1 – *LOL* Coverage Denials
 - 20.2 - Denials *When* the *LOL* Provision Does Not Apply
 - 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*
- 500- *Glossary*

10 - Financial Liability Protections (FLP) Provisions
(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 of the Act 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	<i>The LOL provisions apply only to claims for items and/or services submitted by healthcare providers or suppliers that have 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.</i>	<i>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)(A) of the Act)</i>
Dependent Services	<i>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</i>	<i>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</i>

Type of Denial	Description	Example
	<i>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.</i>	<i>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).</i>
Higher Levels of Care and “Excess Components”	<i>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.</i>	<i>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).</i>

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
<i>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).</i>	<i>Rests with the beneficiary</i>	<i>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.</i>
<i>If the beneficiary did not know (and should not have known), and the healthcare provider or supplier knew, or should have known.</i>	<i>Rests with the healthcare provider or supplier</i>	<i>The beneficiary may not be charged for any costs related to the denied item and/or service, including copayments and deductibles.</i>
<i>If neither the beneficiary nor the healthcare provider or supplier knew, and could not reasonably be expected to have known.</i>	<i>Neither the beneficiary or the healthcare provider or supplier</i>	<i>The Medicare program makes payment for the assigned claim.</i>

20.1 – LOL Coverage Denials

(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:

<i>Statutory Provision (section of the Act)</i>	<i>Description</i>
<i>§1862(a)(1)(A)</i>	<i>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.</i>
<i>§1862(a)(1)(B) & §1861(s)(10)</i>	<i>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.</i>
<i>§1862(a)(1)(C)</i>	<i>In the case of hospice care, items and services that are not reasonable and necessary for the palliation or management of terminal illness.</i>
<i>§1862(a)(1)(E)</i>	<i>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).</i>
<i>§1862(a)(1)(F)</i>	<i>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.</i>
<i>§1862(a)(1)(F)</i>	<i>Screening for glaucoma, which is performed more frequently than is provided under §1861(uu) of the Act.</i>
<i>§1862(a)(1)(G)</i>	<i>Prostate cancer screening tests (as defined in §1861(oo) of the Act), which are performed more frequently than is covered under such section.</i>
<i>§1862(a)(1)(H)</i>	<i>Colorectal cancer screening tests, which are performed more frequently than is covered under §1834(d) of the Act.</i>
<i>§1862(a)(1)(I)</i>	<i>The frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation.</i>
<i>§1862(a)(1)(J)</i>	<i>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.</i>
<i>§1862(a)(1)(K)</i>	<i>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.</i>
<i>§1862(a)(1)(L)</i>	<i>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).</i>
<i>§1862(a)(1)(M)</i>	<i>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.</i>
<i>§1862(a)(1)(N)</i>	<i>An ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under §1861(s)(2)(AA) of the Act.</i>
<i>§1862(a)(1)(O)</i>	<i>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.</i>

Statutory Provision (section of the Act)	Description
§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.
§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	<i>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.</i>	<ul style="list-style-type: none"> • <i>Personal comfort items (§1862(a)(6) of the Act).</i> • <i>Routine physicals and most screening tests (§1862(a)(7) of the Act).</i> • <i>Most immunizations (vaccinations) (§1862(a)(7) of the Act).</i> • <i>Routine eye care, most eyeglasses and examinations (§1862(a)(7) of the Act).</i> • <i>Hearing aids and hearing aid examinations (§1862(a)(7) of the Act).</i> • <i>Cosmetic surgery (§1862(a)(10) of the Act).</i> • <i>Orthopedic shoes and foot supports (orthotics) (§1862(a)(8) of the Act).</i> <p>NOTE: §22.1 of this chapter provides a more expansive list of examples.</p>
Technical	<i>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</i>	<ul style="list-style-type: none"> • <i>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).</i> • <i>Payment for a dressing is denied because it does not meet the definition for “surgical dressings” (§1861(s)(5) of the Act).</i>

Type of Denial	Description	Example(s)
	<i>condition of payment required by regulations.</i>	<ul style="list-style-type: none"> • <i>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).</i> • <i>Drugs and biologicals which are usually self-administered by the patient.</i> • <i>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)</i> • <i>Other items or services that must be denied under 42 CFR 410.12 through 410.105 of the Medicare regulations.</i>

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:

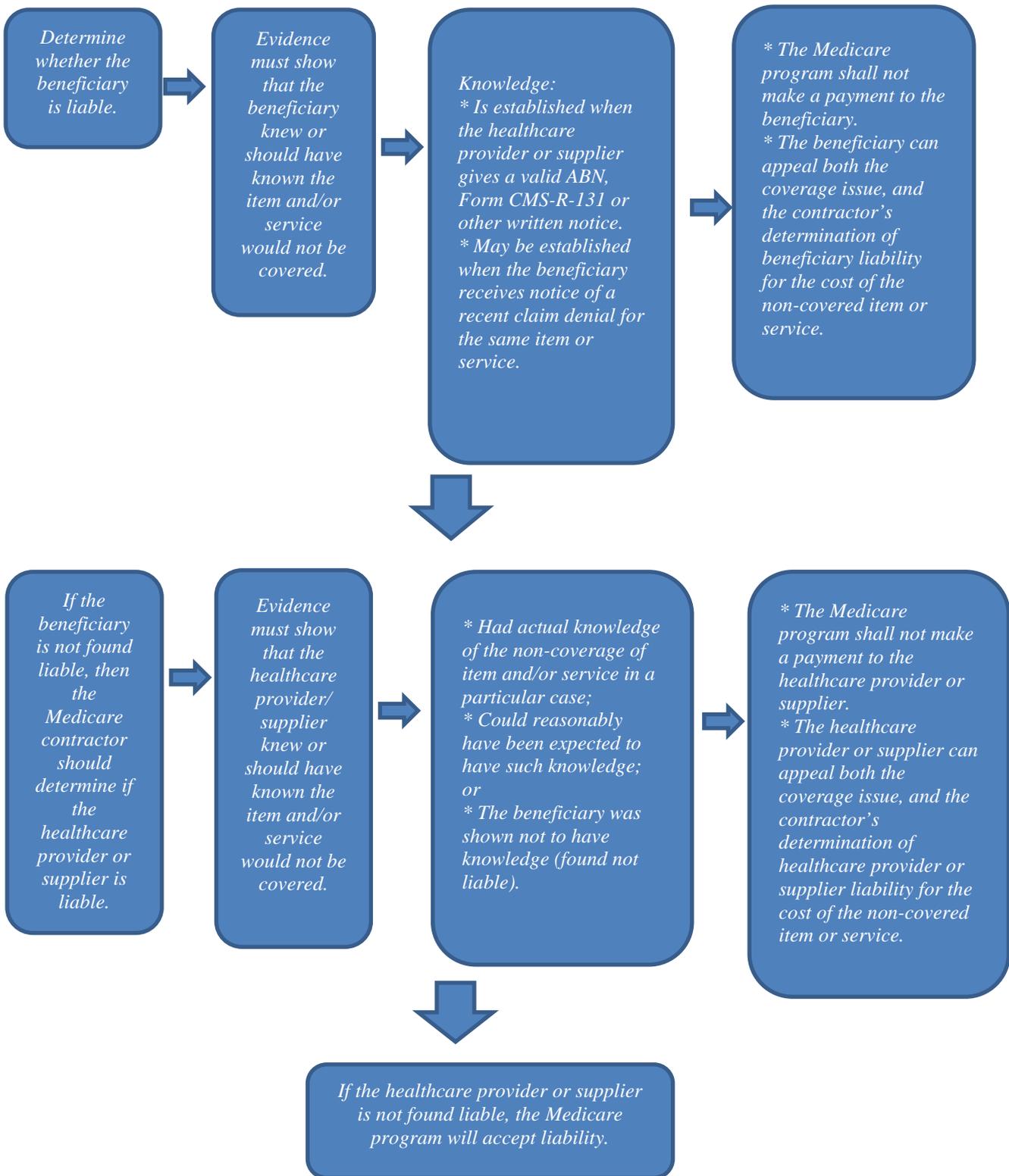
Statutory Provision (section of the Act)	Description
<i>§1862(a)(12)</i>	<i>Dental care and dentures (in most cases).</i>
<i>§1862(a)(13)</i>	<i>Routine foot care and flat foot care.</i>
<i>§1862(a)(19)</i>	<i>Services under a physician's private contract.</i>
<i>§1862(a)(3)</i>	<i>Services paid for by a governmental entity that is not Medicare.</i>
<i>§1862(a)(4)</i>	<i>Health care received outside of the U. S. not covered by Medicare.</i>
<i>§1862(a)(11)</i>	<i>Services by immediate relatives.</i>
<i>§1862(a)(5)</i>	<i>Services required as a result of war.</i>
<i>§1862(a)(2)</i>	<i>Services for which there is no legal obligation to pay.</i>
<i>§1862(a)(21)</i>	<i>Home health services furnished under a plan of care, if the agency does not submit the claim.</i>
<i>§1862(a)(16)</i>	<i>Items and services excluded under the Assisted Suicide Funding Restriction Act of 1997.</i>
<i>§1862(a)(17)</i>	<i>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).</i>
<i>§1862(a)(14)</i>	<i>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.</i>
<i>§1862(a)(18)</i>	<i>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.</i>

<i>Statutory Provision (section of the Act)</i>	<i>Description</i>
<i>§1862(a)(15)</i>	<i>Services of an assistant at surgery without prior approval from the peer review organization.</i>
<i>§1862(a)(20)</i>	<i>Outpatient occupational and physical therapy services furnished incident to a physician's services.</i>
<i>§1862(a)(22)</i>	<i>Claims submitted other than in an electronic form specified by the Secretary, subject to the exceptions set forth in §1862(h) of the Act.</i>
<i>§1862(a)(23)</i>	<i>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.</i>
<i>§1862(a)(24)</i>	<i>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.</i>

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.

<i>Provision</i>	<i>Description</i>	<i>Beneficiary Knowledge</i>
<i>Limitation On Liability</i>	<i>§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.</i>	<ul style="list-style-type: none"> • 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.
<i>Medical Equipment and Supplies RR</i>	<i>§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.</i>	<ul style="list-style-type: none"> • Knowledge must be evidenced by a signed written notice and agreement to pay personally in case of a denial.
<i>Physician RR</i>	<i>§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.</i>	<ul style="list-style-type: none"> • 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*
- 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*

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.*

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.

<i>Written Notice Standard</i>	<i>Description</i>
<i>Proper Written Notice Documents</i>	<ul style="list-style-type: none"> • An approved standard form (e.g., Form CMS-R-131); or • A CMS approved model notice language (e.g., Form CMS-10055)
<i>Qualified Notifiers</i>	<p>“Notifiers” are generally the healthcare provider or supplier that furnished or ordered the item(s) and/or service(s).</p>
<i>Capable Recipient</i>	<p>The beneficiary must:</p> <ul style="list-style-type: none"> • 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.
<i>Identification of Notifier</i>	<p>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.</p> <p>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</p>

<i>Written Notice Standard</i>	<i>Description</i>
	<i>Medicare contractor will consider the written notice form to be valid so long as it was otherwise properly executed.</i>

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.

<i>Exception</i>	<i>Description</i>
<i>Items or Services Which Are Always Denied for Medical Necessity</i>	<i>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.</i>
<i>Experimental Items and Services</i>	<i>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.</i>
<i>Frequency Limited Items and Services</i>	<i>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 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”).</i>
<i>Medical Equipment and Supplies Denied Because the Supplier Had No Supplier Number or the Supplier Made an Unsolicited Telephone Contact</i>	<i>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</i>

<i>Exception</i>	<i>Description</i>
	<i>notices to all beneficiaries does not apply in these cases.</i>

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/HCFR Special Advisory Bulletin on the Patient Anti-Dumping Statute: “A hospital would violate the patient anti-dumping statute if it delayed a medical screening examination or necessary stabilizing treatment in order to prepare an ABN and obtain a beneficiary signature. The best practice would be for a hospital not to give financial responsibility forms or notices to an individual, or otherwise attempt to obtain the individual’s agreement to pay for services before the individual is stabilized. This is because the circumstances surrounding the need for such services, and the individual’s limited information about his or her medical condition, may not permit an individual to make a rational, informed consumer decision.” This policy applies in any case in which EMTALA applies, not only to EMTALA cases seen in emergency rooms (ERs). 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.

500 - Glossary

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

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

Advance written notice of non-coverage (hereinafter referred to as “written notice”) – 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 written notice of non-coverage ((e.g. Advance Beneficiary Notice of Non-coverage (ABN), Form CMS-R-131, Skilled Nursing Facility Advanced Beneficiary Notice of Non-Coverage (SNF ABN), Form CMS-10055, Home Health Change of Care Notice (HHCCN), Form CMS-10280), as defined in 42 CFR 411.404.

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

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

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

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

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

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

Financial Liability Protections (FLP) Provisions – The FLP provisions of the Social Security Act protect beneficiaries, healthcare providers, and suppliers under certain circumstances from unexpected liability for

charges associated with claims that Medicare does not pay. The FLP provisions apply after an item or service's coverage determination is made.

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

Home Health Change of Care Notice (HHCCN, Form CMS-10280) - Used by Home Health Agencies (HHAs) to notify Original Medicare beneficiaries receiving home health care benefits of plan of care changes. HHAs are required to provide written 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 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 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 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.