

§ 414.410

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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:

- (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

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 subpart C of this part, without the application of §414.210(g), or subpart D of this part, without the application of §414.105.

(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