

(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