

accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

(1) *Support services.* The amount of payment for home dialysis support 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]

### **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.

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*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 con-

tinue 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 with or without 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 as follows:

(1) DME other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.402, group 3 complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such 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.

(5) Lymphedema compression treatment items.

*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 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

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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; 86 FR 42422, Aug. 4, 2021; 88 FR 77875, Nov. 13, 2023]

### § 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 designated 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 by a contract supplier for that program.

(2) *Exceptions.* (i) A grandfathered supplier may furnish a grandfathered item to a beneficiary in accordance with paragraph (j) of this section.

(ii) Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy. The provisions of this paragraph do not supersede Medicare secondary payer statutory and regulatory provisions, including the Medicare secondary payment rules located in §§411.32 and 411.33 of this subchapter, and payment will be calculated in accordance with those rules.

(iii) If a beneficiary is outside of the CBA in which he or she maintains a permanent residence, he or she may obtain an item from a—

(A) Contract supplier, if the beneficiary obtains the item in another CBA and the item is included in the

competitive bidding program for that CBA; or

(B) Supplier with a valid Medicare billing number, if the beneficiary obtains the item in an area that is not a CBA, or if the beneficiary obtains the item in another CBA but the item is not included in the competitive bidding program for that CBA.

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with §414.404(b) of this subpart.

(3) Unless paragraph (e)(2) of this section applies:

(i) Medicare will not make payment for an item furnished in violation of paragraph (e)(1) of this section, and

(ii) A beneficiary has no financial liability to a noncontract supplier that furnishes an item included in the competitive bidding program for a CBA in violation of paragraph (e)(1) of this section, unless the beneficiary has signed an advanced beneficiary notice.

(4) CMS separately designates the Medicare billing number of all noncontract suppliers to monitor compliance with paragraphs (e)(1) and (e)(2) of this section.

(f) *Purchased equipment.* (1) The single payment amounts for new purchased durable medical equipment, including power wheelchairs that are purchased when the equipment is initially furnished and enteral nutrition equipment are calculated based on the bids submitted and accepted for these items. For contracts entered into beginning on or after January 1, 2011, payment on a lump sum purchase basis is only available for power wheelchairs classified as complex rehabilitative power wheelchairs.

(2) Payment for used purchased durable medical equipment and enteral nutrition equipment is made in an amount equal to 75 percent of the single payment amounts calculated for new purchased equipment under paragraph (f)(1) of this section.

(g) *Purchased supplies and orthotics.* The single payment amounts for the following purchased items are calculated based on the bids submitted and accepted for the following items:

(1) Supplies used in conjunction with durable medical equipment.

(2) Enteral nutrients.

(3) Enteral nutrition supplies.

(4) OTS orthotics.

(5) Lymphedema compression treatment items.

(h) *Rented equipment*—(1) *Capped rental DME*. Subject to the provisions of paragraph (h)(2) of this section, payment for capped rental durable medical equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(2) For contracts entered into beginning on or after January 1, 2011, the monthly fee schedule amount for rental of power wheelchairs equals 15 percent of the single payment amounts calculated for new durable medical equipment under paragraph (f)(1) of this section for each of the first 3 months, and 6 percent of the single payment amounts calculated for these items for each of the remaining months 4 through 13.

(3) *Additional payment to certain contract suppliers for capped rental DME*. (i) Except as specified in paragraph (h)(3)(ii) of this section, Medicare makes 13 monthly payments to a contract supplier that furnishes capped rental durable medical equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section. Payment is made using the methodology described in paragraph (h)(1) of this section. The contract supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made in accordance with this paragraph.

(ii) Medicare does not make payment to a contract supplier under paragraph (h)(3)(i) of this section if the contract supplier furnishes capped rental durable medical equipment to a beneficiary who previously rented the equipment from another contract supplier.

(4) *Maintenance and servicing of rented DME*. Separate maintenance and servicing payments are not made for any rented durable medical equipment.

(5) *Payment for rented enteral nutrition equipment*. Payment for rented enteral nutrition equipment is made in an amount equal to 10 percent of the single payment amounts calculated for new enteral nutrition equipment under paragraph (f)(1) of this section for each of the first 3 months, and 7.5 percent of the single payment amount calculated for these items under paragraph (f)(1) of this section for each of the remaining months 4 through 15. The contract supplier to which payment is made in month 15 for furnishing enteral nutrition equipment on a rental basis must continue to furnish, maintain and service the equipment until a determination is made by the beneficiary's physician or treating practitioner that the equipment is no longer medically necessary.

(6) *Maintenance and servicing of rented enteral nutrition equipment*. Payment for the maintenance and servicing of rented enteral nutrition equipment beginning 6 months after 15 months of rental payments is made in an amount equal to 5 percent of the single payment amounts calculated for these items under paragraph (f)(1) of this section.

(7) *Payment for inexpensive or routinely purchased durable medical equipment*. Payment for inexpensive or routinely purchased durable medical equipment furnished on a rental basis is made in an amount equal to 10 percent of the single payment amount calculated for new purchased equipment.

(8) *Payment amounts for rented DME requiring frequent and substantial servicing*—(i) *General rule*. Except as provided in paragraph (h)(7)(ii) of this section, the single payment amounts for rented durable medical equipment requiring frequent and substantial servicing are calculated based on the rental bids submitted and accepted for the furnishing of these items on a monthly basis.

(ii) *Exception*. The single payment amounts for continuous passive motion exercise devices are calculated based on the bids submitted and accepted for

the furnishing of these items on a daily basis.

(i) *Monthly payment amounts for oxygen and oxygen equipment*—(1) *Basic payment amount.* Subject to the provisions of paragraph (i)(2) of this section, the single payment amounts for oxygen and oxygen equipment are calculated based on the bids submitted and accepted for the furnishing on a monthly basis of each of the five classes of oxygen and oxygen equipment described in §414.226(c)(1).

(2) *Additional payment to certain contract suppliers.* (i) Except as specified in paragraph (i)(2)(iii) of this section, Medicare makes monthly payments to a contract supplier that furnishes oxygen equipment to a beneficiary who would otherwise be entitled to obtain the item from a grandfathered supplier under paragraph (j) of this section as follows:

(A) If Medicare made 26 or less monthly payments to the former supplier, Medicare makes a monthly payment to the contract supplier for up to the number of months equal to the difference between 36 and the number of months for which payment was made to the former supplier.

(B) If Medicare made 27 or more monthly payments to the former supplier, Medicare makes 10 monthly payments to the contract supplier.

(ii) Payment is made using the methodology described in paragraph (i)(1) of this section. On the first day after the month in which the final rental payment is made under paragraph (i)(2)(i) of this section, the contract supplier must transfer title of the oxygen equipment to the beneficiary.

(iii) Medicare does not make payment to a contract supplier under paragraph (i)(2) of this section if the contract supplier furnishes oxygen equipment to a beneficiary who previously rented the equipment from another contract supplier.

(j) *Special rules for certain rented durable medical equipment and oxygen and oxygen equipment*—(1) *Supplier election.* (i) A supplier that is furnishing durable medical equipment or is furnishing oxygen or oxygen equipment on a rental basis to a beneficiary prior to the implementation of a competitive bidding program in the CBA where the bene-

ficiary maintains a permanent residence may elect to continue furnishing the item as a grandfathered supplier.

(ii) A supplier that elects to be a grandfathered supplier must continue to furnish the grandfathered items to all beneficiaries who elect to continue receiving the grandfathered items from that supplier for the remainder of the rental period for that item.

(2) *Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA.* Payment for grandfathered items furnished during the first competitive bidding program implemented in a CBA is made as follows:

(i) For inexpensive and routinely purchased items described in §414.220(a), payment is made in the amount determined under §414.220(b).

(ii) For other durable medical equipment or capped rental items described in §414.229, payment is made in the amount determined under §414.229(b).

(iii) For items requiring frequent and substantial servicing described in §414.222, payment is made in accordance with paragraph (a)(1) of this section.

(iv) For oxygen and oxygen equipment described in §414.226(c)(1), payment is made in accordance with paragraph (a)(1) of this section.

(3) *Payment for grandfathered items furnished during all subsequent competitive bidding programs in a CBA.* Beginning with the second competitive bidding program implemented in a CBA, payment is made for grandfathered items in accordance with paragraph (a)(1) of this section.

(4) *Choice of suppliers.* (i) Beneficiaries who are renting an item that meets the definition of a grandfathered item in §414.402 of this subpart may elect to obtain the item from a grandfathered supplier.

(ii) A beneficiary who is otherwise entitled to obtain a grandfathered item from a grandfathered supplier under paragraph (j) of this section may elect to obtain the same item from a contract supplier at any time after a competitive bidding program is implemented.

(iii) If a beneficiary elects to obtain the same item from a contract supplier, payment is made for the item accordance with paragraph (a)(1) of this section.

(5) *Notification of beneficiaries and CMS by suppliers that choose to become grandfathered suppliers.* (i) *Notification of beneficiaries by suppliers.* (A) *Requirements of notification.* A noncontract supplier that elects to become a grandfathered supplier must provide a 30-day written notification to each Medicare beneficiary that resides in a competitive bidding area and is currently renting a competitively bid item from that supplier. The 30-day notification to the beneficiary must meet the following requirements:

(1) Be sent by the supplier to the beneficiary at least 30 business days before the start date of the implementation of the competitive bidding program for the CBA in which the beneficiary resides.

(2) Identify the grandfathered items that the supplier is willing to continue to rent to the beneficiary.

(3) Be in writing (for example, by letter or postcard) and the supplier must maintain proof of delivery.

(4) State that the supplier is willing to continue to furnish certain rented Durable Medical Equipment (DME), oxygen and oxygen equipment, and supplies that the supplier is currently furnishing to the beneficiary (that is, before the start of the competitive bidding program) and is willing to continue to provide these items to the beneficiary for the remaining rental months.

(5) State that the beneficiary has the choice to continue to receive a grandfathered item(s) from the grandfathered supplier or may elect to receive the item(s) from a contract supplier after the end of the last month for which a rental payment is made to the noncontract supplier.

(6) Provide the supplier's telephone number and instruct the beneficiary to call the supplier with any questions and to notify the supplier of his or her decision to use or not use the supplier as a grandfathered supplier.

(7) State that the beneficiary can obtain information about the competitive bidding program by calling 1-800-

MEDICARE or on the Internet at <http://www.Medicare.gov>.

(B) *Record of beneficiary's choice.* The supplier should obtain an election from the beneficiary regarding whether to use or not use the supplier as a grandfathered supplier. The supplier must maintain a record of its attempts to communicate with the beneficiary to obtain the beneficiary's election regarding grandfathering. When the supplier obtains such an election, the supplier must maintain a record of the beneficiary decision including the date the choice was made, and how the beneficiary communicated his or her choice to the supplier.

(C) *Notification.* If the beneficiary chooses not to continue to receive a grandfathered item(s) from their current supplier, the supplier must provide the beneficiary with 2 more notices in addition to the 30-day notice prior to the supplier picking up its equipment.

(1) *10-day notification:* Ten business days prior to picking up the item, the supplier should have direct contact (for example, a phone call) with the beneficiary or the beneficiary's caregiver and receive acknowledgement that the beneficiary understands their equipment will be picked up. This should occur on the first anniversary date after the start of the CBP or on another date agreed to by the beneficiary or the beneficiary's caregiver. The beneficiary's anniversary date occurs every month and is the date of the month on which the item was first delivered to the beneficiary by the current supplier. When a date other than the anniversary date is chosen by the beneficiary or the beneficiary's caregiver, the noncontract supplier will still receive payment up to the anniversary date after the start of the CBP, and the new contract supplier may not bill for any period of time before the anniversary date.

(2) *2-day notification:* Two business days prior to picking up the item the supplier should contact the beneficiary or the beneficiary's caregiver by phone to notify the beneficiary of the date the supplier will pick up the item. This date should not be before the beneficiary's first anniversary date that occurs after the start of the competitive



bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(D) *Pickup procedures.* (1) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(2) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgement from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(3) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are suitable to the beneficiary.

(4) The contract supplier may not submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP, and the contract supplier may not begin billing until the first anniversary date that occurs after the beginning of the CBP.

(5) The noncontract supplier must submit a claim to be paid up to the first anniversary date that occurs after the beginning of the CBP. Therefore, they should not pick up the equipment before that date unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(ii) *Notification to CMS by suppliers.* A noncontract supplier that elects to become a grandfathered supplier must provide a written notification to CMS of this decision. This notification must meet the following requirements:

(A) State that the supplier agrees to continue to furnish certain rented DME, oxygen and oxygen equipment that it is currently furnishing to beneficiaries (that is, before the start of the competitive bidding program) in a CBA

and will continue to provide these items to these beneficiaries for the remaining months of the rental period.

(B) Include the following information:

(1) Name and address of the supplier.

(2) The 6-digit NSC number of the supplier.

(3) Product category(s) by CBA for which the supplier is willing to be a grandfathered supplier.

(C) State that the supplier agrees to meet all the terms and conditions pertaining to grandfathered suppliers.

(D) Be provided by the supplier to CMS in writing at least 30 business days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding Program.

(6) *Suppliers that choose not to become grandfathered suppliers.* (i) *Requirement for non-grandfathered supplier.* A noncontract supplier that elects not to become a grandfathered supplier is required to pick up the item it is currently renting to the beneficiary from the beneficiary's home after proper notification.

(ii) *Notification.* Proper notification includes a 30-day, a 10-day, and a 2-day notice of the supplier's decision not to become a grandfathered supplier to its Medicare beneficiaries who are currently renting certain DME competitively bid item(s) and who reside in a CBA.

(iii) *Requirements of notification.* These notifications must meet all of the requirements listed in paragraph (j)(5)(i) of this section for the 30-day, 10-day and 2-day notices that must be sent by suppliers who decide to be grandfathered suppliers, with the following exceptions for the 30-day notice.

(A) State that, for those items for which the supplier has decided not to be a grandfathered supplier, the supplier will only continue to rent these competitively bid item(s) to its beneficiaries up to the first anniversary date that occurs after the start of the Medicare DMEPOS Competitive Bidding Program.

(B) State that the beneficiary must select a contract supplier for Medicare to continue to pay for these items.

(C) Refer the beneficiary to the contract supplier locator tool on and to 1-800-MEDICARE to obtain information

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about the availability of contract suppliers for the beneficiary's area.

(iv) *Pickup procedures.* (A) The pickup of the noncontract supplier's equipment and the delivery of the new contract supplier's equipment should occur on the same date, that is, the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program unless an alternative arrangement has been made with the beneficiary and the new contract supplier.

(B) Under no circumstance should a supplier pick up a rented item prior to the supplier's receiving acknowledgment from the beneficiary that the beneficiary is aware of the date on which the supplier is picking up the item and the beneficiary has made arrangements to have the item replaced on that date by a contract supplier.

(C) When a beneficiary chooses to switch to a new contract supplier, the current noncontract supplier and the new contract supplier must make arrangements that are agreeable to the beneficiary.

(D) The contract supplier cannot submit a claim with a date of delivery for the new equipment that is prior to the first anniversary date that occurs after the beginning of the CBP.

(7) *Payment for accessories and supplies for grandfathered items.* Accessories and supplies that are used in conjunction with and are necessary for the effective use of a grandfathered item may be furnished by the same grandfathered supplier that furnishes the grandfathered item. Payment is made in accordance with paragraph (a)(1) of this section.

(k) *Payment for maintenance, servicing and replacement of beneficiary-owned items.* (1) Payment is made for the maintenance and servicing of beneficiary-owned items, provided the maintenance and servicing is performed by a contract supplier or a noncontract supplier having a valid Medicare billing number, as follows:

(i) Payment for labor is made in accordance with § 414.210(e)(1) of subpart D.

(ii) Payment for parts that are not items (as defined in § 414.402) is made in accordance with § 414.210(e)(1) of subpart D.

(iii) Payment for parts that are items (as defined in § 414.402) is made in accordance with paragraph (a)(1) of this section.

(2) Additional payments are made in accordance with § 414.210(e)(2), (e)(3) and (e)(5) of this part for the maintenance and servicing of oxygen equipment if performed by a contract supplier or a noncontract supplier having a valid Medicare billing number.

(3) Beneficiaries must obtain a replacement of a beneficiary-owned item, other than parts needed for the repair of beneficiary-owned equipment from a contract supplier. Payment is made for the replacement item in accordance with paragraph (a)(1) of this section.

(l) *Exceptions for certain items and services paid in accordance with special payment rules.* The payment rules in paragraphs (f) thru (h), (j)(2), (j)(3), and (j)(7), and (k) of this section do not apply to items and services paid in accordance with the special payment rules at § 414.409.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 74 FR 62009, Nov. 25, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 88 FR 77875, Nov. 13, 2023]

### § 414.409 Special payment rules.

(a) *Payment on a bundled, continuous rental basis.* In no more than 12 CBAs, in conjunction with competitions that begin after January 1, 2015, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and continuous positive airway pressure (CPAP) devices. The CBAs and competitions where these payment rules apply are announced in advance of each competition, with the payment rules in this section used in lieu of the payment rules at § 414.408(f) thru (h), (j)(2), (j)(3), and (j)(7), and (k). The single payment amounts are established based on bids submitted and accepted for furnishing rented standard power wheelchairs and CPAP devices on a monthly basis for each month of medical need during the contract period. The single payment amount for the monthly rental of the DME includes payment for the rented equipment, maintenance and servicing of the rented equipment, and replacement of supplies and accessories necessary for

the effective use of the rented equipment. Separate payment for replacement of equipment, repair or maintenance and servicing of equipment, or for replacement of accessories and supplies necessary for the effective use of equipment is not allowed under any circumstance.

(b) *Payment for grandfathered DME items paid on a bundled, continuous rental basis.* Payment to a supplier that elects to be a grandfathered supplier of DME furnished in CBPs where these special payment rules apply is made in accordance with §414.408(a)(1).

(c) *Supplier transitions for DME paid on a bundled, continuous rental basis.* Changes from a non-contract supplier to a contract supplier at the beginning of a CBP where payment is made on a bundled, continuous monthly rental basis results in the contract supplier taking on responsibility for meeting all of the monthly needs for furnishing the covered DME. In the event that a beneficiary relocates from a CBA where these special payment rules apply to an area where rental cap rules apply, a new period of continuous use begins for the capped rental item as long as the item is determined to be medically necessary.

(d) *Responsibility for repair and maintenance and servicing of power wheelchairs.* In no more than 12 CBAs where payment for power wheelchairs is made on a capped rental basis, for power wheelchairs furnished in conjunction with competitions that begin after January 1, 2015, contract suppliers that furnish power wheelchairs under contracts awarded based on these competitions shall continue to repair power wheelchairs they furnish following transfer of title to the equipment to the beneficiary. The responsibility of the contract supplier to repair, maintain and service beneficiary-owned power wheelchairs does not apply to power wheelchairs that the contract supplier did not furnish to the beneficiary. For power wheelchairs that the contract supplier furnishes during the contract period, the responsibility of the contract supplier to repair, maintain and service the power wheelchair once it is owned by the beneficiary continues until the reasonable useful lifetime of the equipment expires, coverage for the

power wheelchair ends, or the beneficiary relocates outside the CBA where the item was furnished. The contract supplier may not charge the beneficiary or the program for any necessary repairs or maintenance and servicing of a beneficiary-owned power wheelchair it furnished during the contract period.

[79 FR 66264, Nov. 6, 2014]

#### **§414.410 Phased-in implementation of competitive bidding programs.**

(a) *Phase-in of competitive bidding programs.* CMS phases in competitive bidding programs so that competition under the programs occurs—

(1) In CY 2009, in Cincinnati—Middletown (Ohio, Kentucky and Indiana), Cleveland—Elyria—Mentor (Ohio), Charlotte—Gastonia—Concord (North Carolina and South Carolina), Dallas—Fort Worth—Arlington (Texas), Kansas City (Missouri and Kansas), Miami—Fort Lauderdale—Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside—San Bernardino—Ontario (California).

(2) In CY 2011, in an additional 91 MSAs (the additional 70 MSAs selected by CMS as of June 1, 2008, and the next 21 largest MSAs by total population based on 2009 population estimates, and not already phased in as of June 1, 2008). CMS may subdivide any of the 91 MSAs with a population of greater than 8,000,000 into separate CBAs, thereby resulting in more than 91 CBAs.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

(4) For competitions (other than for national mail order items and services) after CY 2011 and prior to CY 2015, the following areas are excluded:

(i) Rural areas.

(ii) MSAs not selected under paragraphs (a)(1) or (a)(2) of this section with a population of less than 250,000.

(iii) An area with low population density within an MSA not selected under paragraphs (a)(1) or (a)(2) of this section.

(b) *Selection of MSAs for CY 2007 and CY 2009.* CMS selects the MSAs for purposes of designating CBAs in CY 2007 and CY 2009 by considering the following variables:

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- (1) The total population of an MSA.
- (2) The Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA.
- (3) The total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA.
- (4) An MSA's geographic location.

(c) *Exclusions from a CBA.* CMS may exclude from a CBA a rural area (as defined in § 412.64(b)(1)(ii)(C) of this subchapter), or an area with low population density based on one or more of the following factors—

(1) Low utilization of DMEPOS items by Medicare beneficiaries receiving fee-for-service benefits relative to similar geographic areas;

(2) Low number of DMEPOS suppliers relative to similar geographic areas; or

(3) Low number of Medicare fee-for-service beneficiaries relative to similar geographic areas.

(d) *Selection of additional CBAs after CY 2009.* (1) Beginning after CY 2009, CMS designates through program instructions or by other means additional CBAs based on CMS' determination that the implementation of a competitive bidding program in a particular area would be likely to result in significant savings to the Medicare program.

(2) Beginning after CY 2009, CMS may designate through program instructions or by other means a nationwide CBA or one or more regional CBAs for purposes of implementing competitive bidding programs for items that are furnished through the mail by nationwide or regional mail order contract suppliers.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011]

## § 414.411 Special rule in case of competitions for diabetic testing strips conducted on or after January 1, 2011.

(a) *National mail order competitions.* A supplier must demonstrate that their bid submitted as part of a national mail order competition for diabetic testing strips covers the furnishing of a sufficient number of different types of diabetic testing strip products that, in the aggregate, and taking into account

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volume for the different products, includes at least 50 percent of all the different types of products on the market. A type of diabetic testing strip means a specific brand and model of testing strips.

(b) *Other competitions.* CMS may apply this special rule to non-mail order or local competitions for diabetic testing strips.

[75 FR 73623, Nov. 29, 2010]

## § 414.412 Submission of bids under a competitive bidding program.

(a) *Requirement to submit a bid.* Except as provided under § 414.404(b), in order for a supplier to receive payment for items furnished to beneficiaries under a competitive bidding program, the supplier must submit a bid to furnish those items and be awarded a contract under this subpart.

(b) *Grouping of items into product categories.* (1) Composite bids, as defined in § 414.402, are submitted for lead items, as defined in § 414.402.

(2) The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under—

(i) Subpart C of this part, without the application of § 414.210(g);

(ii) Subpart D of this part, without the application of § 414.105; or

(iii) Subpart Q of this part, without the application of § 414.1690.

(3) The bids submitted for standard power wheelchairs paid in accordance with the special payment rules at § 414.409(a) cannot exceed the average monthly payment for the bundle of items and services that would otherwise apply to the item under subpart D of this part.

(4) The bids submitted for continuous positive airway pressure (CPAP) devices paid in accordance with the special payment rules at § 414.409(a) cannot exceed the 1993 fee schedule amounts for these items, increased by the covered item update factors provided for these items in section 1834(a)(14) of the Act.

(5) Suppliers shall take into consideration the special payment rules at § 414.409(d) when submitting bids for furnishing power wheelchairs under competitions where these rules apply.

(c) *Furnishing of items.* A bid must include all costs related to furnishing all items in the product category, including all services directly related to the furnishing of the items.

(d) *Commonly-owned or controlled suppliers.* (1) For purposes of this paragraph—

(i) An ownership interest is the possession of equity in the capital, stock or profits of another supplier;

(ii) A controlling interest exists if one or more of owners of a supplier is an officer, director or partner in another supplier; and

(iii) Two or more suppliers are commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s).

(2) A supplier must disclose in its bid each supplier in which it has an ownership or controlling interest and each supplier which has an ownership or controlling interest in it.

(3) Commonly-owned or controlled suppliers must submit a single bid to furnish a product category in a CBA. Each commonly-owned or controlled supplier that is located in the CBA for which the bid is being submitted must be included in the bid. The bid must also include any commonly-owned or controlled supplier that is located outside of the CBA but would furnish the product category to the beneficiaries who maintain a permanent residence in the CBA.

(e) *Mail order suppliers.* (1) Suppliers that furnish items through the mail must submit a bid to furnish these items in a CBA in which a mail order competitive bidding program that includes the items is implemented.

(2) Suppliers that submit one or more bids under (e)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(f) *Applicability of the mail order competitive bidding program.* Suppliers that do not furnish items through the mail are not required to participate in a nationwide or regional mail order competitive bidding program that includes the same items. Suppliers may continue to furnish these items in—

(1) A CBA, if the supplier is awarded a contract under this subpart; or

(2) An area not designated as a CBA.

(g) *Requiring bid surety bonds for bidding entities—*(1) *Bidding requirements.* For competitions beginning on or after January 1, 2017, and no later than January 1, 2019, a bidding entity may not submit a bid(s) for a CBA unless it obtains a bid surety bond for the CBA from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provides proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission.

(2) *Bid surety bond requirements.* (i) The bid surety bond issued must include at a minimum:

(A) The name of the bidding entity as the principal/obligor;

(B) The name and National Association of Insurance Commissioners number of the authorized surety;

(C) CMS as the named obligee;

(D) The conditions of the bond as specified in paragraph (g)(3) of this section;

(E) The CBA covered by the bond;

(F) The bond number;

(G) The date of issuance; and

(H) The bid bond value of \$50,000.00.

(ii) The bid surety bond must be maintained until it is either collected upon due to forfeiture or the liability is returned for not meeting bid forfeiture conditions.

(3) *Forfeiture of bid surety bond.* (i) When a bidding entity is offered a contract for a CBA/product category ("competition") and its composite bid for the competition is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts within the competition and the bidding entity does not accept the contract offer, its bid surety bond submitted for that CBA will be forfeited and CMS will collect on the bond via Electronic Funds Transfer (EFT) from the respective bonding company. As one bid surety bond is required for each CBA in which the bidding entity is submitting a bid, the failure to accept a contract offer for any product category within the CBA when the entity's bid is at or below the median composite bid rate will result in forfeiture of the bid surety bond for that CBA.

(ii) Where the bid(s) does not meet the specified forfeiture conditions in

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paragraph (h)(3)(i) of this section, the bid surety bond liability will be returned within 90 days of the public announcement of contract suppliers for the CBA. CMS will notify the bidding entity that it did not meet the specified forfeiture requirements and the bid surety bond will not be collected by CMS.

(4) *Penalties.* (i) A bidding entity that has been determined to have falsified its bid surety bond may be prohibited from participation in the DMEPOS Competitive Bidding Program for the current round of the Competitive Bidding Program in which it submitted a bid and also from participating in the next round of the Competitive Bidding Program. Offending suppliers will also be referred to the Office of Inspector General and Department of Justice for further investigation.

(ii) A bidding entity, whose composite bid is at or below the median composite bid rate, that—

(A) Accepts a contract award; and

(B) Is found to be in breach of contract for nonperformance of the contract to avoid forfeiture of the bid surety bond will have its contract terminated and will be precluded from participation in the next round of the DMEPOS Competitive Bidding Program.

[72 FR 18085, Apr. 10, 2007, as amended at 79 FR 66264, Nov. 6, 2014; 81 FR 77966, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018; 88 FR 77876, Nov. 13, 2023]

#### § 414.414 Conditions for awarding contracts.

(a) *General rule.* The rules set forth in this section govern the evaluation and selection of suppliers for contract award purposes under a competitive bidding program.

(b) *Basic supplier eligibility.* (1) Each supplier must meet the enrollment standards specified in § 424.57(c) of this chapter.

(2) Each supplier must disclose information about any prior or current legal actions, sanctions, revocations from the Medicare program, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions or debarments imposed against it, or against any members of the board of directors, chief corporate

officers, high-level employees, affiliated companies, or subcontractors, by any Federal, State, or local agency. The supplier must certify in its bid that this information is completed and accurate.

(3) Each supplier must have all State and local licenses required to perform the services identified in the request for bids. CMS may not award a contract to any entity in a CBA unless the entity meets applicable State licensure requirements.

(4) Each supplier must submit a bona fide bid that complies with all the terms and conditions contained in the request for bids.

(5) Each network must meet the requirements specified in § 414.418.

(c) *Quality standards and accreditation.* Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of § 424.58 of this subchapter, unless a grace period is specified by CMS.

(d) *Financial standards*—(1) *General rule.* Each supplier must submit along with its bid the applicable covered documents (as defined in § 414.402) specified in the request for bids.

(2) *Process for reviewing covered documents*—(i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

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

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

(ii) *CMS feedback to a supplier with missing covered documents.* (A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

(e) *Evaluation of bids.* CMS evaluates composite bids submitted for a lead item within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the lead item in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category;

(3) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(4) Calculating the pivotal bid for the product category; and

(5) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

(f) *Expected savings.* A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D.

(g) *Special rules for small suppliers—(1) Target for small supplier participation.* CMS ensures that small suppliers have the opportunity to participate in a competitive bidding program by taking the following steps:

(i) Setting a target number for small supplier participation by multiplying 30 percent by the number of suppliers that meet the requirements in paragraphs (b) through (d) of this section and whose composite bids are equal to or lower than the pivotal bid calculated for the product category;

(ii) Identifying the number of qualified small suppliers whose composite

bids are at or below the pivotal bid for the product category;

(iii) Selecting additional small suppliers whose composite bids are above the pivotal bid for the product category in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid, until the number calculated in paragraph (g)(1)(i) of this section is reached or there are no more composite bids submitted by small suppliers for the product category.

(2) The bids by small suppliers that are selected under paragraph (g)(1)(iii) of this section are not used to calculate the single payment amounts for any items under §414.416 of this subpart.

(h) *Sufficient number of suppliers.* (1) Except as provided in paragraph (h)(3) of this section, CMS will award at least five contracts, if there are five suppliers satisfying the requirements in paragraphs (b) through (f) of this section; or

(2) CMS will award at least two contracts, if there are less than five suppliers meeting these requirements and the suppliers satisfying these requirements have sufficient capacity to satisfy beneficiary demand for the product category calculated under paragraph (e)(1) of this section.

(3) The provisions of paragraph (h)(1) of this section do not apply to regional or nationwide mail order CBAs under §414.410(d)(2) of this subpart.

(i) *Selection of new suppliers after bidding.* (1) Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program. CMS selects additional contract suppliers by—

(i) Referring to the arrayed list of suppliers that submitted bids for the product category included in the competitive bidding program for which beneficiary demand is not being met; and

(ii) Beginning with the supplier whose composite bid is the first composite bid above the pivotal bid for that product category, determining if that supplier is willing to become a contract supplier under the same terms

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and conditions that apply to other contract suppliers in the CBA.

(2) Before CMS awards additional contracts under paragraph (i)(1) of this section, a supplier must submit updated information demonstrating that the supplier meets the requirements under paragraphs (b) through (d) of this section.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2880, Jan. 16, 2009; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 81 FR 77967, Nov. 4, 2016; 83 FR 21925, May 11, 2018; 83 FR 57072, Nov. 14, 2018]

### § 414.416 Determination of competitive bidding payment amounts.

(a) *General rule.* CMS establishes a single payment amount for each item furnished under a competitive bidding program.

(b) *Methodology for setting payment amount.* (1) The single payment amount for a lead item furnished under a competitive bidding program is equal to the maximum bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category.

(2) The single payment amount for a lead item must be less than or equal to the amount that would otherwise be paid for the same item under subpart C or subpart D of this part.

(3) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, the United States Virgin Islands), for the item to the average of the 2015 fee schedule amounts for all areas for the lead item.

[72 FR 18085, Apr. 10, 2007, as amended at 81 FR 77967, Nov. 4, 2016; 83 FR 57072, Nov. 14, 2018]

### § 414.418 Opportunity for networks.

(a) A network may be comprised of at least 2 but not more than 20 small suppliers.

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(b) The following rules apply to networks that seek contracts under this subpart:

(1) Each network must form a single legal entity that acts as the bidder and submits the bid. Any agreement entered into for purposes of forming a network must be submitted to CMS. The network must identify itself as a network and identify all of its members.

(2) Each member of the network must satisfy the requirements in § 414.414(b) through (d).

(3) A small supplier may join one or more networks but cannot submit an individual bid to furnish the same product category in the same CBA as any network in which it is a member. A small supplier may not be a member of more than one network if those networks submit bids to furnish the same product category in the same CBA.

(4) The network cannot be anti-competitive, and this section does not supersede any Federal law or regulation that regulates anticompetitive behavior.

(5) A bid submitted by a network must include a statement from each network member certifying that the network member joined the network because it is unable independently to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire geographic area of the CBA.

(6) At the time that a network submits a bid, the network's total market share for each product category that is the subject of the network's bid cannot exceed 20 percent of the Medicare demand for that product category in the CBA.

(c) If the network is awarded a contract, each supplier must submit its own claims and will receive payment directly from Medicare for the items that it furnishes under the competitive bidding program.

[72 FR 18085, Apr. 10, 2007]

### § 414.420 Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

(a) *Prescription for a particular brand item or mode of delivery.* (1) A physician



or treating practitioner may prescribe, in writing, a particular brand of an item for which payment is made under a competitive bidding program, or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary.

(2) When a physician or treating practitioner prescribes a particular brand or mode of delivery of an item under paragraph (a)(1) of this section, the physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

(b) *Furnishing of a prescribed particular brand item or mode of delivery.* If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(c) *Payment for a particular brand of item or mode of delivery.* Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item, as directed by a prescription written by the beneficiary's physician or treating practitioner.

(d) *Prohibition on billing for an item different from the particular brand of item or mode of delivery prescribed.* A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner. Payment will not be made to a contract supplier that

submits a claim prohibited by this paragraph.

[72 FR 18085, Apr. 10, 2007]

#### § 414.422 Terms of contracts.

(a) *Basic rule.* CMS specifies the terms and conditions of the contracts entered into with contract suppliers under this subpart. A contract supplier must comply with all terms of its contract, including any option exercised by CMS, for the full duration of the contract period.

(b) *Recompeting competitive bidding contracts.* CMS recompetes competitive bidding contracts at least once every 3 years.

(c) *Nondiscrimination.* The items furnished by a contract supplier under this subpart must be the same items that the contract supplier makes available to other customers.

(d) *Change of ownership (CHOW).* (1) CMS may transfer a contract to a successor entity that merges with, or acquires, a contract supplier if the successor entity—

(i) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) Submits to CMS the documentation described under § 414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not needed to make a financial determination. This documentation must be submitted prior to the effective date of the CHOW; and

(iii) Submits to CMS a signed novation agreement acceptable to CMS stating that it assumes all obligations under the contract. This documentation must be submitted no later than 10 days after the effective date of the CHOW.

(2) Except as specified in paragraph (d)(3) of this section, CMS may transfer the entire contract, including all product categories and competitive bidding areas, to a successor entity.

(3) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract

supplier sells a distinct company (for example, a subsidiary) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a successor entity, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the successor entity that meets all competitive bidding requirements; that is, financial, accreditation, and licensure;

(ii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iii) All requirements of paragraph (d)(1) of this section are met;

(iv) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(v) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

(e) *Furnishing of items.* Except as otherwise prohibited under section 1877 of the Act, or any other applicable law or regulation:

(1) A contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.

(2) A skilled nursing facility defined under section 1819(a) of the Act or a nursing facility defined under section 1919(a) of the Act that has elected to furnish items only to its own residents and that is also a contract supplier may furnish items under a competitive bidding program to its own patients to whom it would otherwise furnish Part B services.

(3) Contract suppliers for diabetic testing supplies must furnish the brand of diabetic testing supplies that work with the home blood glucose monitor selected by the beneficiary. The contract supplier is prohibited from influencing or incentivizing the beneficiary by persuading, pressuring, or advising them to switch from their current

brand or for new beneficiaries from their preferred brand of glucose monitor and testing supplies. The contract supplier may not furnish information about alternative brands to the beneficiary unless the beneficiary requests such information.

(f) *Disclosure of subcontracting arrangements.* (1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

(g) *Breach of contract.* (1) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract.

(2) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions, which will be specified in the notice of breach of contract:

(i) Suspend the contract supplier's contract;

(ii) Terminate the contract;

(iii) Preclude the contract supplier from participating in the competitive bidding program; or

(iv) Avail itself of other remedies allowed by law.

[72 FR 18085, Apr. 10, 2007, as amended at 74 FR 2881, Jan. 16, 2009; 75 FR 73623, Nov. 29, 2010; 76 FR 70315, Nov. 10, 2011; 79 FR 66264, Nov. 6, 2014; 81 FR 77967, Nov. 4, 2016; 83 FR 57073, Nov. 14, 2018; 84 FR 60808, Nov. 8, 2019]

**§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.**

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contract and where CMS has issued a notice of breach of contract indicating its intent to take action(s) pursuant to § 414.422(g)(2).

(a) *Breach of contract.* CMS may take one or more of the actions specified in § 414.422(g)(2) as a result of a supplier's breach of their DMEPOS Competitive Bidding Program contract.

(b) *Notice of breach of contract—(1) CMS notification.* If CMS determines a supplier to be in breach of its contract, it will notify the supplier of the breach of contract in a notice of breach of contract.

(2) *Content of the notice of breach of contract.* The CMS notice of breach of contract will include the following:

(i) The details of the breach of contract.

(ii) The action(s) that CMS is taking as a result of the breach of the contract pursuant to § 414.422(g)(2), and the duration of or timeframe(s) associated with the action(s), if applicable.

(iii) The right to request a hearing by a CBIC hearing officer and, depending on the nature of the breach, the supplier may also be allowed to submit a corrective action plan (CAP) in lieu of requesting a hearing by a CBIC hearing officer, as specified in paragraph (c)(1)(i) of this section.

(iv) The address to which the written request for a hearing must be submitted.

(v) The address to which the CAP must be submitted, if applicable.

(vi) The effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless:

(A) A timely hearing request has been filed; or

(B) A CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

(c) *Corrective action plan (CAP)—(1) Option for a CAP.* (i) CMS has the op-

tion to allow a supplier to submit a written CAP to remedy the deficiencies identified in the notice at its sole discretion, including where CMS determines that the delay in the effective date of the breach of contract action(s) caused by allowing a CAP will not cause harm to beneficiaries. CMS will not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime, or for any other reason determined by CMS.

(ii) If a supplier chooses not to submit a CAP, if CMS determines that a supplier's CAP is insufficient, or if CMS does not allow the supplier the option to submit a CAP, the supplier may request a hearing on the breach of contract action(s).

(2) *Submission of a CAP.* (i) If allowed by CMS, a CAP must be submitted within 30 days from the date on the notice of breach of contract. If the supplier decides not to submit a CAP the supplier may, within 30 days of the date on the notice, request a hearing by a CBIC hearing officer.

(ii) Suppliers will have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable to CMS or is not properly implemented, suppliers will receive a subsequent notice of breach of contract. The subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to paragraph (c)(1)(i) of this section.

(d) *The purpose of the CAP.* The purpose of the CAP is:

(1) For the supplier to remedy all of the deficiencies that were identified in the notice of breach of contract.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) *Review of the CAP.* (1) The CBIC will review the CAP. Suppliers may only revise their CAP one time during the review process based on the deficiencies identified by the CBIC. The CBIC will submit a recommendation to CMS for each applicable breach of contract action concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as

identified in the notice of breach of contract.

(2) If CMS accepts the CAP, including the supplier's designated timeframe for its completion, the supplier must provide a follow-up report within 5 days after the supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement a CAP that was accepted by CMS, or if CMS does not accept the CAP submitted by the supplier, then the supplier will receive a subsequent notice of breach of contract, as specified in paragraph (b) of this section.

(f) *Right to request a hearing by the CBIC Hearing Officer.* (1) A supplier who receives a notice of breach of contract (whether an initial notice of breach of contract or a subsequent notice of breach of contract under § 414.422(e)(3)) has the right to request a hearing before a CBIC hearing officer who was not involved with the original breach of contract determination.

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be submitted to the CBIC within 30 days from the date of the notice of breach of contract.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is not submitted and the supplier fails to timely request a hearing, the breach of contract action(s) will take effect 45 days from the date of the notice of breach of contract.

(g) *The CBIC Hearing Officer schedules and conducts the hearing.* (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the parties' request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the parties at least 30 days before the date of the hearing.

(4) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days' notice of the change.

(5) The hearing officer's scheduling notice must provide the parties to the hearing the following information:

(i) A description of the hearing procedure.

(ii) The specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract or that the breach of contract action(s) is not appropriate.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the hearing officer.

(v) A notification that all evidence submitted, both from the supplier and CMS, will be provided in preparation for the hearing to all affected parties at least 15 days prior to the scheduled date of the hearing.

(h) *Burden of proof and evidence submission.* (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the hearing officer with convincing evidence that it has not breached its contract or that the breach of contract action(s) is not appropriate.

(2) The supplier's evidence must be submitted with its request for a hearing.

(3) If the supplier fails to submit the evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from introducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the hearing officer within 10 days of receiving the scheduling notice.

(5) The hearing officer will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing at least 15 days prior to the scheduled date of the hearing.

(i) *Role of the hearing officer.* The hearing officer will conduct a thorough

and independent review of the evidence including the information and documentation submitted for the hearing and other information that the hearing officer considers pertinent for the hearing. The role of the hearing officer includes, at a minimum, the following:

(1) Conduct the hearing and decide the order in which the evidence and the arguments of the parties are presented;

(2) Determine the rules on admissibility of the evidence;

(3) Examine the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties;

(5) Determine the rules for requesting documents and other evidence from other parties;

(6) Ensure a complete record of the hearing is made available to all parties to the hearing;

(7) Prepare a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the hearing officer and considered as part of the hearing; and

(8) Comply with all applicable provisions of Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) *Hearing officer recommendation.* (1) The hearing officer will issue a written recommendation(s) to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the hearing officer has demonstrated that an extension is needed due to the complexity of the matter or heavy workload. In situations where there is more than one breach of contract action presented at the hearing, the hearing officer will issue separate recommendations for each breach of contract action.

(2) The recommendation(s) will explain the basis and the rationale for the hearing officer's recommendation(s).

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced

during the hearing along with its recommendation(s).

(k) *CMS' final determination.* (1) CMS' review of the hearing officer's recommendation(s) will not allow the supplier to submit new information.

(2) After reviewing the hearing officer's recommendation(s), CMS' decision(s) will be made within 30 days from the date of receipt of the hearing officer's recommendation(s). In situations where there is more than one breach of contract action presented at the hearing, and the hearing officer issues multiple recommendations, CMS will render separate decisions for each breach of contract action.

(3) A notice of CMS' decision will be sent to the supplier and the hearing officer. The notice will indicate:

(i) If any breach of contract action(s) included in the notice of breach of contract, specified in paragraph (b)(1) of this section, still apply and will be effectuated, and

(ii) The effective date for any breach of contract action specified in paragraph (k)(3)(i) of this section.

(4) This decision(s) is final and binding.

(l) *Effect of breach of contract action(s)*—(1) *Effect of contract suspension.*

(i) All locations included in the contract cannot furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items for the duration of the contract suspension.

(ii) The supplier must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items on a recurring basis of the suspension of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice.

(B) The notice to the beneficiary must inform the beneficiary that they must select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(2) *Effect of contract termination.* (i) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

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(ii) The supplier must notify all beneficiaries, who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice of termination.

(B) The notice to the beneficiary must inform the beneficiary that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(3) *Effect of preclusion.* A supplier who is precluded will not be allowed to participate in a specific round of the Competitive Bidding Program, which will be identified in the original notice of breach of contract, as specified in paragraph (b)(1) of this section.

(4) *Effect of other remedies allowed by law.* If CMS decides to impose other remedies under § 414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract, as specified in paragraph (b)(2) of this section.

[81 FR 77967, Nov. 4, 2016, as amended at 83 FR 57073, Nov. 14, 2018; 84 FR 60809, Nov. 8, 2019]

### § 414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

[72 FR 18085, Apr. 10, 2007]

### § 414.425 Claims for damages.

(a) *Eligibility for filing a claim for damages as a result of the termination of sup-*

*plier contracts by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).* (1) Any aggrieved supplier, including a member of a network that was awarded a contract for the Round 1 Durable Medical Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS CBP) that believes it has been damaged by the termination of its competitive bid contract, may file a claim under this section.

(2) A subcontractor of a contract supplier is not eligible to submit a claim under this section.

(b) *Timeframe for filing a claim.* (1) A completed claim, including all documentation, must be filed within 90 days of January 1, 2010 (the effective date of these damages provisions), unless that day is a Federal holiday or Sunday in which case it will fall to the next business day.

(2) The date of filing is the actual date of receipt by the CBIC of a completed claim that includes all the information required by this rule.

(c) *Information that must be included in a claim.* (1) Supplier's name, name of authorized official, U.S. Post Office mailing address, phone number, email address and bidding number, and National Supplier Clearinghouse Number;

(2) A copy of the signed contract entered into with CMS for the Round 1 DMEPOS Competitive Bidding Program;

(3) A detailed explanation of the damages incurred by this supplier as a direct result of the termination of the Round 1 competitive bid contract by MIPPA. The explanation must include all of the following:

(i) Documentation of the supplier's damages through receipts.

(ii) Records that substantiate the supplier's damages and demonstrate that the damages are directly related to performance of the Round 1 contract and are consistent with information the supplier provided as part of their bid.

(4) The supplier must explain how it would be damaged if not reimbursed.

(5) The claim must document steps the supplier took to mitigate any damages they may have incurred due to the

contract termination, including a detailed explanation of the steps of all attempts to use for other purposes, return or dispose of equipment or other assets purchased or rented for the use in the Round 1 DMEPOS CBP contract performance.

(d) *Items that will not be considered in a claim.* The following items will not be considered in a claim:

- (1) The cost of submitting a bid.
- (2) Any fees or costs incurred for consulting or marketing.
- (3) Costs associated with accreditation or licensure.
- (4) Costs incurred before March 20, 2008.
- (5) Costs incurred for contract performance after July 14, 2008 except for costs incurred to mitigate damages.
- (6) Any profits a supplier may have expected from the contract.
- (7) Costs that would have occurred without a contract having been awarded.
- (8) Costs for items such as inventory, delivery vehicles, office space and equipment, personnel, which the supplier did not purchase specifically to perform the contract.
- (9) Costs that the supplier has recouped by any means, and may include use of personnel, material, suppliers, or equipment in the supplier's business operations.

(e) *Filing a claim.* (1) A claim, with all supporting documentation, must be filed with the CMS Competitive Bidding Implementation Contractor (CBIC).

(2) Claims must include a statement from a supplier's authorized official certifying the accuracy of the information provided on the claim and all supporting documentation.

(3) The CBIC does not accept electronic submissions of claims for damages.

(f) *Review of claim.* (1) *Role of the CBIC.* (i) The CBIC will review the claim to ensure it is submitted timely, complete, and by an eligible claimant. When the CBIC identifies that a claim is incomplete or not filed timely, it will make a recommendation to the Determining Authority not to process the claim further. Incomplete or untimely claims may be dismissed by the

Determining Authority without further processing.

(ii) For complete, timely claims, the CBIC will review the claim on its merits to determine if damages are warranted and may seek further information from the claimant when making its recommendation to the Determining Authority. The CBIC may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iii) The CBIC will make a recommendation to the Determining Authority for each claim filed and include an explanation that supports its recommendation.

(iv) The recommendation must be either to award damages for a particular amount (which may not be the same amount requested by the claimant) or that no damages should be awarded.

(A) If the CBIC recommends that damages are warranted, the CBIC will calculate a recommended reasonable amount of damages based on the claim submitted.

(B) The reasonable amount will consider both costs incurred and the contractor's attempts and action to limit the damages;

(v) The recommendation will be sent to the Determining Authority for a final determination.

(2) *CMS' role as the Determining Authority.* (i) The Determining Authority shall review the recommendation of the CBIC.

(ii) The Determining Authority may seek further information from the claimant or the CBIC in making a concurrence or non-concurrence determination.

(iii) The Determining Authority may set a deadline for receipt of additional information. A claimant's failure to respond timely may result in a denial of the claim.

(iv) If the Determining Authority concurs with the CBIC recommendation, the Determining Authority shall submit a final signed decision to the CBIC and direct the CBIC to notify the claimant of the decision and the reasons for the final decision.

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(v) If the Determining Authority non-concurs with the CBIC recommendation, the Determining Authority may return the claim for further processing or the Determining Authority may:

(A) Write a determination granting (in whole or in part) a claim for damages or denying a claim in its entirety;

(B) Direct the CBIC to write said determination for the Determining Authority's signature; or

(C) Return the claim to the CBIC with further instructions.

(vi) The Determining Authority's determination is final and not subject to administrative or judicial review.

(g) *Timeframe for determinations.* (1) Every effort will be made to make a determination within 120 days of initial receipt of the claim for damages by the CBIC or the receipt of additional information that was requested by the CBIC, whichever is later.

(2) In the case of more complex cases, or in the event of a large workload, a decision will be issued as soon as practicable.

(h) *Notification to claimant of damage determination.* The CBIC must mail the Determining Authority's determination to the claimant by certified mail return receipt requested, at the address provided in the claim.

[74 FR 62011, Nov. 25, 2009]

## § 414.426 Adjustments to competitively bid payment amounts to reflect changes in the HCPCS.

If a HCPCS code for a competitively bid item is revised after the contract period for a competitive bidding program begins, CMS adjusts the single payment amount for that item as follows:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes

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is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components. Contract suppliers must furnish the item and submit claims using the new HCPCS code.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number. Payment for these items will be made in accordance with Subpart C or Subpart D.

[72 FR 18085, Apr. 10, 2007]

## Subpart G—Payment for Clinical Diagnostic Laboratory Tests

SOURCE: 71 FR 69786, Dec. 1, 2006, unless otherwise noted.

### § 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act and 1834A of the Act—procedures for determining the basis for, and amount of, payment for a clinical diagnostic laboratory test (CDLT).

[81 FR 41098, June 23, 2016]

### § 414.502 Definitions.

For purposes of this subpart—

*Actual list charge* means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

*Advanced diagnostic laboratory test (ADLT)* means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of