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—

(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 §414.404(b)(1)(i)(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.


§ 414.411 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