

§ 414.411

- (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

42 CFR Ch. IV (10–1–24 Edition)

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

§ 414.414

42 CFR Ch. IV (10–1–24 Edition)

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.