Medicare Part B
Enteral Nutrition
Reimbursement Manual

9th EDITION
This manual is intended as a guide to Medicare enteral nutrition claims. Medicare is a federal health insurance program in the United States for people age 65 years or older, some disabled people under age 65, and people of all ages with permanent kidney failure. Medicare Part A provides hospital insurance, and Medicare Part B provides medical insurance (see page 2). Enteral nutrition costs for qualified Medicare beneficiaries may be reimbursed under Part B. For specific questions, you may call the Abbott Nutrition Helpline, 1-800-558-7677, or log on to www.AbbottNutrition.com under “Medicare, Medicaid and Private Insurance.”

Information contained in this manual is taken from a variety of sources including but not limited to official published government documents. The editor, publisher, and distributor of this manual assume no responsibility for changes in Medicare guidelines or interpretation by Medicare carriers. Information in this manual in no way implies acceptance of any individual claim by Medicare and/or its carriers. Each health care supplier is ultimately responsible for verifying codes, coverage, and payment policies used for individual patient claims to ensure they are accurate and appropriate for the services and items provided.
Medicare Part A (Hospital Insurance)

Medicare Part A helps cover costs of hospital inpatient stays, post-hospital extended care in skilled nursing facilities (SNFs), and post-hospital care furnished by a home health agency in the patient’s home. Program payments for services rendered to beneficiaries by providers (i.e., hospitals, SNFs, and home health agencies) are generally made to the provider. The cost of the insurance includes an annual deductible along with monthly premiums. The monthly premiums are usually deducted from the individual’s monthly Social Security check.

Hospices also provide Part A hospital insurance services such as short-term inpatient care. In order to be eligible to elect hospice care under Medicare, an individual must be entitled to Part A of Medicare and be certified as being terminally ill. An individual is considered to be terminally ill if the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.

Medicare Part B

Enteral nutrition benefits are covered under Medicare Part B, also known as Supplementary Medical Insurance or SMI. Part B coverage may be purchased with or without accompanying Part A coverage. The cost of the insurance is usually deducted from the individual’s monthly Social Security check. If the beneficiary is not enrolled in Part B, he/she does not have coverage for enteral nutrition in the home setting or beyond a Part A skilled care nursing home stay.

Each beneficiary must pay an annual deductible expense before a benefit payment can be made. Expenses are based on Medicare-allowed amounts and allocated to the deductible in the order in which the bills are received by Medicare. After the deductible has been satisfied, Medicare Part B pays 80% of allowable charges for physician services, durable medical equipment (DME), parenteral and enteral nutrition, and other medical services such as speech and physical therapy. The remaining 20% of the allowed amount is the responsibility of the beneficiary and is referred to as “coinsurance.” Suppliers are required to bill the coinsurance. Failure to do so could result in fines and penalties being imposed on the supplier (see the Fraud and Abuse section of this publication on page 43). Patients may purchase private insurance policies (“Medigap”) to cover coinsurance and deductible amounts not covered by Medicare.

Tube-fed residents of Skilled Nursing Facilities will have enteral nutrition covered during the initial 100 days of the stay by Medicare Part A’s facility payment. Part B coverage can begin for eligible patients after the patient’s Part A benefit is completed.
Managed Care, HMO, or VA Patients

If the facility or home care agency has negotiated a contract with a managed care organization, an HMO, or the Veterans Administration, the cost of enteral nutritional therapy may be included in the negotiated price. If the contract does not include nutritional therapy, the provider can bill the managed care, HMO, or VA organizations for enteral formulas and supplies. However, payment rates and coverage policies vary by payer.

Third-Party Insurance

An increasing number of patients have private insurance that covers enteral nutrition expenses. Other private insurance policies called “Medigap” policies are designed to cover coinsurance and deductible expenses not fully reimbursed by Medicare.

Medicaid

Medicaid is a federal-state program enacted in 1965. Medicaid provides health insurance for people who are poor, blind, or have a disability. Funds come from the federal government and state tax revenues. In nearly all states, Medicaid has coverage policies for residents of nursing facilities who are not under a Medicare Part A skilled benefit period. People who do not have Part B coverage may have enteral nutrition coverage under the state Medicaid daily rate payment system if they are eligible. Policies and payment rates vary by state. Consult your state Medicaid carrier for more details.

Direct Patient Payment

Patients may pay directly for enteral nutrition care if other insurance sources are not available.
Medicare is a federal health insurance program for people who are:

- 65 years of age or older
- some disabled people under age 65
- under 65 with permanent kidney failure

Medicare eligibility is determined by the Social Security Administration and is administered by the Centers for Medicare and Medicaid Services (CMS). An individual may become entitled through Social Security based on his or her own earnings or those of a spouse, parent, or child.

**Medicare Carriers and DME MACs**

Medicare does not process claims for covered services itself. Claims are processed by independent insurers who have contracts with CMS to pay claims and administer the Medicare program subject to national Medicare guidelines and regulations. There are two basic types of contractors for Medicare Part B: 1) Carriers and 2) Durable Medical Equipment Medicare Administrative Contractors (DME MACs). Carriers process claims for physician services, outpatient care, laboratory services, ambulance services, radiology services, and certain medications. DME MACs process Part B claims for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS).

Enteral therapy is classified as a prosthetic benefit that is payable as DMEPOS, therefore, enteral nutrition claims fall under the jurisdiction of the four Jurisdictional DME MACs. One of the main goals of DME MAC regionalization is the application of more uniform pricing and coverage criteria to all DME claims. The Centers for Medicare and Medicaid Services also closely monitor DMEPOS payment criteria to control potential fraud and abuse.

Claims are filed to one of the four DME MACs based on the permanent residence (defined as the address to which the Social Security check is mailed) of the beneficiary. The following page provides information about which states are covered by each of the DME MACs. Again, claims-filing jurisdiction is based upon beneficiary residence, not on supplier location.
### Jurisdiction of DME MACs

Claims jurisdiction is determined by the state in which the beneficiary permanently resides.

**DME MACs**

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<th>Region</th>
<th>Jurisdiction</th>
<th>DME MACs</th>
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<tr>
<td><strong>A</strong></td>
<td>Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont</td>
<td>National Heritage Insurance Company (NHIC)  &lt;br&gt; DME-Written Inquiries  &lt;br&gt; P.O. Box 9146  &lt;br&gt; Hingham, MA 02043-9146  &lt;br&gt; (866) 590-6731  &lt;br&gt; <a href="http://www.medicarenhic.com/dme">www.medicarenhic.com/dme</a></td>
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<tr>
<td><strong>B</strong></td>
<td>Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin</td>
<td>National Government Services, Inc.  &lt;br&gt; P.O. Box 6036  &lt;br&gt; Indianapolis, IN 46206-6036  &lt;br&gt; (866) 590-6727  &lt;br&gt; <a href="http://www.ngsmedicare.com">www.ngsmedicare.com</a></td>
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<td><strong>C</strong></td>
<td>Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands, Virginia, and West Virginia</td>
<td>CIGNA Government Services  &lt;br&gt; P.O. Box 20010  &lt;br&gt; Nashville, TN 37202  &lt;br&gt; (866) 270-4909  &lt;br&gt; <a href="http://www.cignagovernmentservices.com/jc/index.html">www.cignagovernmentservices.com/jc/index.html</a></td>
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<td><strong>D</strong></td>
<td>Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Northern Mariana Islands, Oregon, South Dakota, Utah, Washington, and Wyoming</td>
<td>Noridian Administrative Services (NAS)  &lt;br&gt; P.O. Box 6727  &lt;br&gt; Fargo, ND 58108-6727  &lt;br&gt; (866) 243-7272  &lt;br&gt; <a href="http://www.noridianmedicare.com/dme/">www.noridianmedicare.com/dme/</a></td>
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1. To be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries, DMEPOS providers must enroll in the Medicare Program by submitting the Medicare enrollment application (form CMS-855S) to the National Supplier Clearinghouse (NSC). An enrollment application may be obtained by downloading form CMS-855S from the CMS website: www.cms.hhs.gov/cmsforms/downloads/cms855s.pdf. New applicants must include a National Provider Identifier (NPI) number on the CMS 855S enrollment application. NPI applications are available online at https://nppes.cms.hhs.gov or by calling the Enumerator at (800) 465-3203 or TTY (800) 692-2326.

In lieu of the Medicare paper enrollment application, providers may enroll in the Medicare program via the Internet-based Provider, Enrollment, Chain and Ownership System (PECOS). Information on this method of enrollment may be found at https://www.cms.gov/MedicareProviderSupEnroll/04_InternetbasedPECOS.asp.

Enrollment data for all active DMEPOS suppliers will eventually be moved from the enrollment system at the National Supplier Clearinghouse to the online PECOS system.

2. All DMEPOS suppliers must obtain accreditation through a CMS-deemed accreditation organization. Further information on the DMEPOS accreditation requirements can be found at the CMS website: http://www.cms.gov/MedicareProviderSupEnroll/07_DMEPOSAccreditation.asp#TopOfPage.
3. Some DMEPOS suppliers are required to obtain and submit a surety bond on a continuing basis of not less than $50,000 for each practice location (NPI number). Additional information about Surety Bond requirements, including a list of DMEPOS suppliers exempt from the bonding requirements, can be found at the CMS website: http://www.cms.gov/MedicareProviderSupEnroll/05_DMEPOS%20Surety%20Bond.asp#TopOfPage.

4. Enteral nutrition providers should frequently review patients receiving enteral nutrition to determine whether they continue to meet Medicare eligibility and coverage requirements for reimbursement on pages 8-14.

5. For qualified patients, claims are typically submitted monthly to the appropriate DME MAC for processing. Retrospective billing is recommended since billing must be for actual days patients used supplies during a month. Retrospective billing reduces the need for claim adjustments based on hospital admission or other interruption of therapy.

6. Normally, two to five procedure codes are needed for billing each month of enteral therapy. Procedure codes are assigned to enteral items or groups of items supplied to a patient. These codes are referred to as HCPCS codes and are linked to Medicare-allowed payment amounts. Separate codes are required for billing the following:
   - Enteral nutritional formula(s)
   - Supply kits (pump, gravity, or syringe), including all supplies needed to administer enteral therapy
   - Feeding tubes (nasogastric, gastrostomy, or jejunostomy)
   - Enteral feeding pump (rental or purchase)
   - IV pole

7. Unless a supplier meets specific exception criteria for paper claim submission, claims must be submitted electronically via the HIPAA compliant ASC X12N 837 format, Version 4010. The transition to the Version 5010 format is currently underway, and must be in place for all electronic claims by January 1, 2012. More information on the Version 5010 format and transition may be found at https://www.cms.gov/ICD10/11a_Version_5010.asp#TopOfPage.

   Electronic claim submissions must also include a DME Information Form (DIF) completed and signed by the supplier. (See details concerning DIFs on pages 19-22.)

8. Fees have been set by Medicare for reimbursement of enteral therapy. You can access HCPCS codes and fees in effect by date of service from the Durable Medical Equipment Coding System (DMECS) available online at https://www.dmepdac.com/dmecs/index.html. You may download (unzip) DMEPOS fee schedules from the CMS website, accessed from DME MACs websites listed on page 5.

9. Enteral nutrition formula is billed in “units.” A unit is defined as 100 Calories.
   - Calculation of units:
     Cal per day ÷ 100 = units per day
   - e.g., 6 cans/day x 250 Cal/can = 1500 Cal/day ÷ 100 = 15 units/day
   - 15 units per day x 30 days per month = 450 units per month

10. Coinsurance and deductibles must be billed to appropriate payers. Routine waiver of coinsurance is considered Medicare abuse and can result in fines and penalties.
Medicare considers enteral nutritional therapy as a prosthetic device benefit. This benefit pays for prosthetic devices that replace missing, inoperable, or malfunctioning body organs. In the case of enteral nutritional therapy, the prosthetic device is the nasogastric, gastrostomy, or jejunostomy tube. Accordingly, to qualify for Medicare coverage, enteral nutritional therapy must be given via an enteral feeding tube. Medicare does not cover oral nutritional supplements.

In addition to having the feeding administered via a feeding tube, the patient must also have permanent nonfunction or disease of the structures that normally permit food to reach the small bowel, or a disease of the small bowel that impairs digestion and/or absorption of an oral diet. Either condition must necessitate reliance on enteral nutritional therapy to provide sufficient nutrients to maintain the patient’s weight and strength commensurate with his or her overall health status. The patient’s medical record must identify and document this physiologic need for therapy, and the following two basic criteria must be met:

1. A diagnosed functional impairment of the gastrointestinal (GI) tract necessitating enteral feeding, and
2. Permanence of that condition necessitating enteral feeding.

Additional documentation is required if:

- The feeding is administered via an enteral feeding pump, and/or
- The formula is other than one classified as HCPCS B4150 or B4152 — nutritionally complete enteral formulas consisting of semi-synthetic intact protein or protein isolates with a caloric density of 1.0 to 2.0 Cal/mL.

When the above coverage requirements are met, medically necessary supplies, equipment, and nutrients may be reimbursed for beneficiaries enrolled in Medicare Part B. The beneficiary must be enrolled in Medicare Part B to receive enteral nutritional therapy coverage. Medicare does not reimburse professional services used to administer or monitor enteral nutritional therapy.

### Permanence of the Condition

A condition is deemed permanent if, in the judgment of the attending physician and substantiated in the medical record, the condition is of long and indefinite duration—ordinarily, but not limited to, at least 3 months. If the physician believed the condition would last at least 90 days, but the actual time the patient required tube feeding was less than 90 days, the therapy may still be covered if proper documentation was made in the medical record. Enteral nutritional therapy is not covered in situations involving temporary conditions or impairments.

### Diagnosis

For a patient to qualify for enteral therapy reimbursement, he or she must have a diagnosis that directly contributes to the nonfunctioning of part of the digestive tract. Claims submitted for enteral nutrition will be paid or reimbursed by Medicare only if
the therapy is covered, reasonable, and necessary to treat the particular patient, given his or her clinical condition. Medical necessity is determined on a case-by-case basis. While there is no single authoritative list of acceptable diagnoses, enteral nutrition is likely to be considered medically necessary and therefore appropriate if ordered for patients with the conditions listed below. For patients who may qualify due to a swallowing disorder, an assessment by a speech therapist and/or a radiographic swallowing study to document the condition is strongly recommended.

Generally accepted diagnoses, when associated with a functional impairment of the gastrointestinal tract:

- Alzheimer's disease
- Amyotrophic lateral sclerosis
- Aneurysm
- Anoxic encephalopathy
- Bowel infarction
- Cancer of any part of the upper GI tract
- Cancer of the brain
- Cerebral palsy
- Cerebrovascular accident (CVA)
- CVA history with residual effects
- Cerebrovascular insufficiency
- Closed head injury
- Comatose
- Degenerative brain disease
- Duodenal obstruction (J tube only)
- Encephalopathy
- Esophageal obstruction
- Esophageal paralysis
- Esophageal perforation
- Gastrectomy—total or partial (J tube only)
- Gastric outlet obstruction (J tube only)
- Gastrointestinal fistula
- Gastrointestinal hemorrhage
- Guillain-Barré syndrome
- Hepatic encephalopathy
- Multi-infarct dementia
- Multiple sclerosis
- Organic brain syndrome
- Parkinson's disease
- Quadriplegia
- Senile dementia

Diagnoses are currently classified by the ICD-9-CM diagnosis codes in *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)*. Books containing the codes can be obtained from many publishers and from the Supervisor of Documents at the Government Printing Office. ICD-9-CM codes are required on paper or electronic CMS-1500 claims as well as on the DME Information Forms (DIF) for enteral and parenteral nutrition. Up to four diagnoses pertaining to the patient’s enteral nutrition claim may be placed on the claim and DIFs. Diagnosis codes entered on claims and referenced on individual claim lines must be valid for the date of service on the claim and must be reported to the highest level of specificity (three, four, or five digits) for that category of codes.

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**International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)**

The compliance date for implementation of the *International Classification of Diseases, 10th Edition, Clinical Modification (ICD-10-CM)* is October 1, 2013 for all covered entities. The ICD-10-CM diagnosis codes are three to seven digits in length and incorporate both alpha and numeric characters, providing much greater clinical detail and specificity than ICD-9-CM. The HIPAA electronic transaction Version 5010 accommodates the ICD-10 codes, and therefore must be in place first before the changeover to ICD-10. For more information concerning the transition to ICD-10-CM, visit https://www.cms.gov/ICD10/01_Overview.asp#TopOfPage.
Functional Impairment of the Gastrointestinal Tract

To meet this coverage requirement, a patient’s condition may result from an anatomic abnormality, a motility disorder, or a disease of the small bowel that impairs digestion and absorption of an oral diet. The functional impairment must be severe enough that adequate oral nutrition cannot be achieved by dietary adjustment (e.g., puréed foods and/or oral nutritional supplements). In policy articles that support Local Coverage Determinations (LCDs) for enteral nutrition, the DME MACs indicate that coverage is possible for patients with partial impairments (e.g., a patient with dysphagia who can swallow small amounts of food, or a patient with Crohn’s disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption). In all cases, however, the tube feeding must be the primary source of nutrition.

Important: Enteral nutritional therapy coverage is for patients who cannot swallow and/or digest and absorb adequate nutrition. Therapy is not covered for patients who refuse to consume adequate oral nutrition due to anorexia, nausea, depression, etc, or who have no GI functional impairment.

Dysphagia resulting from muscular paralysis

When muscular paralysis occurs, the patient is unable to swallow because the damaged brain or spinal cord can no longer signal the muscles of the alimentary tract to function. Paralysis can occur as a result of many diseases and disorders, including:

- CVA (cerebrovascular accident, infarction, or “stroke”)—when certain parts of the brain are deprived of blood/oxygen, paralysis, loss of gag reflex, and other disorders can occur.

- Trauma/Accident—muscular paralysis can occur as a result of traumatic injury.

- Anoxia—paralysis is caused by lack of oxygen to the brain (e.g., following cardiac or respiratory arrest).

- Spinal cord injury—an injury high on the spine can affect the portion of the neurologic system that controls swallowing.

- Birth defects, cerebral palsy.

- Parkinson’s disease.

- Amyotrophic lateral sclerosis, multiple sclerosis, myasthenia gravis, Huntington’s chorea—the patient’s brain and muscles cease to function, causing a loss of the ability to swallow.

Dysphagia resulting from cognitive neurologic disorders

Cognitive neurologic disorders are disease processes that cause the patient to forget how to swallow. Some diseases that may create a functional impairment of a patient’s capacity to swallow include:

- Senile dementia, Alzheimer’s disease, organic brain syndrome—the patient is in the end stages of mental deterioration and no longer understands what food is or how to swallow.

Patients with a cognitive/neurologic disease usually have medical record documentation that supports a dysfunction of the swallowing mechanism. Swallowing assessments or evaluations are recommended.

Mechanical dysfunction of the GI tract

Esophageal obstruction, cancer of the larynx or tongue, esophageal stricture, and gastroparesis are examples of anatomic impairments that physically limit or prevent the passage of oral nutrients into the small bowel. Gastrostomy or jejunostomy feeding tubes are typically placed in these patients.
Enteral Feeding Pumps

Enteral feeding pump supplies (B4035, B9000-B9002 and E0776) will be paid by Medicare only if the pump is medically necessary to administer the feeding. There must be documentation in the medical record to justify the use of a feeding pump. Medical necessity is determined on a case-by-case basis. While there is no single authoritative list of acceptable diagnoses, pump feeding is likely to be considered medically necessary if ordered for patients with the following conditions:

- Severe diarrhea
- History or risk of aspiration pneumonia
- Severe reflux/vomiting
- Regurgitation/aspiration
- Dumping syndrome
- Unstable diabetes mellitus
- Circulatory overload secondary to renal failure or congestive heart failure (fluid-restricted patients)
- Documented medical condition that requires flow rate less than 100 mL/hr
- Jejunal tube feeding

Pump administration must be indicated in box 5 of the DIF. If the medical necessity for the pump is not documented in the patient’s medical record, payment for the pump and the pump supply kit will be denied as not medically necessary.

General Purpose and Calorically Dense Enteral Formulas

General purpose and calorically dense formulas are nutritionally complete with semi-synthetic intact protein or protein isolates (B4150 and B4152). Medicare considers these formulas appropriate for the majority of patients who require enteral nutrition. General purpose formulas providing 1.0 to 1.2 Cal/mL are categorized under the Medicare B4150 code. Their use does not require any additional written justification by the physician or the supplier for reimbursement. Examples of B4150 general purpose formulas include Ensure®, Ensure® Bone Health, Ensure® High Protein, Ensure® Muscle Health, Ensure® Immune Health, Ensure® Powder, Jevity® 1.0 Cal, Jevity® 1.2 Cal, Osmolite® 1 Cal, Osmolite® 1.2 Cal, Promote®, and Promote® With Fiber.

Nutritionally complete, calorically dense formulas with semi-synthetic intact protein or protein isolates provide 1.5 to 2.0 Cal/mL and are categorized as HCPCS B4152. They are typically prescribed for patients who may need to limit their overall fluid intake or increase caloric intake, and, if deemed medically necessary, are also reimbursed without additional medical justification. Examples of calorically dense formulas include Ensure Plus®, Ensure® Clinical Strength, Hi Cal, Jevity® 1.5 Cal, Osmolite® 1.5 Cal, and TwoCal® HN.

Specialized Enteral Formulas

The remaining Medicare categories for adult enteral formulas (B4149 and B4153-B4155) require written justification of their medical necessity before they will be covered. This justification must be maintained in the patient’s medical record. If the medical necessity for specialty nutrients is not met, the formula will be denied as not reasonable and necessary. Medicare does not cover foods that are or can be blenderized and given via an enteral feeding tube.
**B4149 — Blenderized Natural Foods With Intact Nutrients**
These formulas contain natural intact protein or protein isolates. They are appropriate for patients with a documented allergy or intolerance to semi-synthetic formulas.

**B4153 — Hydrolyzed Protein/Amino Acids**
These formulas contain combinations of partially and fully hydrolyzed protein and are typically used for patients whose functional coverage qualifier is a disease of the bowel that impairs nutrient digestion and absorption. Examples of these formulas include Optimental®, Perative®, Pivot® 1.5 Cal, Vital® 1.0 Cal, Vital® 1.5 Cal, Vital AF 1.2 Cal™, and Vital® HN.

**B4154 — Defined Formula for Specialized Non Inherited Metabolic Need**
These formulas are designed to provide defined nutrients for specific disease states. Examples of these formulas include Glucerna® 1.0 Cal, Glucerna® 1.2 Cal, Glucerna® 1.5 Cal, Nepro® with Carb Steady™, Oxepa®, Pulmocare®, and Suplena® with Carb Steady™. The diagnosis code supporting the need for the B4154 formula should be included on the CMS-1500 claim and DIF.

**B4155 — Modular Nutrients**
This category includes modular formula nutrients that are added to an existing formula. These components are designed to supply additional nutrition in the form of carbohydrate or protein. Examples are Juven®, Polycose®, and ProMod® Liquid Protein.

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**Other HCPCS Codes Rarely Used for Medicare Claims**

HCPCS codes B4102 (hydration formulas for adults) and B4103 (pediatric hydration formulas) are not covered by Medicare. The following six additional codes describe pediatric formulas that are rarely used by Medicare patients:

- B4157 Nutritionally Complete Formulas for Inherited Diseases of Metabolism
- B4158 Pediatric General Purpose Formulas
- B4159 Pediatric Soy-Based Formulas
- B4160 Pediatric Calorically Dense Formulas
- B4161 Pediatric Enteral Formulas With Hydrolyzed Proteins
- B4162 Pediatric Formulas for Special Metabolic Needs of Inherited Diseases of Metabolism

**Documentation**

Documentation of specialized enteral formulas requires two steps:

1. Documenting the diagnosis that supports the need for specific nutritional requirements that cannot be effectively satisfied by general purpose formulas. This diagnosis needs to be recorded in the electronic claim to the highest level of specificity and on the DIF.

2. Maintaining additional medical record documentation in the patient’s record to support the medical necessity of the defined formula (B4154).
Tube Usage

Medicare allows for payment of one gastrostomy tube or three nasogastric tubes every 90 days. If additional tubes are used for a Medicare beneficiary, the supplier must provide documentation to support the medical necessity of the extra usage. The most common reasons for more frequent tube replacement are that the tube became clogged or was accidentally dislodged or removed. Medical necessity documentation for replacement of a clogged tube includes explanations of what was done to prevent the tube from clogging and what was done to attempt to restore the tube patency before it was replaced. Medical necessity for replacement of dislodged or inadvertently removed feeding tubes includes documentation of what was done to secure the tube or to prevent the tube’s removal. The documentation must be patient-specific and must provide a convincing reason for replacement of the feeding tube more frequently than Medicare generally allows. References to “facility policy” are generally not convincing. Payment for frequently replaced tubes may require individual case review via the Medicare appeals process.

Enteral nutritional therapy is covered for those patients “who, because of chronic illness or trauma, cannot be sustained through oral feeding....”

“Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy is not covered under Part B in situations involving temporary impairments.”

“Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient’s remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence will be considered met.”

Enteral Nutrition Therapy.
“Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or nonfunction of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition....”

“Typical examples of conditions that would qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding....”

“If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.”
How To Become a Medicare Supplier

To be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries, DMEPOS providers must enroll in the Medicare Program either by submitting the Medicare enrollment paper application (form CMS-855S) to the National Supplier Clearinghouse (NSC), or by enrolling online via the Internet-based Provider, Enrollment, Chain and Ownership System (PECOS).

The paper enrollment application may be downloaded from http://www.cms.gov/CMSForms/CMSForms/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019480.

Information regarding PECOS online enrollment may be found at https://www.cms.gov/MedicareProviderSupEnroll/04_InternetbasedPECOS.asp.

Enrollment data for all active DMEPOS suppliers will eventually be moved from the enrollment system at the National Supplier Clearinghouse to the online PECOS system.

New applicants must include a National Provider Identifier (NPI) number on the paper or electronic enrollment application. NPI applications are available online at https://nppes.cms.hhs.gov/NPPES/Welcome.do.

The first decision to be made in Medicare billing is whether to become a participating provider. There are benefits to becoming a participating provider. When the supplier’s name is added to the list of participating suppliers, the supplier’s name is given to patients when an inquiry is made. In addition, several electronic reports and information sources are available only to participating suppliers.

Participating providers agree to accept assignment on all Medicare claims. Accepting assignment means that the supplier agrees to accept the amount determined by Medicare as the total amount of the claim. Nonparticipating providers have the option of accepting assignment on a case-by-case basis. The benefits of accepting assignment are direct Medicare payment and the transfer of claims payment information to Medigap insurers. Under special arrangement, the DME MACs forward claims payment information to some Medicaid carriers and secondary insurers—regardless of whether a supplier accepts assignment.

If a supplier does not accept assignment, the DME MAC will make payment to the patient. The supplier must then collect payment from the patient for products provided.

**Retrospective billing**

The time period for submission of DMEPOS claims to Medicare is 1 calendar year after the date of service. Medicare will deny claims submitted beyond 1 year after the date of service.
1. Authorization and Release

To meet the billing requirements set forth by Medicare, certain forms must be maintained in supplier files. An “Authorization and Medical Release Statement” or “Assignment of Benefits (AOB)” gives the supplier the authority to bill Medicare on the patient’s behalf and receive payment directly from Medicare. At the same time, it allows the supplier to release any pertinent medical information that may be required by Medicare or the Social Security Administration to process the claim. This “Authorization and Release” form must be signed by the patient or his/her legal representative to be valid.

2. Advance Beneficiary Notice of Noncoverage (ABN)

As previously discussed, suppliers accepting assignment agree to accept the claim determination made by Medicare; any remaining claim balances, except deductible and coinsurance charges cannot be billed to the patient under normal circumstances. The only method by which a supplier can bill the patient for remaining balances or denied claims is with “Advance Beneficiary Notice of Noncoverage,” which is written notification provided to the patient or his/her legal representative prior to delivery of supplies or services. In it, the supplier details why it believes the services may not be covered, or not covered in full, by Medicare. The supplier must detail specific reasons for this belief. The notice must be date-specific as well as product-specific and, finally, be signed by the patient or his/her legal representative. An example of an ABN follows as Exhibit 1 on page 18.

ABNs are designed for use with Medicare patients only, including those who are dually eligible for Medicare and Medicaid. An ABN should not be given to a Medicare patient unless the supplier has a genuine reason to expect that Medicare will deny payment for some or all of the services. For example, ABNs should be given to Medicare patients receiving enteral therapy if the enteral feeding is expected to last fewer than 90 days, or if enteral feeding is not the primary source of nutrition.

Common reasons cited on the form for Medicare nonpayment include “Medicare does not pay for this item or service for your condition” and “Medicare does not pay for this item or service more often than Frequency Limit.” A single ABN covering an extended course of treatment is acceptable provided the ABN identifies all items and services for which the supplier believes Medicare will not pay. For example, if the supplier believes Medicare will not pay for enteral nutrition because the patient does not have a qualifying diagnosis, the ABN must identify the formula, pump, IV pole, and all administration supplies, including the administration bag and tubing. The items or services at issue must be described in sufficient detail so that the patient can understand which items or services may not be paid. HCPCS codes by themselves are not acceptable as descriptions. One year is the limit for use of a single ABN for an extended course of treatment; if the course of treatment extends beyond one year, a new ABN is required for the remainder of the course of treatment.

The supplier must provide the patient with an estimated cost of the items and/or services provided (section F of the ABN). In general, a reasonable estimate will be within $100 or 25% of the actual costs, whichever is greater. Multiple items that are routinely grouped may be bundled into a single-cost estimate.
If a patient receives an ABN, refuses to sign it, but still demands to receive the services specified, the supplier can annotate the form, with the signature of a witness, that the beneficiary received notice but refused to sign the form. Claims can then be submitted to Medicare with a GA modifier by each HCPCS code, indicating that an ABN was given. A patient who receives a service for which payment is subsequently denied for the reasons cited on the ABN can be held liable, whether or not the patient agreed to make payment. However, if a patient refuses to sign a properly delivered ABN, the supplier 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.

One problem faced by providers of enteral products is that supplies are often provided on admission or as orders change. In these situations, a supplier may not have the opportunity to evaluate each patient to determine whether he/she meets all of the established Medicare criteria for the feeding, particularly in cases where specialty formulas and enteral feeding pumps are ordered. Bearing in mind that an ABN must be signed before delivery of service, it may be difficult for the supplier to comply with this requirement. Even if the supplier can determine the eligibility of the beneficiary, the responsible party may not be readily available to sign the waiver—and some beneficiaries are not competent or capable of signing.

Despite these difficulties, there may be situations in which products may be prescribed that do not meet Medicare payment standards and a claim denial is expected. In these situations, the provider should fully explain the difficulties involved to the patient and/or the patient-responsible party, and an ABN should be signed.

Additional information regarding ABNs may be found at the following weblink: https://www.cms.gov/BNI/02_ABN.asp.
ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn’t pay for (D)_____________ below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the (D)_____________ below.

<table>
<thead>
<tr>
<th>(D) _______________</th>
<th>(E) Reason Medicare May Not Pay:</th>
<th>(F) Estimated Cost:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

WHAT YOU NEED TO DO NOW:

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

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

(G) OPTIONS: Check only one box. We cannot choose a box for you.

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

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

- **OPTION 3.** I don’t want the (D)_____________ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

(H) Additional Information:

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

Signing below means that you have received and understand this notice. You also receive a copy.

<table>
<thead>
<tr>
<th>(I) Signature:</th>
<th>(J) Date:</th>
</tr>
</thead>
</table>
3. DME Information Forms (DIF)

New initial DIFs must be filed with the first enteral claim and 1) if the formula is changed to a product with a different HCPCS code, 2) if there is a 60-day break in service, and/or 3) if there is a change in feeding method from gravity or syringe to pump. The CMS-1500 claim and the DIF must be transmitted electronically. Regularly scheduled recertifications are not required unless therapy continues beyond the number of months indicated by the physician on the written order.

When there is a change in enteral prescription, a revised DIF is required, showing the effective date of the prescription change. Examples of circumstances that require a revised DIF include:

- Change in the physician’s orders for the number of calories prescribed or in the days/weeks administered.
- Change in the method of infusion.
- Change in the route of administration.

Suppliers must retain a DME MAC-acceptable copy of the DIF. These files are subject to audit by the DME MACs. An acceptable form of a DIF includes the original “pen and ink” document, a photocopy, a facsimile image, or an electronically maintained document.

All information contained on the DIF should agree with the information listed on the claim form. Any differences may result in a denial. Information contained on the DIF should be substantiated in the patient’s medical record.

DIFs should not be altered with white-out or crossovers. If a correction must be made, the change must be initialed and dated by the supplier representative (to indicate he/she was aware of the change).

DME MACs accept faxed, copied, and electronic orders and DIFs. When reviewing claims where the medical record contains a copied, faxed, or electronically maintained DIF, the DME MAC should accept, where feasible, the copied, faxed, or electronic document as fulfilling requirements for these documents. If evidence indicates that the DIF being reviewed has been falsified, or the supplier is unable to provide adequate assurance of the medical necessity of the items or services, the DME MAC can request additional information, including an original signature, in order to obtain that assurance.

**Physician orders**

The supplier is required to keep on file a physician prescription (order). The treating physician must sign and date the order. A supplier must have an order from the treating physician before dispensing a DMEPOS item to a beneficiary.

**Verbal orders**

Suppliers may dispense enteral nutrition formula and related supplies based on a physician’s verbal order. The verbal dispensing order must include:

- A description of the item.
- The beneficiary’s name.
- The physician’s name.
- The start date of the order.

Suppliers must maintain written documentation of the verbal order and this documentation must be available to the DME MACs upon request. If the supplier does not have an order from the treating physician before dispensing an item, the item is noncovered, and the supplier must not submit a claim for the item to the DME MACs.

For items dispensed on a verbal order, suppliers must obtain a detailed written order that confirms the verbal order before submitting the claim to Medicare.
Detailed written orders

Detailed written orders (DWO) are required for all transactions involving DMEPOS. They may take the form of a photocopy, facsimile image, electronically maintained, or original “pen-and-ink” document and must include the following:

- The start date of the order.
- Quantity and frequency of change for supplies and duration of need for supplies (quantity used and method of administration).
- Sufficient detail including all options or additional features that will be billed or require an upgraded code. The description can be either a narrative description or a brand name/model number.
- Length of need.
- Physician’s signature and date.

Written orders are required for the initial enteral nutrition therapy prescription as well as for any subsequent changes made to the original prescription.


Someone other than the physician may complete the detailed description of the item. However, the treating physician must review the detailed description and personally sign and date the order to indicate agreement. If a supplier does not have a faxed, photocopied, electronic, or pen-and-ink signed DWO in the patient’s record before submitting a claim to Medicare, the claim is subject to denial upon review by the DME MAC or other authorized Medicare review contractor including Recovery Audit Contractors (RACs) and Zone Program Integrity Contractors (ZPICs). Medical necessity information (e.g., an ICD-9-CM diagnosis code, narrative description of the patient’s condition, abilities, and limitations) is NOT in itself considered to be part of the order although it may be put on the same document as the order.

Ordering/referring providers and PECOS enrollment

Only Medicare-enrolled physicians and non-physician practitioners are eligible to order or refer services for Medicare beneficiaries. A provider is considered enrolled in Medicare for the purpose of ordering or referring a service to a beneficiary if their enrollment is current in the CMS internet based PECOS system. The transition is underway to deny Medicare claims if the ordering/referring physician or non-physician practitioner identified on the claim is not enrolled in PECOS. To avoid claim denial, suppliers should verify that the ordering/referring physician or non-physician practitioner is enrolled in the CMS PECOS system via this weblink: https://www.cms.gov/MedicareProviderSupEnroll/06_MedicareOrderingandReferring.asp.
## DME INFORMATION FORM
### CMS-10126 — ENTERAL AND PARENTERAL NUTRITION

All INFORMATION ON THIS FORM MAY BE COMPLETED BY THE SUPPLIER

<table>
<thead>
<tr>
<th>Certification Type/Date: INITIAL <em><strong>/</strong></em>/___ REVISED <em><strong>/</strong></em>/___ RECERTIFICATION <em><strong>/</strong></em>/___</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER</td>
</tr>
<tr>
<td>HICN</td>
</tr>
<tr>
<td>PLACE OF SERVICE</td>
</tr>
<tr>
<td>NAME and ADDRESS of FACILITY if applicable (see reverse)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>EST. LENGTH OF NEED (# OF MONTHS): 1-99 (99=LIFETIME)</td>
</tr>
</tbody>
</table>

### ANSWERS

**ANSWER QUESTIONS 1–6 FOR ENTERAL NUTRITION, AND 6-9 FOR PARENTERAL NUTRITION**

(Circle Y for Yes, N for No, Unless Otherwise Noted)

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is there documentation in the medical record that supports the patient having a permanent non-function or disease of the structures that normally permit food to reach or be absorbed from the small bowel?</td>
<td></td>
</tr>
<tr>
<td>2. Is the enteral nutrition being provided for administration via tube? (i.e., gastrostomy tube, jejunostomy tube, nasogastric tube)</td>
<td></td>
</tr>
<tr>
<td>3. Print HCPCS code(s) of product.</td>
<td></td>
</tr>
<tr>
<td>4. Calories per day for each corresponding HCPCS code(s).</td>
<td></td>
</tr>
<tr>
<td>5. Circle the number for method of administration?</td>
<td></td>
</tr>
<tr>
<td>6. Days per week administered or infused (Enter 1 – 7)</td>
<td></td>
</tr>
<tr>
<td>7. Is there documentation in the medical record that supports the patient having permanent disease of the gastrointestinal tract causing malabsorption severe enough to prevent maintenance of weight and strength commensurate with the patient's overall health status?</td>
<td></td>
</tr>
<tr>
<td>8. Formula components:</td>
<td></td>
</tr>
<tr>
<td>Amino Acid</td>
<td>(ml/day)</td>
</tr>
<tr>
<td>Dextrose</td>
<td>(ml/day)</td>
</tr>
<tr>
<td>Lipids</td>
<td>(ml/day)</td>
</tr>
<tr>
<td>9. Circle the number for the route of administration.</td>
<td></td>
</tr>
<tr>
<td>1 – Central Line (Including PICC)</td>
<td></td>
</tr>
<tr>
<td>2 – Hemodialysis Access Line</td>
<td></td>
</tr>
<tr>
<td>3 – Peritoneal Catheter</td>
<td></td>
</tr>
</tbody>
</table>

### Supplier Attestation and Signature/Date

I certify that I am the supplier identified on this DME Information Form and that the information provided is true, accurate and complete, to the best of my knowledge. I understand that any falsification, omission, or concealment of material fact associated with billing this service may subject me to civil or criminal liability.

**SUPPLIER SIGNATURE** ___________________________ **DATE _____/_____/_____**
INSTRUCTIONS FOR COMPLETING DME INFORMATION FORM
FOR ENTERAL AND PARENTERAL NUTRITION (CMS-10126)

CERTIFICATION TYPE/DATE: If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked “INITIAL.” If this is a revised certification (to be completed when the physician changes the order, based on the patient’s changing clinical needs), indicate the initial date needed in the space marked “INITIAL,” and also indicate the revision date in the space marked “REVISED.” If this is a recertification, indicate the initial date needed in the space marked “INITIAL,” and also indicate the recertification date in the space marked “RECERTIFICATION.” Whether submitting a REVISED or a RECERTIFICATION DIF, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.

PATIENT INFORMATION: Indicate the patient’s name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on his/her Medicare card and on the claim form.

SUPPLIER INFORMATION: Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using a legacy number, e.g. NSC number, use the qualifier 1C followed by the 10-digit number. (For example: 1Cxxxxxxxxxx)

PLACE OF SERVICE: Indicate the place in which the item is being used, i.e., patient’s home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.

FACILITY NAME: If the place of service is a facility, indicate the name and complete address of the facility.

HCPCS CODES: List all HCPCS procedure codes for items ordered that require a DIF. Procedure codes that do not require certification should not be listed in this section of the DIF.

PATIENT DOB, HEIGHT, WEIGHT AND SEX: Indicate patient’s date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if required.

PHYSICIAN NAME, ADDRESS: Indicate the physician’s name and complete mailing address.

PHYSICIAN INFORMATION: Accurately indicate the treating physician’s Unique Physician Identification Number (UPIN) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using UPIN number, use the qualifier 1G followed by the 6-digit number. (For example: 1Gxxxxxxx)

PHYSICIAN’S TELEPHONE NO.: Indicate the telephone number where the physician can be contacted (preferably where records would be accessible pertaining to this patient) if more information is needed.

QUESTION SECTION: This section is used to gather clinical information about the item or service billed. Answer each question which applies to the items ordered, circling “Y” for yes, “N” for no, a number if this is offered as an answer option, or fill in the blank if other information is requested.

SUPPLIER ATTESTATION: The supplier’s signature certifies that the information on the form is an accurate representation of the situation(s) under which the item or service is billed.

SUPPLIER SIGNATURE AND DATE: After completion, supplier must sign and date the DME Information Form, verifying the Attestation.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0679. The time required to complete this information collection is estimated to average 12 minutes per response, including the time to review instructions, search existing resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Blvd, Baltimore, Maryland 21244.

DO NOT SUBMIT CLAIMS TO THIS ADDRESS. Please see http://www.medicare.gov/ for information on claim filing.

Form CMS-10126 (09/05) INSTRUCTIONS EF 08/2006
4. CMS-1500 Form

The Administrative Simplification Compliance Act (ASCA) requires all initial claims for Medicare to be submitted electronically. Suppliers with fewer than 10 FTEs are exempt from this requirement and may submit claims on paper using the CMS-1500 claim form, version 08/05 (Exhibit 4 on pages 25-26). The only acceptable claim forms are those printed in Flint OCR Red, J6983, (or exact match) ink. Although a copy of the CMS-1500 form can be downloaded, copies of the form cannot be used for submission of claims, since copies may not accurately replicate the scale and OCR color of the form, creating problems with data scanning. You can find Medicare CMS-1500 completion and coding instructions, as well as the print specifications in Chapter 26 of the Medicare Claims Processing Manual (Pub.100-04): http://www.cms.hhs.gov/manuals/downloads/clm104c26.pdf.

CMS-1500 forms may be ordered from private printing companies or directly from the Government Printing Office. Credit card orders are accepted at (202) 512-1800 between 8:00 AM and 4:30 PM Eastern time. Direct-mail orders are accepted with check or money order through:

Superintendent of Documents
US Government Printing Office
Washington, DC 20402

The forms are available at varying prices in several formats: single sheet, 2-part snap-apart, and 1-part or 2-part continuous feed. A print negative is also available for purchase for large companies with print offices. Bulk orders are subject to discount, and some customization is available.

5. Filing Claims Electronically

Medicare requires most suppliers to submit claims electronically. There are many benefits to filing Medicare claims electronically, both for suppliers and for DME MACs. For suppliers, filing claims electronically means better cash flow. “Clean claims” received via electronic media may be paid after 14 days; the minimum time for paper claims is 29 days. Additional benefits include on-line claim status inquiry, electronic funds transfer, electronic remittance advice, and the ability to submit claims any time of any day. Furthermore, sending claims electronically avoids mailing costs, delays, and possible lost documents.

The first step to begin electronic claims submission is to acquire HIPAA compliant software. DME MAC e-commerce consultants are available to help suppliers analyze their claims submission needs and to assist in the process of becoming an electronic claims submitter. Once a software package is selected, the supplier must apply for an electronic sender number by completing an Electronic Data Transmission Agreement. Contact your DME MAC for the appropriate forms. The electronic sender number identifies the supplier to Medicare and may be used to submit claims to any of the four DME MACs. Each DME MAC has its own Electronic Data Interchange (EDI) or Electronic Media Claims (EMC) department. The personnel in these departments will process the agreement and assign the supplier an “electronic sender number.”

Once a sender number is obtained, suppliers are encouraged to send “test” claims to ensure that all data are properly encoded and that Medicare can read the files. Claims submitted with errors will be rejected on the front-end and will not enter the DME MAC processing system. These claims will be listed on a front-end error report. It is the submitter’s responsibility to correct the error(s) and retransmit any rejected claims.
6. Physician National Provider Identifier (NPI) Directory

One of the items to complete when submitting the CMS 1500 form is field 17b – the prescribing physician’s NPI number. NPI numbers for individual and organizational providers may be found at https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do.

Pump Billing Information

Rental payments for enteral pumps are limited to 15 months, assuming that all other medical criteria are met by the beneficiary. Medicare has determined that medical need is exhausted if the pump is not medically needed for 2 consecutive months. After a break of 2 months in receiving enteral services, Medicare may grant an additional 15-month rental period if the patient requalifies. Medicare may request medical record documentation to substantiate resumption of pump use after the 2-month break in service. Hospital stays and voluntary nonbilling do not qualify as legitimate breaks in service.

A beneficiary is granted 15 months of pump rental even if there is a change in supplier. After 15 months of rental payments are made, the supplier must continue to provide the feeding pump as long as it is medically necessary; however, no additional rental payments will be made. Medicare will allow maintenance and servicing charges after the rental period is exhausted. A maintenance charge of half of 1 month’s rental will be allowed every 6 months after the rental period has been completed. The supplier should have documentation of pump maintenance each time maintenance is billed.

Payment policies for enteral feeding pumps generally follow the rules for capped rental items. The beneficiary must be given the option of purchasing the pump at the initial time of service, and has the option to purchase the pump at any time during the rental period. Documentation that the beneficiary was notified of the rent/purchase option should be maintained in the medical record.

If the beneficiary chooses to purchase a new pump, append the modifier NU to the pump HCPCS code (B9000 or B9002). If a used pump is purchased, the modifier UE is appended. Medicare issues lump sum reimbursement for purchased pumps. If the pump is rented, append the modifier RR to the initial claim and all subsequent claims. If the beneficiary decides to purchase the pump after rental payments have been made, the rental payments will be deducted from the purchase allowance.

Additional modifiers for enteral pumps include BP if the pump is purchased, BR if the pump is rented, and BU if the beneficiary is undecided. These modifiers need to be appended only once during the rental period, ideally with the first claim submission. The modifiers BU and BR may be changed in subsequent rental months if the beneficiary is initially undecided and then decides to rent or purchase the pump, or if the beneficiary initially rents the pump and then decides to purchase the pump.

The capped rental modifiers KH, KI, and KJ also apply to enteral feeding pumps. The KH modifier is appended to the pump HCPCS code with the initial claim; modifier KI is appended for the second and third pump rental months and KJ is appended for rental months 4 through 15.
HEALTH INSURANCE CLAIM FORM

1500

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

- Medicare
- Medicaid
- CHAMPVA
- FECA

- INSURED'S I.D. NUMBER
- INSURED'S NAME
- INSURED'S ADDRESS
- CITY
- CITY
- ZIP CODE
- TELEPHONE
- INSURED'S POLICY GROUP OR FECA NUMBER
- INSURED'S DATE OF BIRTH
- EMPLOYER'S NAME OR SCHOOL NAME
- IS THERE ANOTHER HEALTH BENEFIT PLAN?
- INSURED'S OR AUTHORIZED PERSON'S SIGNATURE

- SEX

- PATIENT'S NAME
- PATIENT'S ADDRESS
- CITY
- CITY
- ZIP CODE
- TELEPHONE
- PATIENT'S POLICY OR GROUP NUMBER
- PATIENT'S DATE OF BIRTH
- EMPLOYER'S NAME OR SCHOOL NAME
- INSURANCE PLAN NAME OR PROGRAM NAME
- INSURANCE PLAN NAME OR PROGRAM NAME

- OTHER INSURED'S NAME
- OTHER INSURED'S POLICY OR GROUP NUMBER
- OTHER INSURED'S DATE OF BIRTH
- EMPLOYER'S NAME OR SCHOOL NAME
- IS INSURANCE PLAN NAME OR PROGRAM NAME

- MEDICARE
- MEDICAID
- TRICARE
- CHAMPUS

- OTHER INSURED'S CONDITION RELATED TO:

- EMPLOYMENT
- AUTO ACCIDENT
- OTHER ACCIDENT

- PATIENT'S BIRTH DATE
- SEX

- PATIENT'S RELATIONSHIP TO INSURED
- SELF
- SPOUSE
- CHILD
- OTHER

- PATIENT'S STATUS
- SINGLE
- MARRIED
- OTHER

- OTHER INSURED'S RELATIONSHIP TO INSURED

- EMPLOYMENT
- AUTO ACCIDENT
- OTHER ACCIDENT

- OTHER INSURED'S RELATIONSHIP TO PATIENT

- MEDICAID 
- TRICARE
- CHAMPUS

- HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

- DATE(S) OF SERVICE

- FROM

- TO

- PHYSICIAN OR SUPPLIER INFORMATION

- SERVICE FACILITY LOCATION INFORMATION

- BILLING PROVIDER INFO & PH #

- SIGNATURE OF PHYSICIAN OR SUPPLIER

- SIGNATURE OF PROVIDER

- SIGNATURE OF PATIENT

- APPROVED OMB-0938-0999 FORM CMS-1500 (08/05)

NUCC Instruction Manual available at: www.nucc.org

APPROVED CMB-0938-0999 FORM CMS-1500 (08/05)
BECAUSE THIS FORM IS USED BY VARIOUS GOVERNMENT AND PRIVATE HEALTH PROGRAMS, SEE SEPARATE INSTRUCTIONS ISSUED BY APPLICABLE PROGRAMS.

NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.

REFERS TO GOVERNMENT PROGRAMS ONLY
MEDICARE AND CHAMPUS PAYMENTS: A patient’s signature requests that payment be made and authorizes release of any information necessary to process the claim and certifies that the information provided in Blocks 1 through 12 is true, accurate and complete. In the case of a Medicare claim, the patient’s signature authorizes any entity to release to Medicare medical and nonmedical information, including employment status, and whether the person has employer group health insurance, liability, no-fault, worker’s compensation or other insurance which is responsible to pay for the services for which the Medicare claim is made. See 42 CFR 411.24(a). If item 9 is completed, the patient’s signature authorizes release of the information to the health plan or agency shown. In Medicare assigned or CHAMPUS participation cases, the physician agrees to accept the charge determination of the Medicare carrier or CHAMPUS fiscal intermediary as the full charge, and the patient is responsible only for the deductable, coinsurance and noncovered services. Coinsurance and the deductible are based upon the charge determination of the Medicare carrier or CHAMPUS fiscal intermediary if this is less than the charge submitted. CHAMPUS is not a health insurance program but makes payment according to certain provisions with the Uniformed Services. Information on the patient’s sponsor should be provided in those items captioned in “Insured”.; i.e., items 1a, 4, 6, 7, 9, and 11.

BLACK LUNG AND FECA CLAIMS
The provider agrees to accept the amount paid by the Government as payment in full. See Black Lung and FECA instructions regarding required procedure and diagnosis coding systems.

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, CHAMPUS, FECA AND BLACK LUNG)
I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.
For services to be considered as “incident” to a physician’s professional service, 1) they must be rendered under the physician’s immediate personal supervision by his/her employee; 2) they must be an integral, although incidental part of a covered physician’s service; 3) they must be of kinds commonly furnished in physician’s offices, and the services of nonphysicians must be included on the physician’s bill.
For CHAMPUS claims, I further certify that I (or any employee) who rendered services are not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contractor employee of the United States Government, either civilian or military (refer to 5 USC 5336). For Black Lung claims, I further certify that the services performed were for a Black Lung-related disorder.

No Part B Medicare benefits may be paid unless this form is signed by the patient and their physician as required by law and regulations (42 CFR 424.32).

NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF MEDICARE, CHAMPUS, FECA, AND BLACK LUNG INFORMATION
We are authorized by CMS, CHAMPUS and OWCP to ask you for information needed to administer the Medicare, CHAMPUS, FECA, and Black Lung programs. Authority to collect information is in section 205(a), 1862, 1872 and 1874 of the Social Security Act as amended, 42 CFR 411.24(a) and 424.5(a) (6), and 44 USC 3101; 41 CFR 101 et seq and 10 USC 1079 and 1086; 5 USC 8101 et seq; and 38 USC 613; E.O. 9397.
The information we obtain to complete claims under these programs is used to identify you and to determine your eligibility. It is also used to decide if the services and supplies you received are covered by these programs and to insure that proper payment is made.
The information may also be given to other providers of services, carriers, intermediaries, medical review boards, health plans, and other organizations or Federal agencies, for the effective administration of Federal provisions that require other third parties to pay to primary Federal program, and as otherwise necessary to administer these programs. For example, it may be necessary to disclose information about the benefits you have used to a hospital or doctor. Additional discloses are made through routine uses for information contained in systems of records.

FOR MEDICARE CLAIMS: See the notice modifying system No. 09-70-0501, titled, ‘Carrier Medicare Claims Record,’ published in the Federal Register, Vol. 55 No. 177, page 37549, Wed. Sept. 12, 1990, or as updated and republished.


FOR CHAMPUS CLAIMS: PRINCIPLE PURPOSE(S): To evaluate eligibility for medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services/supplies received are authorized by law.
ROUTINE USE(S): Information from claims and related documents may be given to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation consistent with their statutory administrative responsibilities under CHAMPUS/CHAMPPVA; to the Dept. of Justice for representation of the Secretary of Defense in civil actions; to the Internal Revenue Service, private collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressional Offices in response to inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program abuse, utilization review, quality assurance, peer review, program integrity, third-party liability, coordination of benefits, and civil and criminal litigation related to the operation of CHAMPUS.
DISCLOSURES: Voluntary; however, failure to provide information will result in delay in payment or may result in denial of claim. With the one exception discussed below, there are no penalties under these programs for refusing to supply information. However, failure to furnish information regarding the medical services rendered or the amount charged would prevent payment of claims under these programs. Failure to furnish any other information, such as name or claim number, would delay payment of the claim. Failure to provide medical information under FECA could be deemed an obstruction.

It is mandatory that you tell us if you know that another party is responsible for paying for your treatment. Section 1128B of the Social Security Act and 31 USC 3801-3812 provide penalties for withholding this information.
You should be aware that P.L. 100-503, the “Computer Matching and Privacy Protection Act of 1988”, permits the government to verify information by way of computer matches.

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)
I hereby agree to keep such records as are necessary to disclose fully the extent of services provided to individuals under the State’s Title XIX plan and to furnish information regarding any payments claimed for such services as the State Agency or Dept. of Health and Social Services may request.
I further agree to accept, as payment in full, the amount paid by the Medicaid program for those claims submitted for payment under that program, with the exception of authorized deductible, coinsurance, co-payment or similar cost-sharing charge.
SIGNATURE OF PHYSICIAN (OR SUPPLIER): I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.
NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.
Proof-of-Delivery Requirements*

Suppliers are not required to submit proof of delivery with their claims. However, they are expected to retain proof-of-delivery documentation as described herein to be furnished to the DME MAC on request. Documentation must be maintained by the supplier for 7 years.

All services that do not have appropriate proof of delivery from the supplier will be denied and overpayment refund will be requested. Suppliers who consistently do not provide documentation to support their services may be referred to the Office of Inspector General (OIG) for imposition of Civil Monetary Penalties (CMPs) or Administrative Sanctions. Suppliers or anyone having a financial interest in the delivery of an item may not sign or accept an item on behalf of the patient.

The proof-of-delivery requirements are outlined below according to the method of delivery. The three methods of delivery are:

1. Supplier delivers items directly to the beneficiary or designee (any person who can sign and accept the delivery on behalf of the patient).

2. Supplier uses a delivery/shipping service to deliver items.

3. Supplier utilizes a return postage-paid delivery invoice from the beneficiary or designee as a form of proof of delivery.

The general requirements for each method of delivery are as follows:

1. If the supplier delivers items directly to the beneficiary or designee, a delivery slip that has been signed and dated by the beneficiary or designee is required to verify the DMEPOS item(s) received. The delivery slip should include the beneficiary’s name, the quantity of items delivered, a detailed description of the item(s) being delivered, the brand name, and serial number if applicable. If a designee signs the delivery slip, their relationship to the beneficiary should be noted on the delivery slip and the signature should be legible. The date of signature on the delivery slip must be the date that the item was received and shall also be the date on the claim for payment.

2. If the supplier uses a delivery/shipping service to deliver items, acceptable proof of delivery would include the delivery service’s tracking slip and a supplier’s shipping invoice. If possible, the supplier’s records should also include the delivery service’s package identification number for the package sent to the beneficiary. The delivery service’s tracking slip should reference each individual package, the delivery address, the corresponding package identification number given by the shipping service, and, if possible, the date delivered. The shipping date should be the date of service on the claim.

When performing compliance audits or developing complaints, Medical Review Departments may request documentation to support claims submitted by the supplier. Often, the documentation returned from the supplier does not include a delivery service log, or includes a delivery service log that only indicates that numerous packages were picked up from the supplier—but not the individual package identification numbers associated with each patient. Without a delivery service’s tracking log that identifies each individual package with a unique identification number and the delivery address, the services may be denied and an overpayment refund may be requested.
3. If the supplier utilizes a return postage-paid delivery invoice from the beneficiary or designee as a form of proof of delivery, descriptive information including the beneficiary’s name, the quantity and detailed description of the DMEPOS item, and brand name and serial number should be on the invoice. The invoice must also be signed and dated by the beneficiary or their designee.

Audits indicate that packages are often delivered to the wrong address or left at the door or on the porch of the patient’s residence. Patients often indicate they did not receive the items/supplies that were shipped by the supplier. In situations where the patient denies receipt of the items/services, these services may be denied and an overpayment refund may be requested unless the supplier proves delivery with detailed documentation as described.

When enteral nutrition therapy is delivered to nursing facility residents, suppliers should obtain copies of documentation necessary to prove both delivery to and usage by the beneficiary. Suppliers may work with the nursing facility staff to implement an inventory control to ensure that supplies are identified and retained for use only by the specific beneficiary for whom the supplies are intended. Medical records in the nursing facility must document the beneficiary’s use of all supplies/items billed to Medicare. The documentation may be in the nurse’s notes or in a special treatment record or form. The date of the service on the claim should be the date the DMEPOS item(s) was received by the nursing facility.

If a Medicare claim is denied or partial payment made, payment may be obtained through Medicare’s structured appeals process. Requesting a redetermination or reconsideration can be a difficult and time-consuming process. On the other hand, an understanding of the rules and regulations can make the appeals process run more smoothly. See the appeals process flow chart (Exhibit 5).

This section will clarify the Medicare claims appeals process. It answers important questions such as:

- Who may request a redetermination or reconsideration?
- How does the appeals process begin?
- What supporting documentation should be provided?
- How long will it take to receive a response?
- What can be done if a claim is denied at the first appeal (redetermination)?
- What does reconsideration by a Qualified Independent Contractor (QIC) involve?
- What are the options if a claim is denied again?

### Overview

The first thing to do when Medicare denies or partially pays a claim for services rendered is to decide whether to request a redetermination or an adjustment. Begin by reviewing the claims group, reason, Medicare Outpatient Adjudication (MOA), and remark and reason codes on the remittance notice. An adjustment is appropriate in cases of clerical errors and similar mistakes. Examples of situations calling for adjustments include, but are not limited to, the following:

- Wrong date of service entered
- Wrong Medicare number submitted
- Wrong name entered
- Improper charge submitted

In cases that require a simple adjustment, a request for an adjustment should be submitted to the appropriate DME MAC. If the claim remark and reason codes indicate that it was never adjudicated, it can simply be reverted in your billing software and resubmitted. If a claim was adjudicated and denied completely, the claim must go through the appeals process. Appeals must be requested based on the original denial or first claim submitted.

There are five levels of appeal:

- First Appeal: Redetermination
- Second Appeal: Reconsideration by a Qualified Independent Contractor (QIC)
- Third Appeal: Administrative Law Judge (ALJ) Hearing
- Fourth Appeal: Departmental Appeals Board (DAB) Review
- Final Appeal: Federal Court Review

A redetermination or QIC reconsideration may be requested by any of three parties:

- The beneficiary who received the services.
- A participating supplier (i.e., one who has agreed to take assignment on all items or services payable on behalf of a Medicare beneficiary).
- A nonparticipating supplier who has accepted assignment with respect to items or services furnished to a beneficiary, but only for those items or services billed on an assigned basis.
**Medicare Appeals Process**

EXHIBIT 5. Medicare Appeals Process Flow Chart

Reference: Medicare Claims Processing Manual 100-04, Chapter 29.
A redetermination is an independent evaluation of a previously processed claim by someone who was not the original processor. Medicare allows 120 days from the initial determination date on the remittance advice to file a redetermination request and there is no monetary threshold to be met. A redetermination can be requested in several ways:

- By a letter from the supplier or beneficiary.
- Through the use of Form CMS-20027 (Exhibit 6).

Regardless of the method chosen, the redetermination request must include the beneficiary’s name, health insurance claim number, name and address of supplier, date of initial determination, the specific service(s) and/or item(s) for which the redetermination is being requested, the specific dates of service, and the name and signature of the person filing the request. It must also specifically state that a redetermination is requested and precisely state the reason for the request. Any additional information that may help the requester to receive payment for the claim should also be provided.

Supporting documentation for a redetermination

If the denial or partial payment of a claim involved a medical necessity reason, several types of documents to support the claim may be provided:

- A detailed letter from the patient’s physician. This letter should be patient and diagnosis specific. For example, if payment for a specialized metabolic need formula (B4154) is denied, the letter should clearly state why the patient needs a specialized metabolic formula rather than a standard product. Generalizations like “physician protocol” or “required by policy” should be avoided. In cases involving specialized enteral formulas, the letter from the physician should state whether a B4150 product was tried first.
- Laboratory reports or clinical studies that support the physician’s letter or a statement from the supplier.
- Nursing home records.
- Physician’s records.
- Notes of conversations between the physician and the hospital, nursing home, or supplier.

Extension of the filing deadline

The 120-day period to file for a redetermination may be extended for “good cause.” Examples of good cause for a supplier to request an extension may be, but are not limited to:

- Incorrect or incomplete information about the subject claim and/or appeal was furnished by official sources (CMS, the contractor, or the Social Security Administration) to the supplier; or,
- Unavoidable circumstances such as major floods, fires, tornados, and other natural catastrophes prevented the supplier from timely filing a request for redetermination.

When seeking an extension of a filing deadline based on good cause, the requestor must write to the DME MAC and state the specific reason an extension is being requested. The requestor can mention that he/she is aware that a waiver of timely filing for a review or hearing is allowed under 42 CFR §405.942. The DME MAC may or may not honor the request for additional time.
# Medicare Redetermination Request Form

1. **Beneficiary’s Name:**

2. **Medicare Number:**

3. **Description of Item or Service in Question:**

4. **Date the Service or Item was Received:**

5. **I do not agree with the determination of my claim. MY REASONS ARE:**
   
   ____________________________________________________________________________
   
   ____________________________________________________________________________
   
   ____________________________________________________________________________

6. **Date of the initial determination notice**
   
   *(If you received your initial determination notice more than 120 days ago, include your reason for not making this request earlier.)*
   
   ____________________________________________________________________________
   
   ____________________________________________________________________________
   
   ____________________________________________________________________________

7. **Additional Information Medicare Should Consider:**
   
   ____________________________________________________________________________
   
   ____________________________________________________________________________
   
   ____________________________________________________________________________

8. **Requester’s Name:**

9. **Requester’s Relationship to the Beneficiary:**

10. **Requester’s Address:**

11. **Requester’s Telephone Number:**

12. **Requester’s Signature:**

13. **Date Signed:**

14. **☐** I have evidence to submit. *(Attach such evidence to this form.)*
   
   **☐** I do not have evidence to submit.

**NOTICE:** Anyone who misrepresents or falsifies essential information requested by this form may upon conviction be subject to fine or imprisonment under Federal Law.
DME MAC response to a redetermination

CMS allows 60 days for the DME MAC to respond to a request for redetermination. Sometimes the DME MAC will request additional information. In most cases, however, the DME MAC will make a disposition on the claim with the information at hand. The redetermination decision is considered final, unless reconsideration is requested. Redetermination is a prerequisite for a reconsideration. The only exception would be if the DME MAC takes an unusually long time to respond to the initial claim.

Second Appeal: Reconsideration by Qualified Independent Contractors (QIC)

The Medicare Benefits Improvement and Protection Act (BIPA) of 2000 mandates that all second level appeals or reconsiderations of Medicare claims are conducted by Qualified Independent Contractors (QICs). A QIC is an independent adjudicator, unaffiliated with the DME MAC, who has medical, legal, and other relevant expertise. RiverTrust Solutions, Inc. is the QIC for all DME MAC reconsideration requests.

The QIC reconsideration is an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), the QIC’s reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals and be based on clinical experience, the patient’s medical records, and medical, technical, and scientific evidence of record to the extent applicable. It is important to note that all evidence to support the claim must be submitted at the QIC reconsideration level. New evidence cannot be introduced after the QIC reconsideration at the next level of appeal without a good explanation and a favorable ruling as to whether that explanation meets the good faith standard.

Interpretive CMS and DME MAC documents such as National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and CMS Transmittals and manual instructions are given substantial deference by the QIC officials.

A QIC reconsideration request does not have a minimum dollar limit. A written reconsideration request must be made to the QIC within 180 days of the DME MAC redetermination decision. As with DME MAC redetermination requests, a request to extend the 180-day filing period may be filed with the QIC. Reconsideration requests may include multiple claims within the 180-day period and may be requested using Form CMS-20033 (Exhibit 7). The QIC must notify the appellant of its decision within 60 days of receiving the written redetermination request.

Third Appeal: Administrative Law Judge (ALJ) Hearing

If a party is dissatisfied with a QIC’s reconsideration or if the adjudication period for the QIC to complete its reconsideration has elapsed, an ALJ hearing may be requested. Each calendar year the dollar amount for both ALJ hearings and Federal Court Review (the final appeal level) is recalculated in accordance with the percentage increase in the medical care component of the consumer price index for all urban consumers. An ALJ hearing request must meet the current dollar
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<td>Beneficiary’s Name: ____________________________________________________________</td>
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<td><strong>2.</strong></td>
<td>Medicare Number: ____________________________________________________________</td>
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<td><strong>3.</strong></td>
<td>Description of Item or Service in Question: __________________________________</td>
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<td>Date the Service or Item was Received: ______________________________________</td>
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<td>I do not agree with the determination of my claim. MY REASONS ARE:</td>
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<td>Date of the redetermination notice__________________________________________</td>
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<td><em>(If you received your redetermination more than 180 days ago, include your reason for not making this request earlier.)</em></td>
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<td>Additional Information Medicare Should Consider: ______________________________</td>
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<td>Requester’s Name: __________________________________________________________</td>
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<td><strong>9.</strong></td>
<td>Requester’s Relationship to the Beneficiary: ________________________________</td>
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<td>Requester’s Address: ______________________________________________________</td>
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<td><strong>11.</strong></td>
<td>Requester’s Telephone Number: ________________________________</td>
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<td><strong>12.</strong></td>
<td>Requester’s Signature: ____________________________________________________</td>
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<td><strong>13.</strong></td>
<td>Date Signed: ______________________________________________________________</td>
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<tr>
<td><strong>14.</strong></td>
<td>☐ I have evidence to submit. (Attach such evidence to this form.)</td>
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<td>☐ I do not have evidence to submit.</td>
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<tr>
<td><strong>15.</strong></td>
<td>Name of the Medicare Contractor that Made the Redetermination:_______________</td>
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**NOTICE:** Anyone who misrepresents or falsifies essential information requested by this form may upon conviction be subject to fine or imprisonment under Federal Law.
threshold. Suppliers may be able to meet the dollar threshold for an ALJ hearing by combining the disputed claim with other claims that have had unsatisfactory QIC reconsideration decisions.

The request for the ALJ review must be made in writing within 60 days after receipt of the reconsideration notice. The request must include all of the following:

1. The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed.
2. The name and address of the appellant, when the appellant is not the beneficiary.
3. The name and address of the designated representatives, if any.
4. The document control number assigned to the appeal by the QIC, if any.
5. The dates of service.
6. The reasons the appellant disagrees with the QIC’s reconsideration or other determination being appealed.
7. A statement of any additional evidence to be submitted and the date it will be submitted.

The QIC reconsideration notice will specify where to send the ALJ hearing request, and the QIC will forward the case file to the appropriate HHS Office of Medicare Hearings and Appeals (OMHA) field office. The supplier may also request a complete copy of the case file. OMHA jurisdiction is based on the appellant’s address of record. Once the request is received by the OMHA field office, the case is assigned to an ALJ. The ALJ notifies the supplier of the hearing date. If you have questions concerning a pending appeal or about appealing a decision, contact the OMHA field office that serves your state or territory (see page 40).

**Fourth Appeal: Departmental Appeals Board (DAB) Review**

If the appellant does not agree with the ALJ’s decision, he/she may ask the Departmental Appeals Board to review the decision. There is no monetary threshold to be met with a DAB appeal, however a written appeal request must be made within 60 days of the ALJ decision. The request must specify the issues and findings that are being contested. The ALJ written decisions will provide details regarding the procedures to follow when filing a request for DAB review. Generally, the Departmental Appeals Board will issue a decision within 90 days of receipt of a request for review.

**Reopenings of initial determinations, redeterminations, reconsiderations, hearings and reviews**

A reopening is a remedial action taken to change a final determination or decision that resulted in either an overpayment or underpayment, even though the final determination or decision may have been correct at the time it was made based on the evidence of record. The action may be taken by:

- a DME DAB to revise the initial determination or redetermination;
- a QIC to revise the reconsideration;
- an ALJ to revise the hearing decision; or
- the DAB to revise the hearing or review decision.

Granting a supplier’s request for a reopening is at the discretion of the contractor and is not mandatory. The contractor’s decision on whether to reopen is final and not subject to appeal. Specific time frames are defined for reopenings in accordance with which Medicare contracted entity is reopening the claim. The right for
a reopening may be exercised if it is felt that the contractor made a mistake or if there is additional information to provide. There is no dollar limit for reopenings, so this route may be appropriate if a claim amount is less than that needed for a specific level of appeal. To begin the process, a letter requesting a reopening is initiated. Forms to request a reopening of initial and redeterminations may be found at the respective DME MAC websites. If the reopening request is denied, the appeal process may still be undertaken if the time and dollar requirements for the specific level of appeal are met. More information on claim reopenings may be found in the Medicare Claims Processing Manual 100-04, Chapter 34. www.cms.hhs.gov/manuals/downloads/clm104c34.pdf.

Final Appeal: Federal Court Review

If the appellant is not satisfied with the ALJ decision and the amount in controversy meets the current year minimum, a judicial review before a Federal District Court judge may be requested. The request must be made within 60 days of receipt of the DAB’s decision. The DAB’s decision notice will contain information about the procedures for requesting a judicial review.
### HHS Office of Medicare Hearings and Appeals (OMHA)  
Field Offices and State Jurisdictions

| Arlington, Virginia  
(Mid-Atlantic Field Office) | Mid-Atlantic Field Office Jurisdiction |
|--------------------------|--------------------------------------|
| 1700 N. Moore St., Suite 1600  
Arlington, VA 22209  
Phone: 866-231-3087 | HHS Region 3  
District of Columbia  
Maryland  
Virginia |

| Cleveland, Ohio  
(Mid-West Field Office) | Mid-West Field Office Jurisdiction |
|------------------------|----------------------------------|
| BP Tower, Suite 1300  
200 Public Square  
Cleveland, OH 44114-2316  
Phone: 866-236-5089 | HHS Region 1  
Connecticut  
Maine  
Massachusetts  
New Hampshire  
Rhode Island  
Vermont  
HHS Region 2  
New York  
New Jersey  
HHS Region 3  
Delaware  
Pennsylvania  
West Virginia  
HHS Region 4  
Kentucky  
HHS Region 5  
Illinois  
Indiana  
Ohio  
Michigan  
Minnesota  
Wisconsin |

| Irvine, California  
(Western Field Office) | Western Field Office Jurisdiction |
|-----------------------|---------------------------------|
| 27 Technology Drive, Suite 100  
Irvine, CA 92618-2364  
Phone: 866-495-7414 | HHS Region 7  
Iowa  
Kansas  
Missouri  
Nebraska  
HHS Region 8  
Colorado  
Montana  
North Dakota  
South Dakota  
Utah  
Wyoming  
HHS Region 9  
Arizona  
California  
Hawaii  
Nevada  
Guam  
Trust Territory  
of the Pacific Islands  
American Samoa  
HHS Region 10  
Alaska  
Idaho  
Oregon  
Washington |

| Miami, Florida  
(Southern Field Office) | Southern Field Office Jurisdiction |
|------------------------|----------------------------------|
| 100 SE 2nd Street, Suite 1700  
Miami, FL 33131-2100  
Phone: 866-622-0382 | HHS Region 2  
Puerto Rico  
Virgin Islands  
HHS Region 4  
Alabama  
Florida  
Georgia  
Mississippi  
North Carolina  
South Carolina  
Tennessee  
HHS Region 6  
Arkansas  
Louisiana  
New Mexico  
Oklahoma  
Texas |

42CFR Part 405, Subpart 1, provides a full and accurate description of the appeal process.  
http://www.ssa.gov/OP_Home/cfr20/405/405-0000.htm
Medicare will allow an enteral provider to bill prospectively for 1 month only. However, retrospective billing may include multiple months, is simpler, and makes it easier to confirm correct patient information. Prospective claims may be created and filed with Medicare only to learn later that the patient had an order change or therapy was discontinued. When this happens, an under/overbilling situation may occur. In the event that a claim has been under/overbilled, the provider is expected to notify the DME MAC of the billing error. Fines and penalties can be imposed if a Medicare audit shows that overpayments have not been refunded. (See Fraud and Abuse on the next page.)

Underpayments
If a claim is underbilled, the supplier may be able to resolve the problem via the telephone reopening process. This process is used to resolve minor errors or omissions involving units of service, service dates, HCPCS code issues, diagnosis codes and diagnosis reference, modifiers, place of service, and claims incorrectly denied as duplicate charges. If the claim issue cannot be resolved using the telephone reopening process, the supplier may need to appeal the claim through the Medicare appeals process.

Overpayments
If a supplier receives an overpayment for DMEPOS items, the supplier should initiate a voluntary refund to the appropriate DME MAC. Each of the four DME MACs provide instructions and forms for voluntary refunds of overpayments. If the specific DME MAC form is not used, a similar document containing all of the required information should accompany the refund check so that the receipt of the check is properly recorded and applied.
Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs)

PSCs and ZPICs are contractors affiliated with the DME MACs that specialize in benefit integrity (BI) work. The primary goal of the BI unit is to identify cases of suspected fraud and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any mistaken payments are recouped. All suspected cases of fraud are referred to the Office of Inspector General (OIG), Office of Investigations field office (OIFO) for consideration and initiation of criminal or civil prosecution, civil monetary penalty, or administrative sanction actions. Having specific entities that focus on BI enables the four DME MACs to place greater focus on claims processing and customer service. CMS is in the process of transitioning all BI work from PSCs to ZPICs.

Benefit integrity units use a variety of tools including data analysis, fraud complaints, and referrals. They also develop innovative tools and techniques to identify potential Medicare fraud and abuse. These approaches are used in building and referring cases to law enforcement involving those who are suspected of perpetrating Medicare fraud. More information on BI units may be found in chapter 4 of the Medicare Program Integrity Manual (Pub. 100-08) at: http://www.cms.gov/manuals/downloads/pim83c04.pdf.

Fraud

*Fraud* is intentional deception or misrepresentation that the individual makes, knowing it to be false and that it could result in some unauthorized benefit to them. *Abuse* describes incidents or practices of providers, physicians, or suppliers, or services and equipment which, although not usually fraudulent, are inconsistent with accepted sound medical, business, or fiscal practices. These practices may, directly or indirectly, result in unnecessary costs to the program, improper payment, or payment for services which fail to meet professionally recognized standards of care, or which are medically unnecessary.

Examples of fraud include but are not limited to:

- Incorrect reporting of diagnoses or procedures to maximize payments.
- Billing for services not furnished and/or supplies not provided.
- Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both Medicare and the beneficiary for the same service, or billing both Medicare and another insurer in an attempt to get paid twice.
- Soliciting, offering, or receiving a kickback, bribe, or rebate, e.g., paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment.

Examples include:

- Physicians acting either in the capacity of a consultant or attending physician who are offered percentages of Medicare payment if they refer patients needing Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) services to specific DMEPOS suppliers.
– Skilled nursing facilities or nursing homes that are offered—at no charge—durable medical equipment, formula for Part A patients, computers, billing services, or rebates as an inducement to refer patients to a specific PEN supplier.

– Unbundled or fragmented charges.

– Falsification of DIFs (i.e., misrepresenting the diagnosis for the patient to justify the services or equipment furnished—e.g., indicating the patient cannot swallow, when in fact he or she can).

The CMS Office of the Inspector General regularly issues Fraud Alerts, Advisory Opinions, and reports of these topics. For more information, visit the OIG website at www.oig.hhs.gov.

**Supplier Standards**

CMS has established 30 Supplier Standards that govern the business practices of the DMEPOS supplier industry. These standards are defined in the Medicare Enrollment Application (www.cms.hhs.gov/cmsforms/downloads/cms855s.pdf), and suppliers must follow these standards and disclose them to all customers/patients who are Medicare beneficiaries.

**MEDICARE DMEPOS SUPPLIER STANDARDS**

(www.palmettogba.com/Palmetto/Providers.Nsf/files/30supplierstandardsabv.pdf/$File/30supplierstandardsabv.pdf)

Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.

2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.

3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.

4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.

5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and offer the purchase option for capped rental equipment.

6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.

7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier’s compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.

9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service, or cell phone during posted business hours is prohibited.

10. A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier’s place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.

11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician’s oral order unless an exception applies.

12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare-covered items, and maintain proof of delivery.

13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.

15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.

16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.

17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.

18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.

19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.

20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.

21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.

22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals).
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.

24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.

25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.

26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c).

27. A supplier must obtain oxygen from a state-licensed oxygen supplier.

28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).

29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.

30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.

**Competitive Bidding**

According to www.dmecompetitivebid.com, the DMEPOS Competitive Bidding Program was mandated by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The statute requires that Medicare replace the current fee schedule payment methodology for selected Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items with a competitive bid process. The intent is to improve the effectiveness of the Medicare methodology for setting DMEPOS payment amounts, which will reduce beneficiary out-of-pocket expenses and save the Medicare program money while ensuring beneficiary access to quality items and services.

Under the program, a competition among suppliers who operate in a particular Competitive Bidding Area (CBA) is conducted. Suppliers are required to submit a bid for selected products. Enteral Nutrients, Equipment and Supplies is a category subject to bidding. Bids are submitted electronically through a web-based application process and required documents are mailed. Bids are evaluated based on the supplier’s eligibility, its financial stability and the bid price. Contracts are awarded to the Medicare suppliers who offer the best price and meet applicable quality and financial standards. Contract suppliers must agree to accept assignment on all claims for bid items and will be paid the bid price amount. The amount is derived from the median of all winning bids for an item.

Beneficiaries with original Medicare who obtain enteral nutrients, equipment and supplies in Competitive Bidding Areas must obtain these items from a winning contract supplier in order for Medicare to pay. This also applies to beneficiaries who do not live in a Competitive Bidding Area but who obtain these items while traveling in an area. For areas not currently impacted by the Medicare Competitive Bidding program, the current Medicare fee schedule payment amounts will continue to be paid.

The Medicare Competitive Bidding Program will be implemented in phases. Round One Rebid phase was fully implemented in 2011 and impacted 9 specific areas of the country. Round Two is scheduled to be fully implemented in 2013 and will impact 91 additional areas in the country.
The Centers for Medicare & Medicaid Services (CMS) has contracted with Palmetto GBA to administer the DMEPOS Competitive Bidding Program. Palmetto GBA is responsible for conducting certain functions including performing bid evaluations, selecting qualified suppliers, setting payments for all competitive bidding areas and overseeing an education program. Palmetto GBA also assists CMS and its contractors in monitoring the program’s effectiveness, access, and quality.

Quality Standards and Accreditation

CMS published the final quality standards for DMEPOS suppliers in October 2008 in accordance with the Medicare Modernization Act. The standards help ensure that Medicare beneficiaries receive quality health care services and include requirements for supplier business services and supplier product-specific services. Suppliers must comply with the quality standards in order to 1) furnish any DMEPOS item or service, for which Medicare Part B makes payment, and 2) to receive or retain a provider or supplier billing number used to submit claims to Medicare for reimbursement. The quality standards may be viewed at: http://www.cms.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandardsCMB.pdf.

All DMEPOS suppliers must also be accredited by a CMS-approved Deemed Accreditation Organization, including those suppliers who are initially enrolling in Medicare. Accrediting organizations are responsible for ensuring suppliers meet the quality standards. The National Supplier Clearinghouse (NSC) will not approve any DMEPOS supplier’s enrollment application if the enrollment package does not contain an approved accreditation upon receipt or in response to a developmental request. The NSC shall reject the enrollment application unless the DMEPOS supplier provides supporting documentation that demonstrates that the supplier has an approved accreditation. The following weblink provides more information on accreditation and a list of CMS-approved Deemed Accreditation Organizations: https://www.cms.gov/MedicareProviderSupEnroll/07_DMEPOSAccreditation.asp#TopOfPage.

Office of Inspector General’s Compliance Guidance

In June 1999, the Department of Health and Human Services’ Office of Inspector General (OIG) issued compliance program guidance that details actions that suppliers of enteral nutrition can take to help prevent violations of the Medicare fraud and abuse laws. The document, titled “Office of Inspector General’s Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry,” provides general and specific guidance about various internal anti-fraud and abuse controls suppliers can voluntarily implement. Additionally, the OIG has released guidance for third-party
medical billing companies that parallels the requirements for the DME compliance program. Both guidances are available on the internet at http://oig.hhs.gov/fraud/complianceguidance.asp It is strongly recommended that providers or billers of enteral nutrition review these documents and ensure that their program meets the recommendations found in the guidances.

The guidance suggests that every company implement a compliance program. At a minimum, seven elements of a compliance program should be in place:

1. Development and distribution of written standards of conduct, as well as written policies and procedures that promote the supplier’s commitment to compliance. These policies should address specific areas of potential fraud, such as the claims development and submission process, completing DIFs, cover letters, retention of records, and waivers of coinsurance and deductibles.

2. Designation of a compliance officer and other appropriate bodies charged with the responsibility for operating and monitoring the compliance program and who report directly to the CEO and the governing body.

3. Development and implementation of regular, effective education and training for all affected employees.

4. Development of effective lines of communication between the compliance officer and all employees, including a process to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect callers from retaliation.

5. Use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problem areas.

6. Development of appropriate disciplinary mechanisms to enforce standards.

7. Development of policies to respond to detected offenses and to initiate corrective action to prevent similar offenses.

Beyond the seven basic elements, the guidance addresses 47 compliance risk areas specific to DMEPOS suppliers that are of particular concern to the OIG. They range from improper telemarketing practices and paying kickbacks for referrals to double billing and falsifying information. Among other things, the guidance cautions against:

- Providing and/or billing for substantially excessive amounts of DMEPOS items or supplies. The OIG recommends that if a DMEPOS supplier is providing and billing for a large number of items or supplies for the same patient, it periodically contact the treating physician to confirm the medical necessity of the items and supplies. Such contact should be documented.

- Engaging in business arrangements that may violate anti-kickback statutes or other similar federal and state statutes or regulations, e.g., providing something of value in exchange for the referral of federal health care program business.

- Improper conduct relevant to completing DIFs. This includes billing for items or supplies prior to receiving a written order or falsifying information on the DIF.
• Billing for services not provided. This guideline includes not fulfilling a contractual agreement, such as when the DMEPOS supplier has agreed to service rental equipment and does not fulfill this obligation. For example, the government assigns the responsibility for maintenance of a rental pump to the supplier who was paid for the 15th month of rental. If another provider accepts the responsibility for ongoing rentals after the 15th month, no additional rental charges will be authorized.

• Billing patients for denied charges without a written notice.

• Using a billing agent whose compensation arrangements violate the reassignment rule.

• Refusing to submit a claim to Medicare for which payment is made on a reasonable charge or fee-schedule basis. If a supplier provides an item or service that is a Medicare benefit and reimbursable under the Medicare program, it is responsible for submitting the claim to Medicare even if it does not accept assignment.

• Failing to maintain medical necessity documentation. DMEPOS providers need to ensure that the patient’s medical record contains and substantiates all of the information contained on the DIF.

• Providing actual or potential referral sources with incentives that may violate the anti-kickback statutes. Examples of arrangements that may run afoul of anti-kickback statutes include practices in which a supplier pays a fee or provides a free gift to a physician for each written order.

• Not notifying the National Supplier Clearinghouse of changes to the information previously provided on the DMEPOS supplier enrollment form within 30 days of the effective date of the change. This includes change of address or ownership.

• Failing to refund overpayments to a health care program or to the patient. This doesn’t mean just repaying an overpayment that the DME MAC requests; it puts the responsibility on the supplier to identify any overpayment received for whatever reason. The OIG strongly recommends that the DMEPOS supplier institute procedures to detect overpayments and to promptly remit such overpayments to the affected payer.

• Employing persons who have been excluded from participation in federal health care programs.

The OIG has made it known that the existence of an effective compliance program will be a factor in determining the administrative sanctions, penalties, or other action to be taken against a supplier who self-reports or is caught in subsequent wrongdoing. All suppliers should review these documents carefully and assure themselves that their programs comply with the examples given in the guidelines.

Audit Process

The emphasis of fraud and abuse audits has recently increased. Suppliers of enteral nutrients, equipment, and supplies to Medicare beneficiaries may be audited by the National Supplier Clearinghouse (NSC), Program Safeguard Contractor (PSC) or Zone Program Integrity Contractor (ZPIC), Comprehensive Error Rate Testing Contractors (CERT), or Recovery Audit Contractors (RAC). Suppliers should be prepared for a review of their company and their billing processes.

National Supplier Clearinghouse

The National Supplier Clearinghouse (NSC) is responsible for ensuring suppliers are
in compliance with the DMEPOS supplier standards. The NSC may conduct site visits or surveys to determine a supplier’s compliance in response to initial enrollment applications, re-enrollments, reactivation of billing privileges, and at any other time deemed necessary. The authorized site inspector will examine documentation of a supplier’s compliance with all Supplier Standards including:

- Local, state, and federal licensure (including the business license)
- Day-to-day operating procedures—physical setup of the facility, its address and business hours (make sure the company is listed in the telephone book)
- Supplier inventory, records, lease/vendor agreements, and invoices
- Beneficiary files, including proof of delivery, written orders, and DIFs
- Disclosure of supplier standards to beneficiaries
- Proof of general liability insurance

Site visits are unannounced and will take place during your posted hours of operation. The authorized site inspector, whether an NSC employee or a contractor, will have with them a photo identification card and a signed letter on CMS letterhead authorizing the individual to conduct the visit. Please note the inspector will have a camera to take various pictures of the facility, sign, inventory, etc. The inspector will also have a questionnaire to complete based on the supplier standards. The inspector will ask to review your files to determine if you are in compliance with certain requirements of the supplier standards. However, the site inspector should not take the files, make copies, or take pictures of the information contained in the files.

Notify the NSC immediately if the site inspector requests to take the original or make copies of the beneficiary files or fails to present the photo ID or signed authorization letter. Do not give any information to an individual who is not properly credentialed. Call the NSC at (866) 238-9652 to report any concerns.

It is important to note the DMEPOS site visit process is a completely separate process from accreditation. The NSC and the accrediting organizations appointed by CMS are enforcing two different sets of standards. The NSC will not conduct a site visit with regards to the accreditation process. Suppliers can expect to receive site visits or surveys from both the NSC and the accrediting organizations.

DMEPOS suppliers must renew their provider numbers every 3 years. The NSC will send a re-enrollment package to the address on file as the provider’s physical location. Suppliers have 30 days to respond or their number will be canceled. This re-enrollment may also trigger an onsite audit. Make sure that all address changes are communicated to the NSC within 30 days of the change (as required under the provider agreement) to ensure that the re-enrollment packet goes to the correct address. Provider enrollment updates may be in writing to the NSC or via the CMS online PECOS system.

More information on conditions a supplier must meet to be eligible to receive payment for a Medicare-covered item may be found at 42 CFR §424.57. Visit the NSC website www.palmettogba.com/nsc for more information on DMEPOS supplier NSC site visits.

Program Safeguard Contractors (PSC) and Zone Program Integrity Contractors (ZPIC) Benefit Integrity Audits

As previously mentioned, PSCs and ZPICs are responsible for DME MAC benefit integrity (BI) and all fraud and abuse activities, including pre- and post-payment reviews, audits, and anti-fraud functions. The BI units are responsible for preventing, detecting, and deterring Medicare fraud by:

- Identifying program vulnerabilities.
• Proactively identifying incidents of potential fraud that exist within its service area and taking appropriate action on each case.

• Investigates (determining the factual basis of) allegations of fraud made by beneficiaries, providers, CMS, OIG, and other sources.

• Exploring all available sources of fraud leads in its jurisdiction, including state Medicaid fraud control units and its corporate anti-fraud unit.

• Initiating appropriate administrative actions to deny or to suspend payments that should not be made to providers where there is reliable evidence of fraud.

• Referring cases to the Office of the Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions.

• Referring any necessary provider and beneficiary outreach to the POE staff at the DME MAC.

• Initiating and maintaining networking and outreach activities to ensure effective interaction and exchange of information with internal components as well as outside groups.

Benefit integrity units are required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent billing practices. Proactive (self-initiated) leads may be generated and/or identified by any internal PSC, ZPIC, or DME MAC component, not just the BI unit. DME MAC personnel conducting each segment of claims adjudication, medical review (MR), and professional relations functions are responsible for identifying fraud and forwarding potential fraud cases to a BI unit. Benefit integrity units will also pursue leads through data analysis, the internet, the Fraud Investigation Database (FID), news media, etc. Each BI unit investigation is unique and tailored to the specific circumstances. If a BI unit determines that a situation is not fraud, the case is referred to the appropriate unit at the DME MAC. For more information, refer to CMS Program Integrity Manual (PUB. 100-08) Chapter 4 - Benefit Integrity at: www.cms.hhs.gov/manuals/downloads/pim83c04.pdf.

**Comprehensive Error Rate Testing (CERT) Program**

CMS established the Comprehensive Error Rate Testing (CERT) program to calculate a national paid claims error rate for the Medicare Fee-For-Service program. On a post-payment basis, the CERT program randomly samples and reviews submitted claims in accordance with Medicare coverage, coding, and billing rules. Supporting medical records are requested from the DMEPOS supplier paid for the claim and evaluated during claim review.

The CERT program considers improper payment as any claim that was paid when it should not have been. When requested medical records are not submitted by the provider, CERT classifies the case as a “no documentation” claim and counts it as an improper payment. Based on claim review, CERT sends providers overpayment letters/notices or makes adjustments for claims where an overpaid or underpaid determination was made. CERT claim denials may be appealed through the Medicare appeals process.

The CERT program uses random samples to select claims and reviewers are often unable to see provider billing patterns that indicate potential fraud when making payment determinations. The CERT program does not, and cannot, label a claim fraudulent. Each of the four DME MACs provides CERT information on their websites. Additional information on CERT, including published error rate reports, may be found at: https://www.cms.gov/CERT/01_overview.asp#TopOfPage.
Recovery Audit Contractors (RAC)

Recover audit contractors are also contracted by CMS to detect and correct improper Medicare payment on a post-payment basis. RACs are paid based on a contingency fee which is a negotiated percentage of the amount of improper payments they correct for both overpayments and underpayments. CMS must approve issues for RAC review and a review notice must be posted before the review can begin. A RAC Validation Contractor (RVC) works with CMS and the RACs to approve new issues the RACs want to pursue for improper payments. The RVC also monitors RACs by performing accuracy reviews on a sample of randomly selected claims on which the RACs have already collected overpayments.

RACs apply statutes, regulations, CMS national coverage, payment and billing policies, as well as LCDs that have been approved by the Medicare claim processing contractors in claim reviews. In general, claims previously reviewed by another entity are not subject to RAC review. RAC reviews may be automated or complex. Automated reviews typically evaluate claims payments based on technical issues such as units of service billed vs. allowed, while complex reviews may focus on medical record review to determine medical necessity.

RACs may request records for complex review every 45 days (eight times per year). Request limits are set at 10% of all claims submitted for the previous full calendar year, divided into eight periods (45 days), up to a current cap of 250 records per request period. RACs may request permission from CMS to exceed the cap limit. Although the RACs may go more than 45 days between record requests, in no case may they make requests more frequently than every 45 days.

Each RAC works with one of the four DME MAC regions. DMEPOS issues currently under review are listed at each RAC website. More information may also be found at: https://www.cms.gov/RAC/01_Overview.asp#TopOfPage.


Audit Preparation

Suppliers are encouraged to be prepared for Medicare audits before they happen. Suggestions for preparedness include:

- Keep up-to-date on LCDs, NCDs, and related articles. Know what documentation is needed for each item you provide. When Medicare audits a claim, they make sure the requirements outlined in LCDs, NCDs, and related articles are met. Develop documentation checklists for your files to assure you always have all of the necessary documentation. Keep records orderly and consistent.

- Whenever possible, get as much clinical documentation up front for the services you provide. It is much easier to get the documentation you need at the time the service is ordered rather than having to go back if faced with an audit.

- Make sure your referral sources know the coverage guidelines and conditions for the items they order.

- Do not rely on supplier-generated forms to document medical necessity. They are not considered part of the medical record and may discourage physicians from documenting the information in their own record.
• Make sure every record has a copy of a signed and dated Assignment of Benefits (AOB) as well as sufficiently detailed, signed, and dated dispensing and detailed written orders.

• Be certain that delivery documentation is sufficiently detailed, signed, and dated.

• Keep current on local, state, and federal licensure requirements. Make copies of licenses, insurance policies, and vendor contracts and store them in a designated place.

• Attend workshops, read advisories, and consult ombudsmen for education updates regarding medical necessity and billing practices for the DMEPOS items you supply.

• Be proactive—it is much more cost-effective to review documentation and files in advance to determine if you have any issues rather than waiting for an auditor to review your claims and potentially extrapolate any identified overpayments.

When you receive a record request:

• Begin compiling the documentation immediately. Claims are often denied because deadlines are missed. If you cannot meet a deadline, call and request an extension.

• Include all medical record documentation supporting the medical necessity for the items being audited. This may include information from hospital admissions and physician office notes. Medicare policies state that supporting documentation must be provided if requested. If necessary, contact the ordering physicians and request specific documentation related to why they prescribed the item in question.

• Conduct a comprehensive review of the documentation prior to submitting it. If you identify issues in your review, prepare a corrective action plan to address those issues immediately.

• Keep copies of all records sent to the auditing agency.

• Continue working with referral sources to obtain needed clinical documentation even after record requests have been submitted. Additional documentation may be helpful if an appeal is needed.

ALJ hearing—A quasi-judicial administrative hearing conducted by a federal ALJ. It results in a new decision by an independent reviewer. An ALJ hearing is the third level of appeal following reconsideration by a QIC.

Amount in controversy—The difference between the amount charged the beneficiary and the amount Medicare allowed, less any remaining Part B deductible, less 20% of the remainder. To meet the amount-in-controversy requirements of the various levels of appeal, a beneficiary or provider may combine claims for Part B services.

Appeal requests—Written statements asking for review of an initial payment determination.

Appeals adjustments—Changes in payment resulting from reconsiderations, redeterminations, ALJ hearings, Departmental Appeals Board reviews, judicial reviews, or reopenings.

Assignee—A representative given authority by the beneficiary to act on his or her behalf.

Beneficiary—A person entitled to receive Medicare benefits.

CMS—Centers for Medicare and Medicaid Services.

CEDI—Common Electronic Data Interchange.

Common working file—A shared database of Medicare claims information used to verify diagnosis, treatment, and payment by various Medicare carriers.

Comprehensive Error Rate Testing (CERT) Program—A program contracted by CMS to calculate the national paid claims error rates for the Medicare Fee-For-Service program. CERT randomly reviews DMEPOS claims on a post-payment basis.

DME MAC Information Form (DIF)—An essential tool in determining coverage. The form is used to document the patient’s physiological need and prescription for parenteral or enteral nutritional therapy (CMS form 10126).

DMEPOS—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.

Dumping syndrome—Rapid emptying of food out of the stomach and into the intestine, which draws fluid into the intestine and causes nausea, light-headedness, weakness, and/or vomiting.
Durable Medical Equipment Medicare Administrative Contractor (DME MAC) — A private company with a government contract to administer Medicare Part B DMEPOS claims.

Enteral nutrition (EN) — Nutrition provided directly into GI tract rather than orally or parenterally.

Enteral supply kit — Contains all the necessary supplies for an enteral patient using the syringe (B4034), pump (B4035), or gravity (B4036) method of nutrient administration. Products such as syringes, split 4 x 4 gauze, feeding bags, and tubing may be included in enteral supply kits.

EOMB — Explanation of Medical Benefits. A form sent to Medicare beneficiaries explaining Medicare payment of DMEPOS items.

Full reversal — Payment of an appealed claim in the allowable amount less co-insurance and deductible.

Functional impairment — A permanent nonfunction or disease of the structures that normally permit food to reach the small bowel, or a disease of the small bowel that impairs digestion and absorption of an oral diet.

Gastrointestinal (GI) tract — The digestive tube from the mouth to the anus, including mouth or buccal cavity, pharynx, esophagus, stomach, small and large intestines, and rectum.

Gastrostomy tube (G tube) — Silicone tube that provides direct access into the stomach.

Gravity feeding — Nutrients delivered into the GI tract by a feeding tube via a drip administration set.

HHA — Home health agency.


Inquiries — All oral and written contacts of a claimant that do not request a re-examination or state dissatisfaction with the previous determination.

Interactive Voice Response (IVR) System — A system that enables providers to obtain claim information electronically by pressing various numbers on a touch-tone telephone.

Jejunostomy tube — A tube placed through or into the jejunal portion of the small bowel.

Malabsorption syndrome — Inadequate absorption of nutrients from the intestinal tract. May be associated with or due to a number of diseases.

Medigap insurance — Private insurance policies designed to cover medical expenses, including co-insurance and deductible expenses not fully reimbursed by Medicare.
**Nasogastric tube**—Tube inserted into the nose and passing through the esophagus into the stomach.

**National Provider Identifier (NPI)**—A 10-digit standard unique identifying number for health care providers. NPI replaced UPIN, OSCAR, PIN, and NSC.

**New and material evidence**—Evidence that was not considered when a previous decision was made and that provides facts that may result in a different conclusion. The information must be “new,” that is, not readily available or known to exist at the time of the initial determination.

**NG tube**—Nasogastric tube.

**NSC**—National Supplier Clearinghouse.

**OBRA**—Omnibus Budget Reconciliation Act.

**OIG**—Office of Inspector General.

**Parenteral nutrition**—Nutrition provided by means of direct infusion of nutrients into a patient’s bloodstream.

**PECOS**—The Medicare internet-based Provider, Enrollment, Chain and Ownership System. In lieu of the Medicare paper enrollment application, providers may enroll and update information in the Medicare program via PECOS.

**PEN**—Parenteral/enteral nutrition.

**PPS**—Prospective Payment System.

**Pulmonary aspiration**—Involuntary passage of fluids or nutritional substances into the lungs.

**Pump feeding**—Nutrients delivered into the GI tract via a feeding tube administration set controlled by a volumetric pump.

**Qualified Independent Contractor (QIC)**—A CMS-contracted agency that considers and rules on all DME MAC PEN reconsideration requests. A QIC reconsideration request must be made in writing using CMS form 20033.

**RAC**—Recovery audit contractors. CMS-contracted companies that work on a contingency fee reviewing Medicare claims on a post-payment basis.

**Reconsideration**—An independent determination of claims rendered by a QIC in an appeal made within 180 days of the redetermination decision by the DME MAC. Reconsideration is the second level of appeal following a redetermination.

**Redetermination**—The first level of appeal when a Part B claim has been denied; a second look at the claim and supporting documentation by a different DME MAC employee. Use CMS form 20027 to request a redetermination.
Reflux—Involuntary return of gastric contents into the esophagus.

Remittance advice—A notice of payments and adjustments sent to providers, billers, and suppliers after a claim has been received and processed. The remittance advice explains the reimbursement decisions including the reasons for payments and adjustments of processed claims.

Reopening—Re-evaluation of the claim determination, but not an appeal right. Discretionary action in response to identification of a clerical error or to new and material information not available at the time of the last adjudication.

SNF—Skilled Nursing Facility.

Supplemental nutrition—Nutritional supplements are required by some home care patients for additional protein and calories. Oral nutritional supplements are often given between meals to boost protein-calorie intake or as the mainstay of the daily nutritional plan. Oral nutritional supplements are not covered under Medicare Part B.

Syringe feeding (bolus)—Delivery of nutrients into the feeding tube via a syringe.

Test of permanence—Met if, at the initiation of treatment, the physician and medical record indicate that the condition is not temporary but is of long/indefinite duration, ordinarily at least 3 consecutive months or 90 consecutive days.