

**List of Subjects**

**42 CFR Part 411**

Kidney diseases, Medicare Reporting and recordkeeping requirements

**42 CFR Part 414**

Administrative practice and procedure, Health facilities, Health professions,  
Kidney diseases, Medicare, Reporting and recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid  
Services is amending 42 CFR Chapter IV as set forth below:

**PART 411--EXCLUSIONS FOR MEDICARE AND LIMITATIONS ON  
MEDICARE PAYMENT**

1. The authority for part 411 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart A-General Exclusions and Exclusions of Particular Services**

2. Section 411.15 is amended by adding a new paragraph (s) to read as follows.

**§411.15 Particular services excluded from coverage.**

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(s) Unless §414.404(d) or §414.408(e)(2) of this subchapter applies, Medicare does not make payment if an item or service that is included in a competitive bidding program (as described in Part 414, Subpart F of this subchapter) is furnished by a supplier other than a contract supplier (as defined in §414.402 of this subchapter).

**PART 414--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH  
SERVICES**

3. The authority citation for part 414 continues to read as follows:

**Authority:** Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

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

4. New §§414.400, 414.402, and 414.404 are added to Subpart F to read as follows:

**§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.

**§414.402 Definitions.**

For purposes of this subpart, the following definitions apply:

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

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 sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers.

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

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

Grandfathered item means any one of the following items for which payment is made on a rental basis prior to the implementation of a competitive bidding program and for which payment is made after implementation of a competitive bidding program to a grandfathered supplier that continues to furnish the items in accordance with §414.408(j):

- (1) An inexpensive or routinely purchased item described in §414.220.

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

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

(4) Other DME described in §414.229.

Grandfathered supplier means a noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.

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

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug, and Cosmetic Act, as defined in §414.202 of this part and 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 drugs.

(3) Enteral nutrients, equipment, and supplies.

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

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

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.

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.

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.

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.

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 areas.

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.

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.

#### **§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 and treating practitioners may furnish certain types of competitively bid items 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.

(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.

(iii) The items are billed under a billing number assigned to the 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).

5. Section 414.406 is amended by adding paragraphs (b), (c), and (d) to read as follows:

**§414.406 Implementation of programs.**

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(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

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6. New §§414.408, 414.410, 414.412, 414.414, 414.416, 414.418, 414.420, 414.422, 414.424, and 414.426 are added to Subpart F to read as follows:

**§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, or occupational therapist in private practice 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.

(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.

(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) Additional payment to certain contract suppliers for capped rental DME.

(i) Except as specified in paragraph (h)(2)(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)(2)(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.

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

(4) 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.

(5) 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.

(6) 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.

(7) 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 beneficiary 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) 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) and (e)(3) of subpart D 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.

**§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 in--

(1) 10 of the largest MSAs in CY 2007;

(2) 80 of the largest MSAs in CY 2009;

(3) Additional CBAs after CY 2009.

(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:

(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.

**§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) Bids are submitted for items grouped into product categories.

(2) The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part.

(c) Furnishing of items. A bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item.

(d) Separate bids. For each product category that a supplier is seeking to furnish under a competitive bidding program, the supplier must submit a separate bid for each item in that product category.

(e) 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.

(f) 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 paragraph (f)(1) of this section may submit the same bid amount for each item under each competitive bidding program for which it submits a bid.

(g) 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.

**§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.

(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 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 accreditation organization that meets the requirements of §424.58 of this subchapter, unless a grace period is specified by CMS.

(d) Financial standards. Each supplier must submit along with its bid the applicable financial documentation specified in the request for bids.

(e) Evaluation of bids. CMS evaluates bids submitted for items within a product category by--

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

(3) Establishing a composite bid for each supplier and network that submitted a bid for the product category.

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

(5) Calculating the pivotal bid for the product category;

(6) 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 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 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 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.

**§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 an item furnished under a competitive bidding program is equal the median of the bids 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. If there is an even number of bids, the single payment amount for the item is equal to the average of the two middle bids.

(2) The single payment amount for an 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.

**§414.418 Opportunity for networks.**

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

(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 anticompetitive, 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.

**§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.

**§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. (1) A contract supplier must notify CMS if it is negotiating a change in ownership 60 days before the anticipated date of the change.

(2) CMS may award a contract to an entity that merges with, or acquires, a contract supplier if--

(i) The successor entity meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) The successor entity submits to CMS the documentation described under §414.414(b) through (d) if that documentation has not previously been submitted by the successor entity or the contract supplier that is being acquired, or is no longer current. This documentation must be submitted within 30 days prior to the anticipated effective date of the change of ownership. A successor entity is not required to duplicate previously submitted information if the previously submitted information is still current;

(iii) The successor entity is acquiring the assets of the existing contract supplier, it submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(iv) A new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph (d)(2)(iii) of this section for CMS review. The successor entity

must submit to CMS, within 30 days after the effective date of the change of ownership and executed novation agreement acceptable to CMS.

(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.

(f) 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:

(i) Require the contract supplier to submit a corrective action plan;

(ii) Suspend the contract supplier's contract;

(iii) Terminate the contract;

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

(v) Revoke the supplier number of the contract supplier; or

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

**§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.

**§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 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.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: \_\_\_\_\_

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**Leslie V. Norwalk,**

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: \_\_\_\_\_

\_\_\_\_\_  
**Michael O. Leavitt,**

Secretary.

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