

this rule, the term "DMEPOS supplier" refers to all individuals or entities that furnish these items.

For purposes of DMEPOS supplier standards, the term "supplier" is currently defined in § 424.57(a) as an entity or individual, including a physician or part A provider, which sells or rents part B covered items to Medicare beneficiaries, and which meets certain standards. We are retaining this definition for purposes of identifying those entities that must meet Medicare DMEPOS supplier standards in order to obtain a supplier number. Those individuals or entities that do not furnish DMEPOS items but only furnish other types of health care services, such as physicians' services or nurse practitioner services, would not be subject to these standards. Moreover, a supplier number is not necessary before Medicare payment can be made with respect to medical equipment and supplies furnished incident to a physician's service.

For Medicare purposes, DMEPOS suppliers either accept or do not accept assignment. If a DMEPOS supplier accepts assignment, it agrees to accept the Medicare approved amount as payment in full for the covered item. Generally, Medicare pays 80 percent of the approved amount and the beneficiary is responsible for applicable coinsurance and any unmet Medicare deductible amounts. DMEPOS suppliers that have voluntarily agreed to enter into an agreement to accept assignment for all items are referred to as "participating suppliers". Participating DMEPOS suppliers are listed in directories available to Medicare beneficiaries and receive part B payment directly from the Medicare program. Nonparticipating DMEPOS suppliers may accept assignment on a case-by-case basis, and for these claims, receive payment directly from Medicare. If a beneficiary receives a service from a nonparticipating DMEPOS supplier on a nonassigned basis, however, payment is made to the beneficiary who in turn pays the DMEPOS supplier. This rule applies to all DMEPOS suppliers for all items furnished to Medicare beneficiaries regardless of whether they accept Medicare assignment or are Medicare participating suppliers.

#### *Durable Medical Equipment*

Durable medical equipment (DME) is included in the definition of "medical and other health services" as indicated by section 1861(s)(6) of the Act. The term DME is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DME, items furnished in skilled nursing facilities

and hospitals. (Equipment furnished in those facilities is paid for as part of their routine or ancillary costs.) The term is also defined in § 414.202 as meaning "equipment, furnished by a supplier or a home health agency that—

- (1) Can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose;
- (3) Generally is not useful to an individual in the absence of an illness or injury; and
- (4) Is appropriate for use in the home." Examples of DME include such items as blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems, and wheelchairs.

#### *Prosthetic Devices*

Prosthetic devices are also included in the definition of "medical and other health services" under section 1861(s)(8) of the Act. They are defined in this section of the Act as "devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens". Other examples of prosthetic devices include cardiac pacemakers, cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves.

#### *Orthotics and Prosthetics*

Section 1861(s)(9) of the Act provides for the coverage of "leg, arm, back, and neck braces, and artificial legs, arms, and eyes \* \* \*" under the term "medical and other health services". As indicated by section 1834(h)(4)(C) of the Act, these items are often referred to as "orthotics and prosthetics."

#### *Supplies*

Section 1861(s)(5) includes "surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;" as one of the "medical and other health services" that is covered by Medicare. Other items that may be furnished by suppliers would include (among others):

- (1) Prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title, and that are furnished within a certain time period after the date of the transplant procedure as noted at section 1861(s)(2)(J) of the Act.
- (2) Extra-depth shoes with inserts or custom molded shoes with inserts for an

individual with diabetes as listed at section 1861(s)(12) of the Act.

(3) Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies included at section 1861(s)(2)(F) of the Act.

(4) Oral drugs prescribed for use as an anticancer therapeutic agent as noted at section 1861(s)(2)(Q) of the Act.

(5) Self-administered erythropoietin (as described in section 1861(s)(2)(O) of the Act).

#### *B. DMEPOS Supplier Standards*

On June 18, 1992, we published a final rule with comment period (57 FR 27290) that established in § 424.57 certain business standards for entities seeking to qualify as Medicare suppliers of DMEPOS items. Currently, in order to obtain a Medicare billing number, a DMEPOS supplier is required to meet, and to certify that it meets, the following supplier standards:

1. Respond to orders received by filling those orders from its own inventory or inventory from other companies with which it has contracted to fill such orders; or fabricating or fitting items for sale from supplies purchased under a contract.
2. Be responsible for delivery of Medicare covered items to Medicare beneficiaries.
3. Honor all warranties express and implied under applicable State law.
4. Answer any questions or complaints a beneficiary has about the item or use of the item that was sold or rented to him or her, and refer beneficiaries with Medicare questions to the appropriate carrier.
5. Maintain and repair items rented to beneficiaries directly or through a service contract with another company.
6. 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/or sold) from beneficiaries.
7. Disclose consumer information to each beneficiary who rents or purchases items. This information consists of the supplier standards to which it must conform.
8. Comply with the disclosure provisions in § 420.206 (Disclosure of persons having ownership, financial, or control interest).

#### *C. Obtaining a DMEPOS Supplier Number for Identification and Billing Purposes*

Since November 1, 1993, every DMEPOS supplier that submits claims to a Durable Medical Equipment Regional Carrier (DMERC) is required to complete and return the Medicare