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services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies.* Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent) of the national median payment as determined by CMS that would have been made under the prospective payment rates established in §413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits.* Updated data are incorporated into the payment limits when the prospective payment rates established at §413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the limits are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49202, Aug. 12, 2010]

§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Prior to January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies. Effective January 1, 2011, payment for EPO used at home by a home dialysis patient is made only to a Medicare-approved ESRD facility in accordance with the per treatment payment as defined in § 413.230.

(b) After January 1, 2011, a home and self training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230

[75 FR 49202, Aug. 12, 2010]

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Subpart F—Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

§ 414.400 Purpose and basis.

This subpart implements competitive bidding programs for certain DMEPOS items as required by sections 1847(a) and (b) of the Act.

[72 FR 18084, Apr. 10, 2007]

§ 414.402 Definitions.

For purposes of this subpart, the following definitions apply:

Affected party means a contract supplier that has been notified that their DMEPOS CBP contract will be terminated for a breach of contract.

Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

Bidding entity means the entity whose legal business name is identified in the “Form A: Business Organization Information” section of the bid.

Breach of contract means any deviation from contract requirements, including a failure to comply with a governmental agency or licensing organization requirements, constitutes a breach of contract.

Competitive bidding area (CBA) means an area established by the Secretary under this subpart.

Competitive bidding program means a program established under this subpart within a designated CBA.

Composite bid means the bid submitted by the supplier for the lead item in the product category.

Contract supplier means an entity that is awarded a contract by CMS to furnish items under a competitive bidding program.

Corrective action plan (CAP) means a contract supplier's written document with supporting information that describes the actions the contract supplier will take within a specified timeframe to remedy a breach of contract.

Covered document means a financial, tax, or other document required to be submitted by a bidder as part of an

original bid submission under a competitive acquisition program in order to meet the required financial standards.

Covered document review date means the later of—

(1) The date that is 30 days before the final date for the closing of the bid window; or

(2) The date that is 30 days after the opening of the bid window.

DMEPOS stands for durable medical equipment, prosthetics, orthotics, and supplies.

Grandfathered item means all rented items within a product category for which payment was made prior to the implementation of a competitive bidding program to a grandfathered supplier that chooses to continue to furnish the items in accordance with § 414.408(j) of this subpart and that fall within the following payment categories for competitive bidding:

(1) An inexpensive or routinely purchased item described in § 414.220 of this part.

(2) An item requiring frequent and substantial servicing, as described in § 414.222 of this part.

(3) Oxygen and oxygen equipment described in § 414.226 of this part.

(4) Other DME described in § 414.229 of this part.

Grandfathered supplier means a non-contract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

Hearing officer means an individual, who was not involved with the CBIC recommendation to take action for a breach of a DMEPOS Competitive Bidding Program contract, who is designated by CMS to review and make an unbiased and independent recommendation when there is an appeal of CMS's initial determination to take action for a breach of a DMEPOS Competitive Bidding Program contract.

Hospital has the same meaning as in section 1861(e) of the Act.

Item means a product included in a competitive bidding program that is identified by a HCPCS code, which may be specified for competitive bidding (for example, a product when it is furnished through mail order), or a combination of codes and/or modifiers, and includes the services directly related

to the furnishing of that product to the beneficiary. Items that may be included in a competitive bidding program are:

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

(i) Inexpensive or routinely purchased items, as specified in § 414.220(a).

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222(a).

(iii) Oxygen and oxygen equipment, as specified in § 414.226(c)(1).

(iv) Other DME (capped rental items), as specified in § 414.229.

(2) Supplies necessary for the effective use of DME other than inhalation and infusion drugs.

(3) Enteral nutrients, equipment, and supplies.

(4) Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.

Item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category.

Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

Mail order contract supplier is a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a competitive bidding area.

Mail order item means any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery.

Metropolitan Statistical Area (MSA) has the same meaning as that given by the Office of Management and Budget.

Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of

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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

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.