

## § 414.404

the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.

*National mail order DMEPOS competitive bidding program* means a program whereby contracts are awarded to suppliers for the furnishing of mail order items across the nation.

*Nationwide competitive bidding area* means a CBA that includes the United States, its Territories, and the District of Columbia.

*Nationwide mail order contract supplier* means a mail order contract supplier that furnishes items in a nationwide competitive bidding area.

*Network* means a group of small suppliers that form a legal entity to provide competitively bid items throughout the entire CBA.

*Noncontract supplier* means a supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.

*Non-mail order item* means any item (for example, diabetic testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.

*Parties to the hearing* means the DMEPOS contract supplier and CMS.

*Physician* has the same meaning as in section 1861(r) of the Act.

*Pivotal bid* means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

*Price inversion* means any situation where the following occurs: One item (HCPCS code) in a grouping of similar items (*e.g.*, walkers, enteral infusion pumps, or power wheelchairs) in a product category includes a feature that another, similar item in the same product category does not have (*e.g.*, wheels, alarm, or Group 2 performance); the average of the 2015 fee schedule amounts (or initial, unadjusted fee schedule amounts for subsequent years for new items) for the code with the feature is higher than the average of

## 42 CFR Ch. IV (10–1–20 Edition)

the 2015 fee schedule amounts for the code without the feature; and, following a competition, the SPA for the code with the feature is lower than the SPA for the code without that feature.

*Product category* means a grouping of related items that are used to treat a similar medical condition.

*Regional competitive bidding area* means a CBA that consists of a region of the United States, its Territories, and the District of Columbia.

*Regional mail order contract supplier* means a mail order contract supplier that furnishes items in a regional competitive bidding area.

*Single payment amount* means the allowed payment for an item furnished under a competitive bidding program.

*Small supplier* means, a supplier that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

*Supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes an item through the mail.

*Total nationwide allowed services* means the total number of services allowed for an item furnished in all states, territories, and the District of Columbia where Medicare beneficiaries reside and can receive covered DMEPOS items and services.

*Treating practitioner* means a physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

*Weighted bid* means the item weight multiplied by the bid price submitted for that item.

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73622, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011; 81 FR 77966, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018]

### § 414.404 Scope and applicability.

(a) *Applicability.* Except as specified in paragraph (b) of this section, this subpart applies to all suppliers that furnish the items defined in § 414.402 to beneficiaries, including providers, physicians, treating practitioners, physical therapists, and occupational therapists that furnish such items under Medicare Part B.

(b) *Exceptions.* (1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

(i) The items furnished are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME, and off-the-shelf (OTS) orthotics.

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

(2) A physical therapist in private practice (as defined in § 410.60(c) of this chapter) or an occupational therapist in private practice (as defined in § 410.59(c) of this chapter) may furnish competitively bid off-the-shelf orthotics without submitting a bid and being awarded a contract under this subpart, provided that the items are furnished only to the therapist's own patients as part of the physical or occupational therapy service.

(3) Payment for items furnished in accordance with paragraphs (b)(1) and (b)(2) of this section will be paid in accordance with § 414.408(a).

[72 FR 18084, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70314, Nov. 10, 2011]

#### § 414.406 Implementation of programs.

(a) *Implementation contractor.* CMS designates one or more implementation contractors for the purpose of implementing this subpart.

(b) *Competitive bidding areas.* CMS designates through program instructions or by other means, such as the request for bids, each CBA in which a competitive bidding program may be implemented under this subpart.

(c) *Revisions to competitive bidding areas.* CMS may revise the CBAs des-

ignated under paragraph (b) of this section.

(d) *Competitively bid items.* CMS designates the items that are included in a competitive bidding program through program instructions or by other means

(e) *Claims processing.* The Durable Medical Equipment Medicare Administrative Contractor designated to process DMEPOS claims for a particular geographic region also processes claims for items furnished under a competitive bidding program in the same geographic region.

[71 FR 48409, Aug. 18, 2006, as amended at 72 FR 18085, Apr. 10, 2007]

#### § 414.408 Payment rules.

(a) *Payment basis.* (1) The payment basis for an item furnished under a competitive bidding program is 80 percent of the single payment amount calculated for the item under § 414.416 for the CBA in which the beneficiary maintains a permanent residence.

(2) If an item that is included in a competitive bidding program is furnished to a beneficiary who does not maintain a permanent residence in a CBA, the payment basis for the item is 80 percent of the lesser of the actual charge for the item, or the applicable fee schedule amount for the item, as determined under subpart C or subpart D.

(b) *No changes to the single payment amount.* The single payment amount calculated for each item under each competitive bidding program is paid for the duration of the competitive bidding program and will not be adjusted by any update factor.

(c) *Payment on an assignment-related basis.* Payment for an item furnished under this subpart is made on an assignment-related basis.

(d) *Applicability of advanced beneficiary notice.* Implementation of a program in accordance with this subpart does not preclude the use of an advanced beneficiary notice.

(e) *Requirement to obtain competitively bid items from a contract supplier.* (1) *General rule.* Except as provided in paragraph (e)(2) of this section, all items that are included in a competitive bidding program must be furnished