**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 414**

**[CMS-1460-ANPRM]**

**RIN: 0938-AS05**

**Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information from Competitive Bidding Programs**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Advance notice of proposed rulemaking (ANPRM).

**SUMMARY**: This advance notice of proposed rulemaking (ANPRM) solicits public comments on different methodologies we may consider using with regard to applying information from the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding programs to adjust Medicare fee schedule payment amounts or other Medicare payment amounts for DMEPOS items and services furnished in areas that are not included in these competitive bidding programs. In addition, we are also requesting comments on a different matter regarding ideas for potentially changing the payment methodologies used under the competitive bidding programs for certain durable medical equipment and enteral nutrition.

**DATES**: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[**OFR--insert date 30 days after date of publication in the **Federal Register]**.

**CUSTOMER SERVICE INFORMATION:** Individuals interested in obtaining information from the Centers for Medicare & Medicaid Services concerning current Medicare payment

policies may call 1-800-MEDICARE (633-4227) or visit the Centers for Medicare & Medicaid website (http://www.cms.gov) or (http://www.medicare.gov).

**ADDRESSES:** In commenting, please refer to file code CMS-1460-ANPRM. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1460-ANPRM,

P.O. Box 8010,

Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1460-ANPRM,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Anita Greenberg, (410) 786-4601.

Karen Jacobs, (410) 786-2173.

Christopher Molling, (410) 786-6399.

Hafsa Vahora, (410) 786-7899.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

## I. Background

A. Adjustments to DMEPOS Fee Schedule Amounts

Medicare pays for most DMEPOS furnished after January 1, 1989, pursuant to fee schedule methodologies set forth in sections 1834 and 1842 of the Social Security Act (the Act). Specifically, sections 1834(a)(1)(A) and (B), and 1834 (h)(1)(A) and (B) of the Act provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. This payment methodology is set forth at 42 CFR Part 414, Subpart D of our regulations. Section 1834 (h)(1)(A) of the Act governs payment for prosthetic devices and orthotics and prosthetics, while sections 1834(a)(2) through (a)(5) and 1834(a)(7) of the Act set forth separate payment categories of durable medical equipment (DME) and describe how the fee schedule for each of the following categories is established: Inexpensive or other routinely purchased items; Items requiring frequent and substantial servicing; Customized items; Oxygen and oxygen equipment; and Other items of DME. Section 1842(s) of the Act, and 42 CFR Part 414, Subpart C of the regulations, govern payment on a fee schedule basis for parenteral and enteral (PEN) nutrients, equipment and supplies.

Section 1847 of the Act establishes a Medicare DMEPOS Competitive Bidding Program ("Competitive Bidding Program"). Under the Competitive Bidding Program, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in competitive bidding areas (CBAs) based on bids submitted by qualified suppliers and accepted by Medicare. For competitively bid items, these new payment amounts, referred to as "single payment amounts," replace the fee schedule payment amounts. Section 1847(b)(5) of the Act provides that Medicare payment for these competitively bid items and services is made on an assignment-related basis equal to 80 percent of the applicable single payment amount, less any

unmet Part B deductible. The fee schedule methodologies continue to set payment amounts for noncompetitively bid DMEPOS items and services.

For DME covered items furnished or after January 1, 2011, sections 1834(a)(1)(F)(ii) and (iii) of the Act authorizes the Secretary to use (and beginning January 1, 2016, requires use of) payment information under the competitive bidding program to adjust the fee schedule amounts for covered items of DME in all non-competitive bidding areas, and beginning January 1, 2016, continue to make such adjustments to the fee schedule amounts as additional covered items are phased in or information is updated as new contracts are awarded. Similarly, section 1834(h)(1)(H)(ii) of the Act authorizes the Secretary to use payment information under the competitive bidding program to adjust the fee schedule amounts for off-the-shelf (OTS) orthotics in all non-competitive bidding areas beginning January 1, 2011. Finally, section 1842(s)(3)(B) of the Act provides authority to use payment information under the competitive bidding program to adjust payment amounts otherwise applicable for enteral nutrients, supplies, and equipment in areas where competitive bidding programs are not established for these items and services.

Section 1834(a)(1)(G) of the Act requires that the methodology used in applying sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii) of the Act be promulgated through notice and comment rulemaking. Section 1834(a)(1)(G) of the Act also requires that we "consider the costs of items and services in areas in which such provisions [sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii)] would be applied compared to the payment rates for such items and services in competitive acquisition areas."

The statute requires that the DMEPOS fee schedule amounts be based on average allowed charges from a base period, increased by annual covered item update factors set forth in

the statute. The average allowed charges are average payments made in various areas of the country under the previous reasonable change payment methodology that based Medicare payments on supplier charges. The rules pertaining to the calculation of reasonable charges are located at 42 CFR Part 405, Subpart E of our regulations. Under this general methodology, several factors were taken into consideration in determining the reasonable charge for an item. Each supplier's "customary charge" for an item, or the 50th percentile of charges for an item over a 12-month period, was one factor used in determining the reasonable charge. The "prevailing charge" in a local area or locality, or the 75th percentile of suppliers' customary charges for the item in the locality, was also used in determining the reasonable charge. For parenteral and enteral nutrition (PEN) items and services only, the "lowest charge level" (LCL) was also taken into consideration and was based on the 25th percentile of all charges for an item in a locality. For the purpose of calculating the LCL and prevailing charges, a "locality" is defined at §405.505 and "may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States". The regulation at §405.505 further specifies that the locality "should include a cross section of the population with respect to economic and other characteristics." In accordance with regulations at §405.509, effective for items furnished on or after October 1, 1985, an additional factor, the "inflation-indexed charge" or IIC, was added to the factors taken into consideration in determining the reasonable charge for an item. The IIC is equal to the lowest of the customary or prevailing charge from the previous year updated by an inflation adjustment factor was also used in determining the reasonable charge for an item. To summarize, the reasonable charges for each item that were used to calculate the fee schedule amounts are equal to the lower of:

- the supplier's actual charge on the claim;
- the supplier's customary charge for the item;
- the prevailing charge in the locality for the item;
- the LCL in the locality for the item, if applicable; or
- the IIC.

Under the reasonable charge payment methodology, it is understood that suppliers took all of their costs of furnishing various DMEPOS items and services in various localities throughout the nation into account in setting the prices they charges for covered items and services. Under § 414.104, the fee schedule amounts for enteral nutrients, supplies, and equipment are national fee schedule amounts based on the lesser of the reasonable charge from 1995 or the reasonable charge that would have been used in determining payment for 2002, updated by the covered item update factors. Under § 414.228, the fee schedule amounts for OTS orthotics are regional fee schedule amounts based on the weighted average of the statewide average allowed charges for items furnished from July 1, 1986 through June 30, 1987, updated by the covered item update factors. The regional fee schedule amounts are limited by a national fee schedule ceiling and floor. Under §414.220 and §414.222, the fee schedule amounts for inexpensive or routinely purchased DME and DME requiring frequent and substantial servicing are statewide fee schedule amounts based on the average allowed charges for items furnished from July 1, 1986 through June 30, 1987, updated by the covered item update factors, and limited by a national fee schedule ceiling and floor. Under §414.226, the fee schedule amounts for oxygen and oxygen equipment are statewide fee schedule amounts based on the average allowed charges for items

furnished from January 1, 1986 through December 31, 1986, updated by the covered item update factors, and limited by a national fee schedule ceiling and floor. Under §414.229, the fee schedule amounts for capped rental DME are statewide fee schedule amounts based on the average allowed charges for items furnished from July 1, 1986 through December 31, 1986, updated by the covered item update factors, and limited by a national fee schedule ceiling and floor.

DMEPOS competitive bidding pricing information is collected using current market prices represented by bids submitted by suppliers for furnishing items and services in certain competitive bidding areas (CBAs). In accordance with section 1847(a)(1)(B) and (D) of the Act, during Rounds 1 and 2 of the phase in of the competitive bidding programs, the CBAs have been either entire Metropolitan Statistical Areas (MSAs), MSAs excluding areas with low population density that are not competitive, or, in the case of New York, Los Angeles, and Chicago, MSAs subdivided into two or more CBAs. In accordance with sections 1834(a)(1)(F)(i), 1834(h)(1)(H)(i), and 1842(s)(3)(A) of the Act, the competitive bidding prices, then, replace the fee schedule amounts in those MSAs. Currently, the program is active in 100 MSAs and 109 CBAs. The 109 CBAs where competitive bidding has been phased in include a wide range of different size urban areas and surrounding counties. They include one CBA (Honolulu, HI) that is not within the contiguous Unites States and CBAs that range in population size from approximately 300 thousand to 10 million (see Table 1). There are 7 CBAs with a population of less than 500,000, 41 CBAs with a population of more than 500,000, but less than 1 million, 27 CBAs with a population of more than 1 million, but less than 2 million, 19 CBAs with a population of 2 to 4 million, and 14 CBAs with a population of over 4 million.

**TABLE 1—CBA POPULATION SIZE**

| CBA | Population |
|---|---|
| Los Angeles County, CA | 9,862,049 |
| New York Metro - West Long Island, NY | 6,688,637 |
| Dallas-Fort Worth-Arlington, TX | 6,447,615 |
| Chicago Metro - Central, IL | 6,225,192 |
| Philadelphia-Camden-Wilmington, PA-NJ-DE-MD | 5,968,252 |
| Houston-Sugar Land-Baytown, TX | 5,867,489 |
| Miami-Fort Lauderdale-Pompano Beach, FL | 5,547,051 |
| Washington-Arlington-Alexandria, DC-VA-MD-WV | 5,476,241 |
| Atlanta-Sandy Springs-Marietta, GA | 5,475,213 |
| Boston-Cambridge-Quincy, MA-NH | 4,588,680 |
| Detroit-Warren-Livonia, MI | 4,403,437 |
| Phoenix-Mesa-Scottsdale, AZ | 4,364,094 |
| San Francisco-Oakland-Fremont, CA | 4,317,853 |
| Riverside-San Bernardino-Ontario, CA | 4,143,113 |
| Seattle-Tacoma-Bellevue, WA | 3,407,848 |
| New York Metro - North New Jersey, NJ | 3,390,339 |
| Minneapolis-St. Paul-Bloomington, MN-WI | 3,269,814 |
| San Diego-Carlsbad-San Marcos, CA | 3,053,793 |
| New York Metro - Bronx, Manhattan, NY | 3,026,698 |
| Orange County, CA | 3,010,759 |
| New York Metro - South New Jersey, NJ | 2,977,504 |
| St. Louis, MO-IL | 2,828,990 |
| Tampa-St. Petersburg-Clearwater, FL | 2,747,272 |
| Baltimore-Towson, MD | 2,690,886 |
| Denver-Aurora, CO | 2,552,195 |

| CBA | Population |
|---|---|
| Pittsburgh, PA | 2,354,957 |
| Portland-Vancouver-Beaverton, OR-WA | 2,241,841 |
| Cincinnati-Middletown, OH-KY-IN | 2,171,896 |
| Sacramento--Arden-Arcade--Roseville, CA | 2,127,355 |
| Cleveland-Elyria-Mentor, OH | 2,091,286 |
| Orlando-Kissimmee, FL | 2,082,421 |
| San Antonio, TX | 2,072,128 |
| Kansas City, MO-KS | 2,067,585 |
| Las Vegas-Paradise, NV | 1,902,834 |
| San Jose-Sunnyvale-Santa Clara, CA | 1,839,700 |
| Columbus, OH | 1,801,848 |
| Charlotte-Gastonia-Concord, NC-SC | 1,745,524 |
| Indianapolis-Carmel, IN | 1,743,658 |
| Austin-Round Rock, TX | 1,705,075 |
| Virginia Beach-Norfolk-Newport News, VA-NC | 1,674,498 |
| Providence-New Bedford-Fall River, RI-MA | 1,600,642 |
| Nashville-Davidson--Murfreesboro--Franklin, TN | 1,582,264 |
| Milwaukee-Waukesha-West Allis, WI | 1,559,667 |
| New York Metro - Suffolk County, NY | 1,512,224 |
| Chicago Metro - South, IL | 1,446,415 |
| New York Metro - North New York, NY | 1,351,732 |
| Jacksonville, FL | 1,328,144 |
| Memphis, TN-MS-AR | 1,304,926 |
| Louisville/Jefferson County, KY-IN | 1,258,577 |
| Richmond, VA | 1,238,187 |
| Oklahoma City, OK | 1,227,278 |

| CBA | Population |
|---|---|
| Hartford-West Hartford-East Hartford, CT | 1,195,998 |
| Chicago Metro - North, IL-WI | 1,195,559 |
| New Orleans-Metairie-Kenner, LA | 1,189,981 |
| Birmingham-Hoover, AL | 1,131,070 |
| Salt Lake City, UT | 1,130,293 |
| Raleigh-Cary, NC | 1,125,827 |
| Buffalo-Niagara Falls, NY | 1,123,804 |
| Rochester, NY | 1,035,566 |
| Tucson, AZ | 1,020,200 |
| Tulsa, OK | 929,015 |
| Fresno, CA | 915,267 |
| Honolulu, HI | 907,574 |
| Bridgeport-Stamford-Norwalk, CT | 901,208 |
| Albuquerque, NM | 857,903 |
| Albany-Schenectady-Troy, NY | 857,592 |
| Omaha-Council Bluffs, NE-IA | 849,517 |
| New Haven-Milford, CT | 848,006 |
| Dayton, OH | 835,063 |
| Allentown-Bethlehem-Easton, PA-NJ | 816,012 |
| Bakersfield, CA | 807,407 |
| Worcester, MA | 803,701 |
| Oxnard-Thousand Oaks-Ventura, CA | 802,983 |
| Baton Rouge, LA | 786,947 |
| Grand Rapids-Wyoming, MI | 778,009 |
| El Paso, TX | 751,296 |
| Columbia, SC | 744,730 |

| CBA | Population |
|---|---|
| McAllen-Edinburg-Mission, TX | 741,152 |
| Greensboro-High Point, NC | 714,765 |
| Chicago Metro - Indiana, IN | 702,458 |
| Akron, OH | 699,935 |
| Knoxville, TN | 699,247 |
| Springfield, MA | 698,903 |
| Bradenton-Sarasota-Venice, FL | 688,126 |
| Little Rock-North Little Rock-Conway, AR | 685,488 |
| Poughkeepsie-Newburgh-Middletown, NY | 677,094 |
| Stockton, CA | 674,860 |
| Toledo, OH | 672,220 |
| Charleston-North Charleston-Summerville, SC | 659,191 |
| Syracuse, NY | 646,084 |
| Greenville-Mauldin-Easley, SC | 639,617 |
| Colorado Springs, CO | 626,227 |
| Wichita, KS | 612,683 |
| Boise City-Nampa, ID | 606,376 |
| Cape Coral-Fort Myers, FL | 586,908 |
| Lakeland-Winter Haven, FL | 583,403 |
| Youngstown-Warren-Boardman, OH-PA | 562,963 |
| Scranton--Wilkes-Barre, PA | 549,454 |
| Jackson, MS | 540,866 |
| Augusta-Richmond County, GA-SC | 539,154 |
| Palm Bay-Melbourne-Titusville, FL | 536,357 |
| Chattanooga, TN-GA | 524,303 |
| Deltona-Daytona Beach-Ormond Beach, FL | 495,890 |

| CBA | Population |
|---|---|
| Visalia-Porterville, CA | 429,668 |
| Flint, MI | 424,043 |
| Asheville, NC | 412,672 |
| Beaumont-Port Arthur, TX | 378,477 |
| Ocala, FL | 328,547 |
| Huntington-Ashland, WV-KY-OH | 285,624 |

Source: U.S. Census Bureau, Population Division, 2009 Population Estimates

Under section 1847(a)(1)(D)(iii) of the Act, competitions occurring before 2015 for items and services other than national mail order for diabetic supplies, may not include rural areas or MSAs with a population of less than 250,000. Therefore, at this time, we do not have competitive bidding pricing information from rural areas or smaller MSAs. As required by section 1834(a)(1)(G) of the Act, we must specify by regulation the methodology to be used for adjusting fee schedule amounts using competitive bidding information.

B. Changes to the Payment Methodologies and Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under Competitive Bidding Programs

Section 1847 of the Act provides CMS with flexibility and discretion with regard to the payment rules for items furnished under competitive bidding programs. We are considering proposing new payment rules for DME and enteral nutrients, supplies, and equipment furnished under competitive bidding programs and request public comments on the issue before we decide whether to conduct notice and comment rulemaking. We believe that bundling payment for all items and services associated with furnishing enteral nutrition or DME into one monthly

payment based on supplier bids for furnishing all items needed for a month would greatly simplify the program, improve beneficiary access to quality items and services, and contribute to greater savings associated with implementation of the DMEPOS competitive bidding program.

The current Medicare payment rules and payment classes for DME mandated by section 1834(a) of the Act were implemented in 1989, and, depending on the item or payment class the item falls under, generally allow payment on a lump sum purchase basis, a capped rental basis, or a continuous monthly rental basis where the monthly payments are not capped and continue for as long as medical necessity and Part B coverage continues. The continuous monthly rental payment amounts include payment for all necessary maintenance and servicing of the equipment and replacement of all essential accessories, whereas payment on a purchase or capped rental basis results in the need to process and pay separately for numerous items that are not DME but are related to furnishing DME, such as repair of equipment or replacement of supplies and accessories used with patient-owned equipment. In the case of enteral nutrition, there are separate billing codes for categories of nutrients, three different daily supply allowances, feeding tubes, and enteral nutrition infusion pumps and IV poles.

The current payment rules that apply to fee schedule DMEPOS items and competitive bid items were developed in the 1980s to reduce expenditures and prevent prolonged rental payments for certain DME and enteral infusion pumps. However, now that Medicare allowed amounts can be established under the competitive bidding program based on supplier bids to account for the average costs of furnishing all covered items and services, we believe it may be appropriate to modify the Medicare payment structure for certain DME and enteral nutrition under the competitive bidding program by requesting a single bid for furnishing all related items

and services needed on a monthly basis (that is, rented equipment, replacement of supplies and accessories, repair or rented equipment, etc.). Bids from suppliers could then be used to establish a monthly payment for the equipment and all related items and services. We believe that capping rentals and paying for purchase of equipment may no longer be necessary to achieve savings for these items and services. Suppliers could bid and be awarded contracts for meeting all of the beneficiary's needs for each month of service, including rental and servicing of necessary equipment as well as the ongoing replacement of supplies and accessories used in conjunction with the equipment and any repairs needed for the equipment. Such an approach could reduce excessive payments for furnishing necessary accessories and items, provided the continuous monthly rental payment amounts were reasonable for all the monthly items and services that would be furnished. In submitting bids under the competitive bidding programs, suppliers would take a number of things into account to develop bids for these monthly items and services, such as the costs of all items and services needed by the beneficiary during each rental month, the typical duration of need by Medicare beneficiaries for the rented items, and the money the supplier saves by replacing inventory less frequently if the title to the equipment remains with the supplier and is not transferred to the beneficiary after the capped rental period. We believe these changes could have a number of positive effects on suppliers. The suppliers would no longer have to worry about counting rental months to determine when they might be losing title to certain items in their inventory. These changes could also benefit patients who would no longer have to arrange for repair of patient-owned equipment or worry about servicing patient-owned equipment for which a manufacturer no longer makes replacement parts available. We believe that suppliers would have an incentive to furnish more durable and dependable

equipment to reduce the number of service calls they make. If a beneficiary owns equipment that needs to be serviced, they are responsible for locating a supplier and making arrangements for the servicing, and the beneficiary incurs a separate charge for the service. By contrast, if a beneficiary is renting equipment, and the rented equipment needs to be serviced, the beneficiary would simply call the supplier of the rented equipment and the supplier would be responsible for servicing the equipment at no additional charge. From a program standpoint, the payment rules for capped rental items are complicated and onerous to administer. The program must keep track of separate payment, coverage, medical necessity, and other rules for hundreds of related codes for replacement supplies and accessories used with the base equipment as well as labor and parts associated with repairing patient-owned equipment. In addition, claims processing systems must count rental months and contractors must identify when legitimate breaks in continuous use occur and can result in the start of new capped rental periods. This leads to costly and complicated claims processing systems and edits for processing millions of claims for these items and services.

The current payment rules that allow separate payment for supplies and accessories used with DME in addition to the payment for the DME itself also significantly complicate the competitive bidding process as special grandfathering payment rules must be implemented, item weights and composite bids must be developed, hundreds or thousands of bid amounts must be entered, and, in turn, thousands of bids and bid amounts must be evaluated and screened and single payment amounts established. In the case of beneficiary-owned wheelchairs, the rules regarding when one of the hundreds of accessories or component must be furnished by a contract supplier or non-contract supplier based on whether the base wheelchair is competitively bid or

whether the service constitutes a repair of the base wheelchair are extremely complicated. A simple, straightforward payment system could significantly reduce billing and payment errors.

Under competitive bidding programs established in accordance with section 1847(a) of the Act, we believe CMS has discretion to implement different payment rules for the items and services subject to competitive bidding, including certain DME and enteral nutrition. Suppliers compete for contracts based on bids representing their costs for furnishing the DME item or enteral nutrition. Regardless of whether suppliers compete based on submitting one bid for furnishing, for example, continuous positive airway pressure (CPAP) devices and all related supplies, accessories, and services needed for one month versus separate, piecemeal bids for the various individual items, contracts are offered to the suppliers that meet all program requirements and offer the best value in terms of bids submitted. In addition, contract suppliers are responsible for furnishing what the beneficiary needs and this does not change based on how the items are billed and paid for under Medicare. The supplier costs generally do not change based on the method of payment used. Therefore, competitive bidding provides a means to simplify and streamline complicated payment rules, resulting in a more efficient program.

By simplifying the payment rules for certain DME and enteral nutrition under the Competitive Bidding Program, the process of competitive bidding could be greatly simplified. For example, suppliers could submit one bid that reflects the costs of furnishing the DME and supplies, accessories, and maintenance and servicing costs associated with furnishing the DME. Under competitive bidding, bid limits for the DME could be developed based on average monthly expenditures per beneficiary in an area for the bundle of items and services related to furnishing the DME (for example, CPAP device rental, masks, tubing, humidifier, maintenance

and servicing). Similarly, bid limits for enteral nutrition could be developed based on average monthly expenditures per beneficiary in an area for the bundle of items and services related to furnishing enteral nutrition (nutrients, supplies, rental of infusion pumps and IV poles, and maintenance and servicing of equipment). These are some possibilities we are exploring with regard to modifications that could be made to current payment rules and methodologies under the CBP in future rulemaking. Whether we would proceed with proposing this would depend on several factors, including issues such as administrative burden and feasibility, as well as other potential issues raised in the public comments we receive.

**II. Questions for Generating Public Comments**

A. Methodology for Adjusting Medicare Payment Amounts for DMEPOS Items and Services Based on Information from Competitive Bidding Programs

We are aware that there continues to be a range of aspects to consider in the development of the methodology used to adjust fee schedule amounts for DMEPOS using information from the competitive bidding programs. Again, we are required by section 1834(a)(1)(G) of the Act, to specify by regulation the methodology to be used for adjusting fee schedule amounts using competitive bidding information. However, prior to proposing the methodology, we are soliciting public comments on a variety of topics for CMS to consider. We are interested in receiving comments on several aspects that we would consider in developing a methodology to adjust DMEPOS fee schedule amounts or other payment amounts in non-competitive areas based on DMEPOS competitive bidding payment information. We are soliciting comments on the following list of questions to assist us in developing potential proposals regarding the methodology for adjusting Medicare payment amounts for DMEPOS items and services based

on information from competitive bidding programs.

- Do the costs of furnishing various DMEPOS items and services vary based on the geographic area in which they are furnished? If so, how should the bidding information obtained from programs established in different regions of the nation be grouped together for the purpose of adjusting current Medicare payment amounts? Should bidding information from programs established in certain regions of the country be used to adjust the payment amounts that currently apply to those regions? Are there certain areas of the country that have unique costs and how should those costs be considered? Is there valid and reliable information that can be used to measure the relative costs of furnishing items and services in these unique areas?
- Do the costs of furnishing various DMEPOS items and services vary based on the size of the market served in terms of population and/or distance covered or other logistical or demographic reasons? Section 1847(a)(1)(D)(iii) of the Act prohibits establishing competitive bidding programs in MSAs with a population of less than 250,000 or in areas outside MSAs prior to 2015. Given the mandate to use information on the payment determined under competitive bidding programs to adjust payment amounts in areas that are not competitive bidding areas by no later than January 1, 2016, what alternative information, if any, should we rely on to determine the relative costs of furnishing items and services in these areas compared to areas where competitive bidding programs have already been implemented?
- How should any future adjustments or payment methodology treat payment amounts for items that have not been included in all competitive bidding programs (for example,

items such as transcutaneous electrical nerve stimulation (TENS) devices that have only been phased into the nine Round 1 areas thus far)?

- Should competitive bidding programs be established in all areas of the country for a few high volume items in order to gather information regarding the costs of furnishing DMEPOS items, in general, in different areas of the country (for example, rural areas as well as urban areas)?
- For payment adjustments or competitive bidding programs in rural areas, what factors should be used in determining a competitive service area in terms of Medicare revenue available and logistical costs of serving the area? Are there ways to determine which rural counties should be served by which suppliers?
- What additional factors should be considered and why?

B. Changes to the Payment Methodologies and Rules for Durable Medical Equipment and Enteral Nutrition Furnished Under Competitive Bidding Programs

We are requesting comments on testing or phasing in bundled payments under competitive bidding programs whereby suppliers would submit one bundled bid for the delivery of all enteral nutrients, supplies, and equipment needed for one month by a beneficiary as well as one bundled bid for furnishing certain DME, including all related supplies, accessories, and services on a monthly basis. Under such an approach, monthly rental payments for DME or enteral nutrition equipment would no longer reach a cap, while separate payment for supplies, accessories, enteral nutrients, or maintenance and servicing would no longer be made. Suppliers would retain title to all equipment regardless of length of need and beneficiaries would be able to switch from supplier to supplier on a monthly basis. The monthly payments for DME and

enteral nutrition would continue for as long as medical necessity and Part B coverage continues and the bid limits would be based on the average monthly costs per beneficiary for the bundle of items and services. We are soliciting comments on the following list of questions regarding proposals we may make to change the payment rules and other rules for DME and enteral nutrition under the DMEPOS competitive bidding program.

- Are lump sum purchases and capped rental payment rules for DME and enteral nutrition equipment that were implemented to prevent prolonged rental payments still needed now that monthly payment amounts can be established under competitive bidding programs for furnishing everything the beneficiary needs each month related to the covered DME item or enteral nutrition?
- Are there reasons why beneficiaries need to own expensive DME or enteral nutrition equipment rather than use such equipment as needed on a continuous monthly basis?
- Would there be any negative impacts associated with continuous bundled monthly payments for enteral nutrients, supplies, and equipment or for certain DME? If so, please explain.
- Certain DME items such as speech generating devices and specialized wheelchairs may be adjusted or personalized to address individual patient needs. Would payment on a bundled, continuous rental basis adversely impact access to these items and services? If so, please provide a detailed explanation regarding how this method of payment would create a negative impact on access to these items and services or other items and services currently subject to competitive bidding.

- If payment on a capped rental, rent-to-own basis or lump sum purchase basis is maintained for certain items under the competitive bidding program, should a requirement be added to the regulations specifying that the supplier that transfers title to the equipment to the beneficiary is responsible for all maintenance and servicing of the beneficiary-owned equipment for the remainder of the equipment's reasonable useful lifetime with no additional payment for these services? The cost of such a mandatory supplier warranty would be factored into the bids submitted by the suppliers and the payment amounts established based on the bids for the items. If such a requirement was established, should the term maintenance and servicing be defined to include all necessary maintenance, servicing and repairs that are currently paid for separately under the Medicare program in addition to any additional adjustments or personalization of the equipment that may be needed once title transfers to the patient? We believe these requirements may be necessary to safeguard the beneficiary and access to necessary services related to beneficiary-owned DME.
- Would payment on a bundled, continuous rental basis for certain items adversely impact the beneficiary's ability to direct their own care, follow a plan of care outlined by a physician, nurse practitioner or other medical provider (for example, occupational, physical or speech therapist), or provide for appropriate care transitions? If so, please explain.
- What are the advantages or disadvantages for beneficiaries and suppliers of bundled bidding and payments for enteral nutrients, supplies, and equipment or DME?

- Should competitive bidding programs utilizing bundled payments be established throughout the entire United States so that all beneficiaries are included under programs where suppliers have an obligation to furnish covered items and all related items and services?
- Is a continuous bundled monthly payment used by commercial payers or State Medicaid programs for enteral nutrients, supplies, and DME and do these approaches inform this potential new payment arrangement for Medicare.

Dated: January 31, 2014.

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**Marilyn Tavenner,**

Administrator,

Centers for Medicare & Medicaid Services.

Approved: February 4, 2014.

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**Kathleen Sebelius,**

Secretary,

Department of Health and Human Services.

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