DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 411, 413 and 414

[CMS-1614-P]

RIN 0938-AS13

Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

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

ACTION: Proposed rule.

SUMMARY: This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. This rule also proposes to set forth requirements for the ESRD quality incentive program (QIP), including payment years (PYs) 2017 and 2018. This rule also proposes to make a technical correction to remove outdated terms and definitions. In addition, this rule proposes to set forth the methodology for adjusting Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP); make alternative payment rules for DME and enteral nutrition under the Medicare DMEPOS CBP; clarify the statutory Medicare hearing aid coverage exclusion and specify devices not subject to the hearing aid exclusion; update the definition of minimal self-adjustment regarding what specialized training is needed by suppliers to provide custom fitting services if they are not certified orthotists; clarify the Change of Ownership (CHOW) and provides for an exception to the current requirements; revise the appeal provisions for termination of a contract and notification to beneficiaries under the Medicare DMEPOS CBP, and add a technical change

related to submitting bids for infusion drugs under the Medicare DMEPOS CBP.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. E.S.T. on [***INSERT DATE 60 DAYS AFTER DISPLAY DATE*.]**

ADDRESSES: In commenting, please refer to file code CMS-1614-P. 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-1614-P,

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-1614-P,

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.

TABLE 32: Technical Corrections to §405.2102

Term	Proposed Action	Other FR Location
Agreement	Delete	--
Arrangement	Delete	--
Dialysis	Delete	--
End-Stage Renal Disease (ESRD)	Delete	406.13(b)
ESRD facility introductory text	Delete	--
Renal dialysis center	Delete	--
Renal dialysis facility	Delete	494.10
Self-dialysis unit	Delete	--
Special purpose renal dialysis facility	Delete	494.120
ESRD Network organization	Delete	--
ESRD service introductory text	Delete	--
Dialysis service	Delete	--
Inpatient dialysis	Delete	--
Outpatient dialysis	Delete	--
Staff-assisted dialysis	Delete	--
Self-dialysis	Delete	494.10
Home dialysis	Delete	494.10
Self-dialysis and home dialysis training	Delete	--
Furnishes directly	Delete	494.10
Furnishes on the premises	Delete	494.180(d)
Medical care criteria	Delete	--
Medical care norms	Delete	--
Medical care standards	Delete	--
Medical care evaluation study (MCE)	Delete	--
Network, ESRD	Retain	N/A
Network organization	Retain	N/A
Qualified personnel	Delete	--
Chief executive officer	Delete	--
Dietitian	Delete	494.140(c)
Medical record practitioner	Delete	--
Nurse responsible for nursing service	Delete	494.140(b)
Physician-director	Delete	494.140(a)
Social worker	Delete	494.140(d)

V. Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs

A. Background

1. Payment Basis for Certain DMEPOS

Section 1834(a) of the Act governs payment for durable medical equipment (DME) covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of 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,
- Other covered items (other than DME), and
- Other items of DME (capped rental items).

Section 1834(h) of the Act governs payment for prosthetic devices, prosthetics, and orthotics (P&O) and sets forth fee schedule payment rules for P&O. Effective for items furnished on or after January 1, 2002, payment is also made on a national fee schedule basis for parenteral and enteral nutrition (PEN) in accordance with the authority under section 1842(s) of the Act. The term "enteral nutrition" will be used throughout this document to describe enteral nutrients supplies and equipment covered as prosthetic devices in accordance with section 1861(s)(8) of the Act and paid for on a fee schedule basis and enteral nutrients under DMEPOS Competitive Bidding Program (CBP), as authorized under section 1847(a)(2)(B) of the Act. Section 1842(o)(1)(D) of the Act mandates that payment for infusion drugs furnished through a covered item of DME on or after January 1, 2004, is equal to 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

For DMEPOS items subject to payment under 1834 of the Act (not subject to the CBP), the Medicare's allowed payment amount is equal to the lesser of the actual charge for the item or the fee schedule amount for the item. The fee schedule amounts are based on average payments made under the previous payment methodology of reasonable charges, which utilized supplier charges for furnishing items and services in local areas throughout the nation to establish the Medicare allowed payment amounts for the items and services. The reasonable charge data used is from a specific period of time that varies slightly by payment class (for example, July 1986 through June 1987 for inexpensive DME). The fee schedule amounts for most items are updated on an annual basis by covered item update factors provided in the statute for DME under section 1834(a)(14) of the Act, for P&O under section 1834(h)(4)(A) of the Act, and for enteral nutrition under section 1842(s)(1)(B) of the Act.

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 the 75th percentile of suppliers' customary charges for the item in the locality, was also used in determining the reasonable charge. For 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. For the purpose of calculating prevailing charges, a "locality" is defined at 42 CFR §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 further specifies that the locality "should include a cross section of the population with

respect to economic and other characteristics." For PEN items and services only, the entire nation was used as the locality for the purpose of calculating the LCL and prevailing charges.

Effective for items furnished on or after October 1, 1985, an additional factor, the inflation-indexed charge (IIC) as cited at 42 CFR §405.509, 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 charge, prevailing charge, LCL (if applicable), and IIC from the previous year updated by an inflation adjustment factor. 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 assumed that suppliers took all of their costs of furnishing various items and services in various localities throughout the nation into account in setting the prices they charge for covered items and services.

We implemented the fee schedule payment methodologies for PENs at 42 CFR Part 414, Subparts C, and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings at 42 CFR Part 414, Subpart D of our regulations. In accordance with section 1834(a)(10) of the Act, the Secretary may adjust DMEPOS fee schedule amounts in situations where it is determined that the amounts are not inherently reasonable. This "inherent reasonableness" authority for adjusting fee schedule payment amounts is governed by paragraphs (8) and (9) of section

1842(b) of the Act and implemented at 42 CFR Part 405, Subpart E of our regulations. Finally, in the case of DMEPOS furnished on or after January 1, 2011, under section 1834(a)(1)(F)(ii) of the Act, the Secretary may (in beginning January 1, 2016, must) use information on the payment determined under the CBP in accordance with section 1847 of the Act to adjust the fee schedule payment amounts for DME that are not in a competitive bidding area (CBA), and the inherent reasonableness authority does not apply. Adjustment of fee schedule amounts based on CBP payment information (and the limitation on using inherent reasonableness) is also authorized under section 1834(h)(1)(H)(ii) of the Act for certain orthotics and section 1842(s)(3)(B) of the Act for enteral nutrition in non-competitive bid areas.

2. Fee Schedule Payment Methodologies

Section 4062(b) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100-203, added section 1834(a) of the Act and mandated the implementation of local fee schedule amounts in 1989 for DME and P&O based on the average of reasonable charges for items and services furnished in carrier service areas throughout the United States. The carriers were (now Medicare administrative contractors) responsible for processing claims for Part B items and services in accordance with section 1842(a) of the Act. The carrier service areas used in establishing the fee schedule amounts could not exceed an entire state. A few states were made up of two carrier service areas and the State of New York had three carrier service areas. A carrier service area is not to be confused with a locality established for the purpose of calculating reasonable charges as described above. For example, although claims for items furnished in the State of Texas were processed by a single carrier, for reasonable charge calculation purposes, Texas was divided into more than 50 different localities. In 1993, the local fee schedule amounts for states with more than one carrier service areas were transitioned to

statewide fee schedule amounts. The reasonable charge data used to calculate the statewide fee schedule amounts therefore reflected the average payment made under the supplier charge based reasonable charge payment methodology for items and services furnished throughout the state, including both rural and urban areas of the state.

Section 4062(b) of OBRA 87 mandated that local fee schedule amounts for both DME and P&O be transitioned to regional fee schedule amounts as part of a multi-year phase in ending in 1993. Section 4152(b) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Public Law 101-508, eliminated the regional fee schedule transition for DME and amended section 1834(a) of the Act to mandate that the local (statewide) fee schedule amounts be limited by a national ceiling (upper) limit, based on the median of the statewide fee schedule amounts, and a national floor (lower limit), based on 85 percent of the median of the statewide fee schedule amounts. The fee schedule ceiling and floor limits for DME were phased in from 1991 through 1993. The conversion to regional fee schedule amounts therefore never took place for DME and instead the statewide fee schedule amounts were limited so that they could not vary by more than 15 percent from the national ceiling to the national floor. The fee schedule amounts for areas outside the contiguous United States are not subject to the national ceiling and floor limits. The transition to regional fee schedule amounts was retained for P&O, although OBRA 90 changed the phase in schedule so that the regional fee schedule amounts were not fully phased in until January 1, 1994, rather than January 1, 1993. As explained in more detail below, the regional fee schedule methodology allows for regional geographic variation in fee schedule payment amounts and a wider range in fees across the nation than the fee schedule methodology used for DME which caps the local, statewide fee schedule amounts at the national median. That being said, we have not seen any problems associated with access to either P&O or DME in rural areas or any

areas of the country since payments have been made based on these fee schedule methodologies. This has been the case even though the average reasonable charges used to compute the statewide fee schedule amounts include a comingling of reasonable charge data for items and services furnished in both urban and rural areas. In addition, we have not seen any problems with access to PEN in rural areas or any areas of the country since payments have been made based on national fee schedule amounts.

3. Regional Fee Schedule Payment Methodology for P&O

The regional fee schedules for P&O are mandated by section 1834(h)(2)(B) of the Act. The regional fee schedule amounts only apply to areas within the contiguous United States. The regional fee schedule amounts are calculated based on the weighted average (weighted by total Part B claims volume) of statewide fee schedule amounts for states in each of the ten CMS Regional Office boundaries identified below. The statewide fee schedule amounts are based on average reasonable charges (statewide fees) for items furnished from July 1, 1986 through June 30, 1987.

The ten CMS Regional Office boundaries are:

- Boston (Region One), including the six states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont;
- New York (Region Two), including the two states of New Jersey and New York;
- Philadelphia (Region Three), including the five states of Delaware, Maryland, Pennsylvania, Virginia, West Virginia and the District of Columbia;
- Atlanta (Region Four), including the eight states of Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, and Tennessee;

- Chicago (Region Five), including the six states of Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin;
- Dallas (Region Six), including the five states of Arkansas, Louisiana, New Mexico, Oklahoma and Texas;
- Kansas City (Region Seven), including the four states of Iowa, Kansas, Missouri and Nebraska;
- Denver (Region Eight), including the six states of Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming;
- San Francisco (Region Nine), including the three states of Arizona, California and Nevada; and
- Seattle (Region Ten), including the three states of Idaho, Oregon and Washington.

As an example, the regional fee schedule amounts for Region Nine are based on the weighted average of the statewide fees for Arizona, California, and Nevada. Since California accounts for the largest volume of Part B claims in the region, the California statewide fees are weighted more heavily in determining the regional fee schedule amounts than the statewide fees for Arizona or Nevada. Once all of the regional fee schedule amounts are established, the regional fee schedule amounts are further limited by a national ceiling equal to 120 percent of the average of the regional fee schedule amounts for all the states and a national floor equal to 90 percent of the average of the regional fee schedule amounts for all the states.

The national ceiling and floor limits for DME and P&O set national parameters on how much the statewide or regional fee schedule amounts can vary. For DME, the upper payment limit or ceiling is based on the national median of the statewide fees, essentially bringing half of

the state fees down to the national median. The lower limit or floor is based on 85 percent of the national median and brings those state fees below the floor amount up to the floor amount. In contrast, the national ceiling and floor parameters for P&O are based on 120 percent and 90 percent, respectively, of the average of the various regional fee schedule amounts. Differences in reasonable charge based fees in various geographic regions of the country are maintained within the parameters of the national ceilings and floors for P&O.

4. DMEPOS Competitive Bidding Programs Payment Rules

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), requires the Secretary to establish and implement CBPs in CBAs throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs mandated by section 1847(a) of the Act are collectively referred to as the "Medicare DMEPOS Competitive Bidding Program." Section 1847(a)(2) of the Act provides that the items and services to which competitive bidding applies are:

- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

The DME and medical supplies category includes items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME, but excludes class III devices

under the Federal Food, Drug, and Cosmetics Act and Group 3 or higher complex rehabilitative power wheelchairs and related accessories when furnished with such wheelchairs. Sections 1847(a) and (b) of the Act specify certain requirements and conditions for implementation of the Medicare DMEPOS CBP.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) was enacted. Section 154 of the MIPPA amended section 1847 of the Act to make certain limited changes to the Medicare DMEPOS CBP, including a revised timeframe for phasing in the programs.

On March 23, 2010, the Affordable Care Act was enacted. Section 6410(a) of the Affordable Care Act amended section 1847(a)(1) of the Act, mandating the phase in of 21 additional Metropolitan Statistical Areas (MSAs).

Section 1847(a) of the Act requires that the DMEPOS CBP be phased in so that competition under the programs occurs in 9 of the largest Metropolitan Statistical Areas (MSAs) in 2009, 91 additional large MSAs in 2011, and additional areas after 2011 (or, in the case of national mail order for items and services, after 2010). Section 1847(a)(1)(D)(ii) of the Act provides discretion to subdivide MSAs and through notice and comment rulemaking we subdivided the New York-Northern New Jersey-Long Island, NY-NJ-PA; Los Angeles-Long Beach-Santa Ana, CA; and Chicago-Naperville-Joliet, IL-IN-WI MSAs. The final rule was published in the **Federal Register** on November 29, 2010 (75 FR 73454) and divided the New York-Northern New Jersey-Long Island, NY-NJ-PA MSA into six CBAs. In addition, the Los Angeles-Long Beach-Santa Ana, CA MSA was divided into two CBAs and the Chicago-Naperville-Joliet, IL-IN-WI MSA was divided into four CBAs (75 FR 73460). Altogether this

created a total of 100 CBAs for the competitions occurring in the 91 MSAs in 2011, or a total of 109 CBAs for the competitions occurring in 100 MSAs in 2009 and 2011.

Finally, section 1847(a)(1)(D)(iii) of the Act specifies that competitions occurring before 2015 for items and services other than national mail order, may not include rural areas or MSAs with a population of less than 250,000.

In addition to the national mail order program for diabetic supplies, the product categories (PCs) that have been phased in thus far in 100 Round 2 CBAs and 9 Round 1 CBAs include the following:

Round 2 CBAs (contract period July 1, 2013, thru June 30, 2016)

- Oxygen, oxygen equipment, and supplies
- Standard (Power and Manual) wheelchairs, scooters, and related accessories
- Enteral nutrients, equipment, and supplies
- Continuous Positive Airway Pressure (CPAP) devices and Respiratory Assist Devices (RADs) and related supplies and accessories
- Hospital beds and related accessories
- Walkers and related accessories
- Negative Pressure Wound Therapy pumps and related supplies and accessories
- Support surfaces (Group 2 mattresses and overlays)

Round 1 CBAs (contract period January 1, 2014, thru December 31, 2016)

- Respiratory Equipment and Related Supplies and Accessories
    - includes oxygen, oxygen equipment, and supplies; CPAP devices and RADs and related supplies and accessories; and standard nebulizers

- Standard Mobility Equipment and Related Accessories
    - includes walkers, standard power and manual wheelchairs, scooters, and related accessories
- General Home Equipment and Related Supplies and Accessories
    - includes hospital beds and related accessories, group 1 and 2 support surfaces, transcutaneous electrical nerve stimulation (TENS) devices, commode chairs, patient lifts, and seat lifts
- Enteral Nutrients, Equipment and Supplies
- Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories
- External Infusion Pumps and Supplies

In addition, contracts and SPAs were in effect in the 9 Round 1 CBAs from January 1 2011 thru December 31, 2013, for the items listed below which are not included in current Round 1 or 2 PCs:

- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2)
- Adjustable Wheelchair Seat Cushions

5. Adjusting Payment Amounts using Information from the DMEPOS Competitive Bidding Program

Section 1834(a)(1)(F)(ii) of the Act provides authority for using information from the DMEPOS CBPs to adjust the DME payment amounts for covered items furnished on or after

January 1, 2011, in areas where competitive bidding is not implemented for the items. Similar authority exists at section 1834(h)(1)(H)(ii) of the Act for OTS orthotics, and at section 1842(s)(3)(B) of the Act for enteral nutrition. Section 1834(a)(1)(F) also requires adjustments to the payment amounts for all DME items subject to competitive bidding furnished in areas where CBPs have not been implemented on or after January 1, 2016.

For items furnished on or after January 1, 2016, section 1834(a)(1)(F)(iii) requires us to continue to make such adjustments to DME payment amounts where CBPs have not been implemented, as additional covered items are phased in or information is updated as contracts are recompeted.

Section 1834(a)(1)(G) of the Act requires that the methodology used to adjust payment amounts for DME and OTS orthotics using information from the CBPs be promulgated through notice and comment rulemaking, which is the purpose of this proposed rule. 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 [competitive bidding] areas." We are proposing to apply the same methodology for making adjustments to the payment amounts for enteral nutrition as authorized by section 1842(s)(3)(B) of the Act.

6. Diversity of Costs

As mentioned above, under section 1834(a)(1)(G) of the Act we must consider the costs of furnishing items and services in areas where prices will be adjusted compared to the payment rates for the items and services furnished in CBAs. We believe that the methodology for using the single payment amounts (SPAs) as a basis for adjusting payment rates in other areas needs to

ensure that adjusted payment amounts in an area are adequate to cover the unique costs of furnishing the items and services in those areas.

The SPAs are based on the median of successful bids for furnishing items and services in MSAs, which are mainly urban areas, from suppliers with costs and characteristics that may or may not be similar to suppliers in other areas. In addition, under the DMEPOS CBP, many low population density areas within MSAs were excluded from the CBAs as authorized by statute, making the geographic bidding areas smaller and more densely populated than they would have been if the initial MSA boundaries had been retained for bidding purposes.

Regarding the size of suppliers submitting the bids used to generate the SPAs compared to the size of suppliers in areas where price adjustments based on the SPAs would occur, it is important to note that small suppliers are given special considerations under the CBP and that a majority of contracts are offered to small suppliers. Section 1847(b)(6)(D) of the Act requires that, in developing procedures relating to bidding and the awarding of contracts, CMS "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program." We have established a number of provisions to ensure that small suppliers are given an opportunity to participate in the DMEPOS CBP. For example, under 42 CFR §414.414(g)(1)(i), we have established a 30 percent target for small supplier participation; thereby, ensuring efforts are made to award at least 30 percent of contracts to small suppliers. Also, CMS worked in coordination with the Small Business Administration (SBA) to develop an appropriate definition of a "small supplier" for this program. Under 42 CFR §414.402, a small supplier is one that generates gross revenues of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue. Under 42 CFR §414.418, small suppliers may join together in "networks" in order to submit bids that meet the various program

requirements. For contracts taking effect on July 1, 2013 in Round 2, in 100 CBAs throughout the country, 63 percent of all contract suppliers are small suppliers, with only 10 percent of contract suppliers being new to the areas. In addition, for contracts taking effect on January 1, 2014 in the Round 1 Recompete, in the 9 initial CBAs, 58 percent of all contract suppliers are small suppliers, with only 3 percent of contract suppliers being new to the areas. Therefore, the majority of bids used in establishing the SPAs come from small suppliers with a history of furnishing the items in the CBAs.

Prior to awarding contracts, each supplier is carefully screened to ensure that it is accredited under applicable Medicare quality standards and meets rigid financial standards, specific Medicare supplier enrollment requirements, and applicable state licensing standards. Each bid is screened to ensure that it is a bona fide bid, and those that fail are excluded from the competition. Approximately 94 percent of bids screened as part of the Round 2 and Round 1 Recompete competitions were determined to be bona fide. The invoices and purchase orders submitted by bidding suppliers to support their bids reflected prices already paid by the supplier (that is, prior to becoming a contract supplier) and for the most part did not reflect large volume purchasing discounts. Once non-bona fide bids are excluded, suppliers are ranked in order based on bid amounts, and the median of bids from the number of suppliers determined to be necessary to meet projected demand are used to establish the SPAs. The projected demand for items and services in a CBA is intentionally overstated for the purpose of ensuring that contracts are awarded to more than a sufficient number of suppliers to serve the beneficiaries in the area. The establishment of the demand level is explained in detail in the competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other issue) published April 10, 2007 (72 FR 18039). Thus, the SPAs are higher than they would otherwise be if

demand was not overstated because the high demand generally results in an increase in the number of contract suppliers which in most cases increases the median bid amount. CMS also conducts its review of supplier capacity and expansion plans during the bid evaluation process. If a supplier is new to an area, new to a PC, or submits estimated capacity that represents substantial growth over current levels, CMS may conduct a more detailed evaluation of that supplier's expansion plan to verify the supplier's ability to provide items and services in the CBA on day one of the contract period. If a bidder's financial data and expansion plan do not support the supplier's estimated capacity, CMS will adjust the capacity to the supplier's historic level, which would be zero for a new supplier. CMS uses the estimated capacity information and the bid amounts to determine the array of winning suppliers in a CBA.

Under Round 2 and the Round 1 Recompete competitions, 92 percent of suppliers accepted contract offers at the SPAs set through the competitions. In addition, CMS reviewed all contract suppliers based on financial standards when evaluating their bids. This process includes review of tax records, credit reports, and other financial data, which leads to the calculation of a score, similar to processes used by lenders when evaluating the viability of a company. All contract suppliers met the financial standards established for the program.

From January 1, 2011, when the initial Round 1 contracts and SPAs took effect, to present, we have seen no indication that beneficiaries have been denied access to necessary items and services subject to the programs in CBAs as a result of the SPAs. In addition, we have been closely monitoring inquiries as well as real time claims and health outcomes data and have seen no negative impacts on access to items and services under the program. Therefore, the SPAs appear to be sufficient to cover the costs of the suppliers furnishing items in the 109 CBAs.

In previous legislation, which we will discuss below, the Congress mandated that the

costs of furnishing DME in different geographic regions of the country be studied. Section 135 of the Social Security Act Amendments of 1994, Public Law 103-432, required an examination of the geographic variations in DME supplier costs in order to determine whether the fee schedules are reasonably adjusted to account for any geographic differences. Jing Xing Health and Safety Resources, Inc. provided assistance to the Health Care Financing Administration, now CMS, in conducting this study. The project entitled "Durable Medical Equipment Supplier Product and Service Cost Study", was completed under Contract Number HCFA 500-95-0044 and submitted to the agency in June 1996. As part of the study, a Federal Advisory Panel was convened, a formal meeting with representatives of the DME industry was held, and a literature review was conducted. The general consensus among industry representatives and government agencies that participated in the study was that there is no conclusive evidence that urban and rural costs differed significantly or that the costs of furnishing DME items and services were higher in urban areas versus rural areas or vice versa.

The 109 CBAs where competitive bidding has been phased in include a wide range of different size urban areas with surrounding counties, and suppliers take the costs of furnishing items and services in these different areas into account when submitting bids under the programs. 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 33). There are 7 CBAs with a population of less than 500,000, 42 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 33: CBA POPULATION SIZE

CBA	Population
Los Angeles County CBA	9,453,357
Nassau-Brooklyn-Queens-Richmond County Metro CBA	6,630,278
Dallas-Fort Worth-Arlington, TX	6,554,334
Central-Chicago Metro CBA	6,179,455
Houston-Sugar Land-Baytown, TX	6,152,650
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	5,995,992
Washington-Arlington-Alexandria, DC-VA-MD-WV	5,662,358
Miami-Fort Lauderdale-Pompano Beach, FL	5,604,979
Atlanta-Sandy Springs-Marietta, GA	5,293,136
Boston-Cambridge-Quincy, MA-NH	4,595,431
San Francisco-Oakland-Fremont, CA	4,407,286
Detroit-Warren-Livonia, MI	4,256,579
Phoenix-Mesa-Glendale, AZ	4,251,146
Riverside-San Bernardino-Ontario, CA	4,157,332
Seattle-Tacoma-Bellevue, WA	3,522,509
Northern NJ Metro CBA	3,473,815
Minneapolis-St. Paul-Bloomington, MN-WI	3,326,864
San Diego-Carlsbad-San Marcos, CA	3,118,844
Orange County CBA	3,067,829
Southern NY Metro CBA	3,015,460
Bronx-Manhattan NY CBA	2,983,009
St. Louis, MO-IL	2,844,160
Tampa-St. Petersburg-Clearwater, FL	2,810,479
Baltimore-Towson, MD	2,751,529
Denver-Aurora-Broomfield, CO	2,568,221
Pittsburgh, PA	2,361,317
Portland-Vancouver-Hillsboro, OR-WA	2,259,089
San Antonio-New Braunfels, TX	2,223,779
Orlando-Kissimmee-Sanford, FL	2,176,846
Sacramento--Arden-Arcade--Roseville, CA	2,174,556
Cincinnati-Middletown, OH-KY-IN	2,121,660
Cleveland-Elyria-Mentor, OH	2,074,790
Kansas City, MO-KS	2,050,306
Las Vegas-Paradise, NV	1,967,341
San Jose-Sunnyvale-Santa Clara, CA	1,898,173
Columbus, OH	1,844,571
Charlotte-Gastonia-Rock Hill, NC-SC	1,832,391
Austin-Round Rock-San Marcos, TX	1,813,495

CBA	Population
Indianapolis-Carmel, IN	1,764,136
Virginia Beach-Norfolk-Newport News, VA-NC	1,673,547
Nashville-Davidson--Murfreesboro--Franklin, TN	1,607,708
Providence-New Bedford-Fall River, RI-MA	1,603,029
Milwaukee-Waukesha-West Allis, WI	1,570,548
Suffolk County CBA	1,488,017
South-West-Chicago-Metro CBA	1,464,818
Jacksonville, FL	1,371,407
North East NY CBA Metro	1,363,882
Memphis, TN-MS-AR	1,309,806
Louisville/Jefferson County, KY-IN	1,277,282
Oklahoma City, OK	1,276,642
Richmond, VA	1,262,088
Hartford-West Hartford-East Hartford, CT	1,214,313
Raleigh-Cary, NC	1,190,534
Northern-Chicago Metro CBA	1,187,661
New Orleans-Metairie-Kenner, LA	1,182,382
Salt Lake City, UT	1,158,617
Buffalo-Niagara Falls, NY	1,133,325
Birmingham-Hoover, AL	1,121,219
Rochester, NY	1,062,561
Tucson, AZ	1,004,374
Honolulu, HI	962,112
Fresno, CA	949,093
Tulsa, OK	945,366
Bridgeport-Stamford-Norwalk, CT	922,063
Albuquerque, NM	896,202
Omaha-Council Bluffs, NE-IA	883,233
Albany-Schenectady-Troy, NY	866,077
New Haven-Milford, CT	862,551
Dayton, OH	839,984
Oxnard-Thousand Oaks-Ventura, CA	830,680
Allentown-Bethlehem-Easton, PA-NJ	826,740
El Paso, TX	826,163
Baton Rouge, LA	811,243
Bakersfield-Delano, CA	810,348
Worcester, MA	800,404
McAllen-Edinburg-Mission, TX	799,023
Grand Rapids-Wyoming, MI	783,733
Columbia, SC	767,793

CBA	Population
Greensboro-High Point, NC	746,685
Little Rock-North Little Rock-Conway, AR	710,371
North Port-Bradenton-Sarasota, FL	708,687
Indiana-Chicago Metro CBA	706,110
Knoxville, TN	705,446
Springfield, MA	698,926
Akron, OH	687,788
Stockton, CA	685,542
Greenville-Mauldin-Easley, SC	683,793
Charleston-North Charleston-Summerville, SC	682,539
Syracuse, NY	671,076
Poughkeepsie-Newburgh-Middletown, NY	665,524
Colorado Springs, CO	665,484
Toledo, OH	649,956
Wichita, KS	634,116
Boise City-Nampa, ID	634,037
Cape Coral-Fort Myers, FL	631,611
Lakeland-Winter Haven, FL	602,671
Augusta-Richmond County, GA-SC	570,656
Scranton--Wilkes-Barre, PA	556,282
Youngstown-Warren-Boardman, OH-PA	553,382
Palm Bay-Melbourne-Titusville, FL	550,416
Jackson, MS	544,285
Chattanooga, TN-GA	533,309
Deltona-Daytona Beach-Ormond Beach, FL	501,906
Visalia-Porterville, CA	439,968
Flint, MI	435,877
Asheville, NC	434,665
Beaumont-Port Arthur, TX	397,872
Ocala, FL	323,229
Huntington-Ashland, WV-KY-OH	289,474
Source: U.S. Census Bureau, Population Division, 2012 Population Estimates Population estimates for MSAs and counties were adjusted to reflect CBA boundaries	

7. Advanced Notice of Proposed Rulemaking

CMS issued an Advance Notice of Proposed Rulemaking (ANPRM): Medicare Program;

Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information From Competitive Bidding Programs. The ANPRM was published in the **Federal Register** on February 26, 2014 (79 FR 10754) and solicited comments on several aspects to consider in developing the proposed methodology to adjust DMEPOS fee schedule amounts or other payment amounts in non-competitive areas based on DMEPOS competitive bidding payment information. Specific questions related to this topic were presented in the notice, including:

- Do the costs of furnishing various DMEPOS items and services vary based on the geographic area in which they are furnished?
- 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?
- Should an interim or different methodology be used to adjust payment amounts for items that have not yet been included in all CBPs (for example, items such as TENS devices that have only been phased into the nine Round 1 areas thus far)?

The comment period for the ANPRM ended on March 28, 2014, and CMS received approximately 185 comments from suppliers, manufacturers, professional, state and national trade associations, physicians, physical therapists, beneficiaries and their caregivers, and one state government office.

Commenters generally agreed that costs do vary by geographic region and that costs in rural and non-contiguous areas are higher than costs in urban areas. However, few commenters offered specific proposals or suggestions for addressing these costs differences and the suggestions that were provided were vague (for example, use the 75th percentile of SPAs rather

than the national median SPA). Several commenters stated that the costs of furnishing DMEPOS items and services in different regions of the country do vary. One commenter representing many suppliers said that there exists no reliable cost data. Another commenter representing many manufacturers and suppliers listed several key variables or factors that influence the cost of furnishing items and services in different areas that should be considered, but the commenter did not provide information on how valid and reliable information related to these factors could be obtained. This commenter stated that information of all bids submitted under the programs should also be considered and not just the bids of winning suppliers. Some commenters expressed concern that the SPAs assume a significant increase in volume to offset lower payment amounts. Some commenters suggested that the price adjustments be phased in rather than making full, one-time adjustments.

B. Proposed Provisions

We propose establishing three methodologies for adjusting DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services based on SPAs established in accordance with the payment rules at §414.408. Use of SPAs that may be established in accordance with the special payment rules proposed in section V to adjust DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services would be addressed in future notice and comment rulemaking. One proposed methodology is described in subsection 1 below and would utilize regional adjustments limited by national parameters for items bid in more than 10 CBAs throughout the country. A second proposed methodology is described in subsection 2 below and would be used for lower volume items or other items that were bid in no more than 10 CBAs for various reasons. A third proposed methodology is described in subsection 5 and would be used for mail order items

furnished in the Northern Mariana Islands. We are also proposing rules that would apply to all of these proposed methodologies.

1. Proposed Regional Adjustments Limited by National Parameters

CBPs are currently in place in 100 of the largest MSAs in the country for items and services that make up over 80 percent of the total allowed charges for items subject to the DMEPOS CBP. SPAs are currently used in 109 CBAs that include areas in every state throughout the country except for Alaska, Maine, Montana, North Dakota, South Dakota, Vermont, and Wyoming. The number of CBAs, as listed in Table 33 that are fully or partially located within a given state range from one to twelve. The Honolulu CBA was phased in under Round 2 of the program. Suppliers submitting bids for furnishing items and services in these areas have received extensive education that they should factor all costs of furnishing items and services in an area as well as overhead and profit into their bids.

For items and services that are subject to competitive bidding and have been included in more than 10 CBAs throughout the country, we propose to adjust the fee schedule payment amounts for these items and services using a methodology that is modeled closely after the regional fee schedule payment methodology in effect for P&O to allow for variations in payment based on bids for furnishing items and services in different parts of the country. Under the proposed methodology, adjusted fee schedule amounts for areas within the contiguous United States would be determined based on regional SPAs or RSPAs limited by a national floor and ceiling. The RSPA would be established using the average of the SPAs for an item from all CBAs that are fully or partially located in the region. The adjusted payment amount for the item would be equal to its RSPA but not less than 90 percent and not more than 110 percent of the

national average, which is the average of the RSPAs weighted by the number of states in the region.

We believe modeling the proposed methodology on the regional fee schedule payment methodology for P&O is appropriate because the regional fee schedule payment methodology for P&O allows for variations in Medicare fee schedule amounts based on supplier charges for furnishing items and services in different regions of the country. The regional fee schedule payment methodology for P&O adjusts the Medicare allowed payments for entire regions of the country, including low population density or rural areas, based primarily on supplier information for furnishing items and services in urban areas. The regional fee schedule payment methodology for P&O has been fully phased in since 1994 in the contiguous United States and has not resulted in any barriers to access since then in any specific region of the country in which it has been applied. The DME and P&O fee schedule amounts are based in a part on statewide average reasonable charges calculated using supplier charges for furnishing items and services in localities throughout each state. Supplier charges for furnishing items in rural areas of the state are combined with charges for furnishing items in urban areas of the state, which represents the bulk of the charges since the vast majority of beneficiaries in each state reside in urban areas rather than rural areas. Although the fee schedule payments are based heavily on charges for furnishing items and services in urban areas, this has not affected access to items and services in rural areas that are paid based on these fee schedule amounts.

We considered modeling the proposed methodology on the fee schedule payment methodology for DME which establishes an upper limit on all fee schedule amounts based on the median of the state fee schedule amounts; however, this methodology does not allow for regional variations in fee schedule amounts, allows for 0 percent variations in state fee schedule amounts

above the national median amount, and only allows for up to 15 percent variation in state fee schedule amounts below the national median amount. The statewide average reasonable charges for DME are updated by an annual covered item update factor and are then limited by a national ceiling and floor based on the median of the statewide amounts and 85 percent of the median of the statewide amounts. The DME fee schedule methodology allows for no variation in payment whatsoever above the national median statewide amount. The maximum variation in fee schedule amounts that is allowed is 15 percent below the national median statewide amount. By contrast, the regional fee schedule methodology for P&O allows for regional variation in fee schedule payment amounts by as much as 10 percent below the national average amount and 20 percent above the national average amount. Similarly, the fee schedules for enteral nutrition are based on national average reasonable charges, and therefore, do not allow for any regional variation in fee schedule amounts. We believe that the model whereby regional fee schedule amounts for P&O are based on supplier charges for furnishing items and services within each region should be adopted when using SPAs to adjust fee schedule payment amounts in a way that reflects bidding in different regions of the country. The regional adjusted amounts are based on supplier bids for furnishing items and services within each region, as explained below.

a. Regional Payment Adjustments

Rather than adjusting state, regional, or national fee schedule amounts or infusion drug payment amounts based on all bids for an item in all CBAs across the country or based on all bids for an item in all CBAs within each state, we propose to adjust the payment amounts based on the average of bids for an item in CBAs that are fully or partially located in different regions of the country. In the first step of the proposed methodology we propose to calculate RSPAs or the average of the SPAs for an item and service in different regions of the country. In keeping

with the example established by the P&O regional fee schedule payment methodology, this would allow variation in payment amounts for different regions of the country. For the purpose of establishing the boundaries for the regions, we propose using 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce. These regions are proposed based on research and analysis conducted by the BEA indicating that the states in each region share economic ties. Further information can be obtained at https://www.bea.gov/regional/definitions/nextpage.cfm?key=Regions

The information provided at this link states that:

> BEA Regions are a set of Geographic Areas that are aggregations of the states. The following eight regions are defined: Far West, Great Lakes, Mideast, New England, Plains, Rocky Mountain, Southeast, and Southwest. The regional classifications, which were developed in the mid-1950s, are based on the homogeneity of the states in terms of economic characteristics, such as the industrial composition of the labor force, and in terms of demographic, social, and cultural characteristics. For a brief description of the regional classification of states used by BEA, see U.S. Department of Commerce, Census Bureau, Geographic Areas Reference Manual, Washington, DC, U.S. Government Printing Office, November 1994, pp. 6-18;6-19.

Therefore, we propose to revise the definition of *region* in §414.202 to mean a region developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce for the purpose of calculating regional single payment amounts (RSPAs); the definition of region for the purposes of the P&O regional fee schedule would also continue to apply for those items and services not adjusted based on prices in competitively bid areas. According to the BEA, the regional classifications are based on the homogeneity of the

states in terms of economic characteristics, such as the industrial composition of the labor force, and in terms of demographic, social, and cultural characteristics. The contiguous areas of the United States that fall under the 8 BEA regions under our proposal are listed in Table 34 below. Further information can be obtained at http://www.bea.gov/

TABLE 34: Bureau of Economic Analysis Regions

Region	Name	States/Areas (count)
1	New England	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont (6)
2	Mideast	Delaware, District of Columbia, Maryland, New Jersey, New York, and Pennsylvania (6)
3	Great Lakes	Illinois, Indiana, Michigan, Ohio, and Wisconsin (5)
4	Plains	Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota (7)
5	Southeast	Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia (12)
6	Southwest	Arizona, New Mexico, Oklahoma, and Texas (4)
7	Rocky Mountain	Colorado, Idaho, Montana, Utah, and Wyoming (5)
8	Far West	California, Nevada, Oregon, and Washington (4)

We are soliciting public comments on whether different regional boundaries (e.g. CMS regions or Census Divisions) should be considered that would better reflect potential regional differences in the costs of furnishing items and services subject to the DMEPOS CBP. In addition to the CMS regions listed in section A.3 above, other established regional boundaries include those defined by the United States Census Bureau in the Department of Commerce for the purpose of reporting and analyzing census data. The Census Bureau uses 4 regions that are further divided into 9 divisions. The Census divisions are as follows:

- New England (Division 1); including the 6 states Connecticut, Maine,

Massachusetts, New Hampshire, Rhode Island and Vermont.

- Middle Atlantic (Division 2); including the 3 states New Jersey, New York and Pennsylvania.
- East North Central (Division 3); including the 5 states Illinois, Indiana, Michigan, Ohio and Wisconsin.
- West North Central (Division 4); including the 7 states Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota and South Dakota.
- South Atlantic (Division 5); including the 9 states Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia and West Virginia.
- East South Central (Division 6); including the 4 states Alabama, Kentucky, Mississippi and Tennessee.
- West South Central (Division 7); including the 4 states Arkansas, Louisiana, Oklahoma, and Texas.
- Mountain (Division 8); including the 8 states Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah and Wyoming.
- Pacific (Division 9); including the 5 states Alaska, California, Hawaii, Oregon and Washington.

Table 35 below lists the states and number of CBAs located in each of the CMS regions, BEA regions, and census divisions.

TABLE 35: States and Number of Current CBAs per CMS Region, BEA Region, and Census Division

10 CMS Regions			9 Census Divisions			8 BEA Regions		
Region	**States**	**CBAs**	**Division**	**States**	**CBAs**	**Region**	**States**	**CBAs**
Boston	CT,ME,MA, NH,RI,VT	7	New England	CT,ME,MA, NH,RI,VT	7	New England	CT,ME,MA, NH,RI,VT	7
New York	NJ,NY	13	Middle Atlantic	NJ,NY,PA	15	Mideast	DE,DC,MD, NJ,NY,PA	17
Phila.	DE,DC,MD, PA,VA,WV	9						
Atlanta	AL,FL,GA, KY,MS,NC, SC,TN	28	South Atlantic	DE,DC,FL, GA,MD,NC, SC,VA,WV	30	Southeast	AL,AR,FL, GA,KY,LA, MS,NC,SC, TN,VA,WV	34
			East South Central	AL,KY,MS, TN	7			
Chicago	IL,IN,MI, MN,OH,WI	19	East North Central	IN,IL,MI, OH,WI	19	Great Lakes	IL,IN,MI, OH,WI	19
Dallas	AR,LA,NM, OK,TX	14	West South Central	AR,LA,OK, TX	13	Southwest	AZ,NM,OK, TX	11
Kansas City	IA,KS,MO, NE	4	West North Central	IA,KS,MN, MO,NE,ND, SD	5	Plains	IA,KS,MN, MO,NE,ND, SD	5
Denver	CO,MT,ND, SD,UT,WY	3	Mountain	AZ,CO,ID, NM,MT,UT, NV,WY	8	Rocky Mountain	CO,ID,MT, UT,WY	4
San Fran.	AZ,CA,NV	16	Pacific	CA,OR,WA	15	Far West	CA,NV,OR, WA	16
Seattle	ID,OR,WA	3						

The regional fee schedule amounts for P&O are based on the average of the statewide fees for P&O, weighted by total Part B claims for paid claims with dates of service from July 1, 1991, thru June 30, 1992, which results in fees for states with a greater volume of Part B claims having more influence on the regional fee schedule amounts than states with a smaller volume of Part B claims. We believe this aspect of the regional fee schedule payment methodology for

P&O tends to favor more heavily populated states. The statewide fees for larger, more urban states where the most Medicare claims are processed, for example, Massachusetts for Region 1, play a larger role in determining the regional price than the statewide fees for smaller, more rural states in the region, for example, Vermont. Table 36 below shows the relative weighs applied to the statewide fees used in calculating the regional P&O fees for the CMS Boston Region or Region 1.

TABLE 36: P&O Regional Fee Weights – CMS Region 1 (Boston) (Weighted by Total Paid Claims for Dates of Service from July 1, 1991, thru June 30, 1992)

State	Total Part B Claims	Percent of Total for Region
MA	11,710,121	48%
CT	6,288,638	26%
RI	2,251,892	9%
ME	2,012,385	8%
NH	1,571,936	6%
VT	759,242	3%
Region	24,594,214	

As can be seen in this table, the regional P&O fees for the Boston Region are weighted heavily in favor of the statewide fees and average reasonable charges from 1986/87 for the more heavily populated urban states of Massachusetts and Connecticut with a greater utilization of Part B items and services, whereas the fees for more rural States like Vermont and Maine have a very minor impact in determining the regional fees. In contrast, we are proposing that the RSPAs be calculated based on a simple average of the SPAs for CBAs in each region, without

weighting in favor of larger, more heavily populated CBAs. Using the New England BEA Region that is comprised of the same 6 states that make up the CMS Boston Region as an example, the proposed RSPA for this region would be based on the average of the SPAs for the following 7 CBAs, with estimated 2012 population in parentheses:

- Boston-Cambridge-Quincy, MA-NH (4,640,802)
- Providence-New Bedford-Fall River, RI-MA (1,601,374)
- Hartford-West Hartford-East Hartford, CT (1,214,400)
- Bridgeport-Stamford-Norwalk, CT (933,835)
- Worcester, MA (923,762)
- New Haven-Milford, CT (862,813)
- Springfield, MA (625,718)

Therefore, rather than weighting the average of the SPAs in favor of more heavily populated CBAs, we propose that the RSPA be based on the simple average of the SPAs for the CBAs in the region, with the SPA for the much smaller Springfield, MA CBA and the SPA for the much larger Boston-Cambridge-Quincy, MA-NH Springfield, MA CBA contributing equally toward calculation of the RSPA. We believe this approach would result in adjustments that factor in the regional costs associated with furnishing items and services in the New England region of the country, while not giving undue weight to the costs of furnishing items and services in larger markets.

b. National Parameters

As explained above, the regional fee schedule amounts for P&O are limited by a national ceiling equal to 120 percent of the average of the regional fee schedule amounts for all the states and a national floor equal to 90 percent of the average of the regional fee schedule amounts for

all the states. This limits the range in the regional fee schedule amounts from highest to lowest to no more than 30 percent, 20 percent above the national average and 10 percent below the national average. By contrast, the fee schedule payment methodology for DME only allows for a variation in statewide fees of 15 percent below the median of statewide fees for all the states. The national limits to the fee schedule amounts for P&O and DME have not resulted in a barrier to access to items and services in any part of the country. We believe this reflects the fact that the costs of furnishing DMEPOS items and services do not vary significantly from one part of the country to another and that national limits on regional prices is warranted. We therefore propose to limit the variation in the RSPAs using a national ceiling and floor in order to prevent unnecessarily high or low regional amounts that vary significantly from the national average prices for the items and services. The national ceiling and floor limits would be based on 110 percent and 90 percent, respectively, of the average of the RSPAs applicable to each of the 48 contiguous states and the District of Columbia (that is, the average of RSPAs is weighted by the number of contiguous states including the District of Columbia per region). We propose that any RSPA above the national ceiling would be brought down to the ceiling and any RSPA below the national floor would be brought up to the floor. We propose that the national ceiling would exceed the average of the RSPAs by the same percentage that the national floor would be under the average of the RSPAs. This allows for a maximum variation of 20 percent from the lowest RSPA to the highest RSPA. We believe that a variation in payment amounts both above and below the national average price should be allowed, and we believe that allowing for the same degree of variation (10 percent) above and below the national average price is more equitable and less arbitrary than allowing a higher degree of variation (20 percent) above the national average price than below (10 percent), as in the case of the national ceiling and floor for the

P&O fee schedule, or allowing for only 15 percent variation below the national average price, as in the case of the national ceiling and floor for the DME fee schedule.

c. Rural and Frontier State Adjustments

Under the DMEPOS CBP, the statute prohibits competitions before 2015 in new CBAs that are rural areas or MSAs with a population of less than 250,000. Even if competitions were to begin in these areas in 2015, it is very unlikely that the SPAs from these areas would be computed and finalized by January 1, 2016. Therefore, we propose that the proposed RSPAs initially be based solely on information from existing programs implemented in 100 MSAs, which are generally comprised of more densely populated, urban areas than areas outside MSAs. We therefore believe that the initial RSPAs would not directly account for unique costs that may be associated with furnishing DMEPOS in states that have few MSAs and are predominantly rural or cover large geographic areas and are sparsely populated. However, in keeping with the discussion above, we do not believe that the cost of furnishing DMEPOS in these areas should deviate significantly from the national average price established based on supplier bids for furnishing items and services in different areas throughout the country.

As explained above, the DMEPOS fee schedule amounts are based primarily on supplier charges for furnishing items and services in urban areas and this has not resulted in problems associated with access to these items and services in rural areas or large, sparsely populated areas. Nonetheless, for the purpose of ensuring access to necessary items and services in states that are more rural or sparsely populated than others, we propose that the adjusted fee schedule amounts for states that are more rural than urban and defined as “rural states” or states where a majority of the counties are sparsely populated and defined as “frontier states” would be no lower than the national ceiling amount discussed in section b above.

We propose in §414.202 that a *rural state* be defined as a state where more than 50 percent of the population lives in rural areas within the state as determined through census data, since a majority of the general population of the state lives in rural areas, it is likely that a majority of DMEPOS items and services are furnished in rural settings in the state. This is in contrast to other states where the majority of the general population of the state lives in urban areas, making it more likely that a majority of DMEPOS items and services are furnished in urban settings or in MSAs. We believe that for states where a majority of the general population lives in rural areas, adjustments to the fee schedule amounts should be based on the national ceiling amount if the RSPA is lower than the national ceiling amount. This higher level of payment would provide more assurance that access to items and services in states within a region that are more rural than urban is preserved in the event that costs of furnishing DMEPOS items and services in rural areas is higher than the costs of furnishing DMEPOS items and services in urban areas.

We propose in §414.202 that a *frontier state*, would be defined as a state where at least 50 percent of counties in the state have a population density of 6 people or less per square mile. In such states, the majority of counties where DMEPOS items and services may be needed are very sparsely populated and suppliers may therefore have to drive considerably longer distances in furnishing these items and services as opposed to other states where the beneficiaries live closer to one another. The designation of states as frontier states or frontier areas is currently used under Medicare Part A to make adjustments to the wage index for hospitals in these remote areas in order to ensure access to services in these areas. The definition of frontier state that is proposed above for the purpose of implementing section 1834(a)(1)(F) and (G) of the Act is consistent with the current definition in section 1886(d)(3)(E)(iii)(II) and (III) of the Act and 42

CFR 412.64(m) of the regulations related to implementation of the hospital wage index adjustments and prospective payment system for hospitals under Part A. We believe that states designated as frontier states have a significant amount of area that is sparsely populated and are more likely to be geographically removed from (that is, a considerable driving distance from) areas where population is more concentrated. However, we solicit comments on alternative definitions of frontier states.

Based on the 2010 Census data, states designated as rural would include Vermont, Maine, West Virginia, and Mississippi. Other than one CBA that is fully located in Mississippi, one CBA that is partially located in Mississippi, and two CBAs that are partially located in West Virginia, the RSPAs would not include SPAs that reflect the costs of furnishing items and services in these states based on where the CBAs are currently located. Current frontier states include North Dakota, South Dakota, Montana, and Wyoming, and the RSPAs would not include SPAs that reflect the costs of furnishing items and services in any of these states based on where the CBAs are currently located. We propose that the designation of rural and frontier states could change as the U.S. Census information changes. We propose that when a state that is not designated as a rural state or frontier becomes a rural state or frontier state based on new, updated information from the U.S. Census Bureau, that adjustments to the fee schedule amounts in accordance with the proposed provision of this section would take effect as soon as such changes can be implemented. Likewise, we propose that at any time a state that is designated as a rural state or frontier no longer meets the proposed definition in this section for rural state or frontier state based on new, updated information from the U.S. Census Bureau, that adjustments to the fee schedule amounts in accordance with the proposed provision of this section would take effect as soon as such changes can be implemented. We propose that the changes to the state

designation would occur based on the decennial Census. The decennial Census uses total population of the state to determine whether the state is predominately rural or frontier. The U.S. Census Bureau also uses current population estimates every 1, 3, and 5 years through the American Community Survey but only samples a small percentage of the population every year, not the total population. Therefore, we propose that the designation of a rural or frontier state occur approximately every 10 years when the total population data is available. For the current proposed fee schedule adjustments, we propose to use the 2010 Census Data. The next update would reflect the 2020 Census Data and any changes in the designation of a rural or frontier state and corresponding fee schedule changes would be implemented after the 2020 Census Data becomes available. For this and subsequent updates, we propose to include a listing of the qualifying rural and frontier States in program guidance that is issued quarterly and to provide at least 6 months advance notice of any adjustments.

Some of the comments received on the ANPRM indicated that the costs of furnishing DMEPOS items and services in rural areas is significantly higher than the costs of furnishing DMEPOS items and services in urban areas. Other commenters suggested that the adjustments to the payment amounts based on information from CBPs be phased in to give suppliers time to adjust to the new payment levels. Although we believe that the costs of furnishing items and services in rural areas are different than the costs of furnishing items and services in urban areas, there is no evidence to support a statement that the difference in costs is significant. However, in order to proceed cautiously on this matter in the interest of ensuring access to covered DMEPOS items and services, we are proposing to phase in the price adjustments, as explained below, so that we can monitor the impact of the adjustments as they are gradually phased in.

In summary, we propose that adjustments to payment amounts for areas within different

regions of the contiguous United States would be based on the un-weighted average of SPAs from CBAs that are fully or partially located within these regions. The regional amounts would be limited by a national ceiling and floor and the adjusted payment amounts for all states designated as rural or frontier states would be equal to the national ceiling. In addition, we are soliciting public comments on whether payment in rural areas of states that are not designated as rural or frontier states should be set differently.

d. Areas Outside the Contiguous United States

Given the unique costs of furnishing DMEPOS items and services in remote, isolated areas outside the contiguous United States such as Alaska, Guam, Hawaii, Puerto Rico, the United States Virgin Islands and other areas, we propose that any SPAs from programs in these areas be excluded from the calculation of the RSPAs in section a. In addition, we propose that the adjustments to the fee schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we propose that the adjustments to the fee schedule amounts for these areas be based on the higher of the average of SPAs for CBAs in areas outside the contiguous United States (for example, Honolulu) or the national ceiling limit applied to the payment adjustments for areas within the contiguous United States. We believe that, to the extent that SPAs from non-contiguous areas are available, these amounts should be used in making adjustments to the payment amounts for other areas outside the contiguous United States since the challenges and costs of furnishing DMEPOS items and services in all remote, isolated areas is similar. We also believe that the payment adjustments for these areas, like those for the proposed rural and frontier states, should not be lower than the national ceiling established for items and services furnished in the contiguous United States. Areas outside the contiguous United States generally have higher shipping fees and other costs. We believe the SPAs in

Honolulu and other areas outside the contiguous United States reflect these costs and could be used to adjust the fee schedule amounts for these areas without limiting access to DMEPOS items and services. However, in the event that the national ceiling limit described in section b above is greater than the average of the SPAs for CBPs in areas outside the contiguous United States, we propose that the higher national ceiling amount be used in adjusting the fee schedule amounts for areas outside the contiguous United States in order to better ensure access to DMEPOS items and services.

We are soliciting comments on these proposals.

2. Methodology for Items and Services Included in Limited Number of Competitive Bidding Programs

In some cases, there may not be a sufficient number of CBAs and SPAs available for use in computing RSPAs, and therefore, a different methodology for implementing section 1834(a)(1)(F)(ii) of the Act would be necessary. For items and services that are subject to competitive bidding and have been included in CBP in no more than 10 CBAs, we propose that payment amounts for these items in all non-competitive bidding areas be adjusted based on 110 percent of the average of the SPAs for the areas where CBPs are implemented. Using a straight average of the SPAs rather than a weighted average of the SPAs gives SPAs for the various CBAs equal weight regardless of the size of the CBA. We believe this avoids giving undo weight to SPAs for more heavily populated areas. We are proposing the additional 10 percent adjustment to the average of the SPAs to account for unique costs such as delivering items in remote, isolated locations, but would make this a uniform adjustment for program simplification purposes. This issue is discussed in more detail below.

Under the DMEPOS CBP, there may be items and services for which implementation of

CBPs could generate significant savings for the beneficiary and/or program, but which are furnished infrequently in most MSAs. In some cases, such items and services could be combined with other items and services under larger PCs or included in mail order competitions, to the extent that these are feasible options. For example, combining infrequently used traction equipment and frequently used hospital beds in the same product for bidding purposes would ensure that any beneficiary that needs traction equipment in the CBA would have access to the item from the suppliers also contracted to furnish hospital beds in the area. This would make it feasible to include traction equipment in numerous MSAs throughout the country and would allow use of the RSPA methodology described above. However, if a PC was established just for traction equipment for bidding purposes, the volume of items furnished in certain MSAs may not be sufficient to generate viable competitions under the program because there may be a limited number of suppliers interested in competing to furnish the items in local areas. Nonetheless, if significant savings for the beneficiary and/or program are possible for the equipment, we are mandated to phase the items in under the DMEPOS CBP.

In addition, for lower volume items within large PCs, such as wheelchair accessories, we propose to include these items in a limited number of local competitions rather than in all CBAs to reduce the burden for suppliers submitting bids under the programs as a whole. In these cases, for the purposes of implementing section 1834(a)(1)(G) of the Act, we propose that payment amounts for these items in all areas where CBPs are not implemented be adjusted based on 110 percent of the average of the SPAs for the areas where CBPs are implemented. We are proposing the additional 10 percent adjustment to the national average price to account for unique costs in certain areas of the country such as delivering items in remote, isolated locations. For example, the PC for standard mobility in the 9Round 1 CBAs includes 25 HCPCS

codes for low volume wheelchair accessories that are not included in the PC for standard wheelchairs, scooters, and related accessories in the 100 Round 2 CBAs. We propose that payment amounts for these items in areas where CBPs are not implemented be adjusted based on 110 percent of the average of the SPAs for the 9Round 1 areas where CBPs are implemented. Alternatively, we could include these low volume items in all PCs in all 109 CBAs and suppliers would need to develop bid amounts and enter bids for these 25 codes for low volume items such as toe loop holders, shock absorbers and IV hangers. Including these 25 Healthcare Common Procedure Coding System (HCPCS) codes for low volume wheelchair accessories in the PCs under the 9 Round 1CBAs means that suppliers submitting bids for wheelchairs have 25 bid amounts to develop and enter per CBA for these items, or a total of 225 bid amounts to develop and enter for these low volume items if bidding for wheelchairs in all 9 Round 1 CBAs. In contrast, including these codes in the PCs under all 109CBAs means that suppliers submitting bids for wheelchairs have 2,725 bid amounts to develop and enter for these low volume items, if biding for wheelchairs in all 109 CBAs. We believe that adjusting fee schedule amounts based on SPAs from 10 or fewer CBAs achieve the savings mandated by the statute for these items while greatly reducing the burden on suppliers and the program in holding competitions for these items in all 109 CBAs across the country.

Finally, if contracts and SPAs for low volume items included in a limited number of CBAs expire and the items are not included in future CBPs, we propose to use the information from the past competitions to adjust the payment amounts for these items nationally based on 110 percent of the average of the SPAs for the areas where CBPs were implemented. Even though the SPAs may no longer be in effect, we believe it is reasonable to use the information to reduce excessive payment amounts for items and services as long as the SPAs did not result in a

negative impact on access to quality items and services while they were in effect and as long as the amounts are adjusted to account for increases in costs over time. For example, 4 codes for adjustable wheelchair seat cushions were included in the Round 1 Rebid, with SPAs that were approximately 25 percent below the fee schedule amounts being in effect in 9 CBAs from January 2011 thru December 2013. These items were not bid in future rounds due to the low volume of use relative to other wheelchair seat cushions. During the course of the 3-year contract period when the SPAs were in effect in the 9 areas, there were no reports of access problems and there were no negative health outcomes as a result of including these items under CBPs. For the future, savings for these items could be achieved by including them in future competitions or by using the previous SPAs, updated by an economic update factor to account for increases in costs. If the decision is made not to include these items in future competitions, we believe savings can and should still be obtained based on information from the previous competitions.

We are soliciting comments on these proposals.

3. Adjusted Payment Amounts for Accessories used with Different Types of Base Equipment

There may be situations where the same accessory or supply identified by a HCPCS code is used with different types of base equipment, and the item (HCPCS code) is included in one or more PCs under competitive bidding for use with some, but not all of the different types of base equipment it is used with. For these situations, we propose to use the weighted average of the SPAs from CBPs and PCs where the item is included for use in adjusting the payment amounts for the item (HCPCS code). We believe that it would be unnecessarily burdensome to have different fee schedule amounts for the same item (HCPCS code) when it is used with similar, but

different types of base equipment. We believe that the costs of furnishing the accessory or supply should not vary significantly based on the type of base equipment it is used with.

Therefore, we seek public comments on addressing situations where an accessory or supply identified by a HCPCS code is included in one or more PCs under competitive bidding for use with more than one type of base equipment. In these situations, we propose to calculate the SPA for each CBA by weighting the SPAs from each PC in that CBA by national allowed services. This would result in the calculation of a single SPA for the item for each CBA. The single SPA per code per CBA would then be used in applying the payment adjustment methodologies proposed above. For example, HCPCS code Exxx1 describes a tray used on a wheelchair. Exxx1 was included in a PC for manual wheelchairs in all CBAs and in a separate, second PC for power wheelchairs in all CBAs. SPAs for Exxx1 under the manual wheelchair PC are different than the SPAs for Exxx1 under the power wheelchair PC.

Under the proposal, national allowed services would be used to compute a weighted average of the SPAs for Exxx1 in each of the CBAs. So, rather than having 2 different SPAs for the same code in the same CBA, we would have 1 SPA for the code for the CBA. If the item is included in only one PC, we propose to use the SPAs for the item from that PC in applying the payment adjustment methodologies proposed above.

We are soliciting comments on these proposals.

4. Adjustments to Single Payment Amounts that Result from Unbalanced Bidding

Within the HCPCS there are instances where there are multiple codes for an item that are distinguished by the addition of a hierarchal feature(s). For example, one code may describe an enteral nutrition infusion pump with an alarm and another code may describe a less sophisticated pump without an alarm. Under competitive bidding, the code with the higher utilization would

receive a higher weight and the bid for this item would have a greater impact on the composite bid and competitiveness of the supplier's overall bid for the PC within the CBP than the bid for the less frequently used alternative. This can result in unbalanced bidding where the bids and SPAs for the item without the additional features is higher than the bids and SPAs for the item with the additional features due to the fact that the item with the features is utilized more than the item without the features and therefore receives a higher weight. We believe that it is not inherently reasonable for payment amounts for equipment with fewer features or functionality to be higher than payment amounts for equipment with additional features or functionality.

For example, HCPCS code B9000 describes an enteral nutrition infusion pump without alarm, whereas code B9002 describes an enteral nutrition infusion pump with alarm. Both codes have identical fee schedule amounts. Based on paid claims data, only 176 Medicare beneficiaries received the pump without the alarm in 2012, whereas 52,531 Medicare beneficiaries received the pump with the alarm in 2012. Both pumps are included in the PC for enteral nutrients, supplies, and equipment. As a result of the significantly higher utilization of code B9002, this code received a much higher item weight under the CBP than code B9000, and, as a result, a supplier could submit a much higher bid for B9000 than for B9002 with virtually no impact on their composite bid. Under Round 2, unbalanced bidding resulted in SPAs for code B9000 without the alarm being 6 percent higher on average than the SPAs for code B9002 with alarm. Unbalanced bidding also occurred under Round 2 in the case of standard power wheelchairs, with SPAs for infrequently used Group 1, standard weight power wheelchairs (codes K0815 and K0816) being 16 percent higher on average than the SPAs for the much more frequently used Group 2 versions (codes K0822 and K0823). Based on paid claims data, only 474 Medicare beneficiaries received Group 1 power wheelchairs described by codes K0815 and

K0816 in 2012, whereas 196,968 Medicare beneficiaries received higher performing Group 2 power wheelchairs described by codes K0822 and K0823 in 2012. The long term solution for avoiding cases of unbalanced bidding is to eliminate duplicate codes in the HCPCS. For the purpose of implementing section 1834(a)(1)(G) of the Act, and in making adjustments to payment amounts under sections 1834(a)(1)(F)(ii), 1834(h)(1)(H)(ii), and 1842(s)(3)(B) of the Act, we propose that the payment amounts for infrequently used codes that describe items and services with fewer features than codes with more features be adjusted so that they are no higher than the payment amounts for the more frequently used codes with more features. For example, the adjusted fee schedule amounts for code B9000 would be set so that they are no higher than the adjusted fee schedule amounts for code B9002. We believe that without this provision, unbalanced bidding could result in fee schedule amounts for items that essentially represent lower levels of service being higher than fee schedule amounts for items representing higher levels of service, based on bids being higher for infrequently used items with lower weights and less features than bids for frequently used items with higher weights and more features. This could result in beneficiaries receiving the item with fewer features and functionality simply because the supplier has a financial incentive to furnish that item. This is especially important in light of the fact that use of the inherent reasonableness authority provided by section 1842(b)(8) and (9) of the Act cannot be used to further adjust payment amounts that are adjusted based on the mandate of section 1834(a)(1)(F)(ii) and the authority provided by sections 1834(h)(1)(H)(ii) and 1842(s)(3)(B) of the Act.

We seek public comments on this issue and our proposed provision to address this issue.

5. National Mail Order Program - Northern Mariana Islands

While Section 1847(a)(1)(A) of the Act provides that CPBs be established throughout the

United States, the definition of United States at section 210(i) of the Act does not include the Northern Mariana Islands. We therefore previously determined that the Northern Mariana Islands are not considered an area eligible for inclusion under a national mail order CBP. For the purpose of implementing the requirements of section 1834(a)(1)(F)(ii) of the Act, we are proposing that the payment amounts established under a national mail order CBP would be used to adjust the fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands. We propose that the adjusted fee schedule amounts would be equal to 100 percent of the amounts established under the national mail order CBP.

We are soliciting comments on these proposals.

6. Updating Adjusted Payment Amounts

In accordance with section 1834(a)(1)(F)(iii) of the Act, the adjusted payment amounts for DME must be updated as additional items are phased in or information is updated. We propose to add regulation text indicating that we would revise the adjusted payment amounts for DME, enteral nutrients, supplies, and equipment, and OTS orthotics each time a SPA is updated following one or more new competitions, which may occur at the end of a contract period, as additional items are phased in, or as new programs in new areas are phased in. This is required by section 1834(a)(1)(F)(iii) for DME. Since we believe it is reasonable to assume that updated information from CBPs would better reflect current costs for furnishing items and services, we are proposing regulations to require similar updates for enteral nutrients, supplies, and equipment, and OTS orthotics.

As we indicated above, if the only SPAs available for an item are those that were established under CBP that are no longer in effect, we propose to use these SPAs to adjust payment amounts using the methodologies described above and we propose to do so following

application of inflation adjustment factors. We propose that the inflation adjustment factor would be based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the last year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect. The adjusted payment amounts would continue to be updated every 12 months using the percentage change in the CPI-U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect. Use of the CPI-U as the update factor is consistent with how pricing amounts for DMEPOS have been updated since October 1, 1985, when the CPI-U was used in calculating the IIC for use in calculating reasonable charges. The CPI-U was used in updating reasonable charge data for use in calculating the initial fee schedule amounts and is used in determining the covered item update factors at sections 1834(a)(14), 1834(h)(4)(A), 1834(i)(1)(B), 1842(s)(1)(B) of the Act. If CBPs are subsequently established for the item, we propose that the SPAs established under these programs would be used in applying the payment adjustment methodologies described above.

If finalized, the payment amounts that would be adjusted in accordance with sections 1834(a)(1)(F)(ii) and (iii) of the Act for DME, section 1834(h)(2)(H)(ii) of the Act for orthotics, and section 1842(s)(2)(B) of the Act for enteral nutrients, supplies, and equipment shall be used to limit bids submitted under future competitions of the DMEPOS CBP in accordance with regulations at §414.414(f). Section 1847(b)(2)(A)(iii) prohibits the awarding of contracts under a CBP unless we are sure that total payments made to contract suppliers in the CBA are less than the payment amounts that would otherwise be made. In order to assure savings under a CBP, the fee schedule amount that would otherwise be paid is used to limit the amount a supplier may submit as their bid for furnishing the item in the CBA. If finalized, the payment amounts that

would be adjusted in accordance with sections 1834(a)(1)(F)(ii) and (iii) of the Act for DME, section 1834(h)(2)(H)(ii) of the Act for orthotics, and section 1842(s)(2)(B) of the Act for enteral nutrients, supplies, and equipment would be the payment amounts that would otherwise be made if payments for the items and services were not made through implementation of a CBP. Therefore, the adjusted fee schedule amounts would become the new bid limits.

We are soliciting comments on these proposals.

7. Summary of Proposed Methodologies

To summarize, under the proposed methodology in subsection 1 above which applies to items and services included in more than 10 CBAs, adjusted fee schedule amounts would be determined based on RSPAs limited by a national floor and ceiling. The RSPA would be established using the average of the SPAs for an item from all CBAs that are fully or partially located in the region. The payment amount for the item, with limited exceptions for areas outside the contiguous United States, would be equal to its RSPA but not less than 90 percent and not more than 110 percent of the national average, which is the average of the RSPAs weighted by the number of states in the region. The proposed methodology is modeled closely after the regional fee schedule payment methodology in effect today for P&O. For the purpose of establishing the regional boundaries, we propose to use 8 regions developed by the Bureau of Economic Analysis (BEA) within the Department of Commerce: New England, Mideast, Great Lakes, Plains, Southeast, Southwest, Rocky Mountain, and Far West. For rural and frontier states, we propose that the payment amount would be 110 percent of the national average. For areas outside the contiguous United States, the payment amount would be the greater of the average of the SPAs in the non-contiguous areas or 110 percent of the national average. As described in subsection 2 above, we propose a different methodology for low volume items with

a limited number of SPAs. In addition, we propose to apply update factors to SPAs no longer in effect to adjust fee schedule amounts if no other data is available. Finally, we propose that adjustments would be made to account for SPAs for lower levels of service that are higher than SPAs for higher levels of service.

A summary of the proposed methodologies is provided in Table 37 below.

TABLE 37 - Summary of Proposed Methodologies for Adjusting Payment in Non-Bid Areas

Proposed Methodology	Calculations
1) Adjustments for Items Included in More than 10 CBAs*	
Regional Adjustments Limited by National Parameters for Items Furnished Within the Contiguous United States	Adjusted payment equal to the RSPA (calculated using the un-weighted average of SPAs from CBAs that are fully or partially located with a BEA region) limited by a national floor and ceiling. The national ceiling and floor would be set at 110 percent and 90 percent, respectively, of the national weighted RSPA average (average of the RSPAs applicable to each of the 48 contiguous states and DC).
Adjustments for Rural and Frontier States	Adjusted payment for designated States based on 110 percent of the national weighted RSPA average
Adjustments for Items Furnished Outside the Contiguous United States	Adjusted payment for non-contiguous areas (e.g., Alaska, Guam, Hawaii) based on the higher of the average of SPAs for CBAs in areas outside the contiguous U.S. or 110 percent of the national weighted RSPA average applied to adjustments within the contiguous U.S.
2) Adjustments for Lower Volume or Other Items Included in 10 or Fewer CBAs*	Adjusted payment based on 110 percent of the un-weighted average of the SPAs for the areas where CBPs are implemented for contiguous and non-contiguous areas of the United States.
3) Adjustments for Items Where the Only Available SPA is from a CBP No Longer in Effect	Payment based on adjusted payment determined under 1) or 2) above and adjusted on an annual basis based on the CPI-U update factors from the mid-point of the last year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into

Proposed Methodology	Calculations
	effect.
4) Adjustments for Accessories Used with Different Types of Base Equipment	
Adjustments for Accessories Included in One CBP Product Category	SPAs for the item from that one Product Category would be used in determining the adjusted payment amounts under methodologies 1) or 2)
Adjustments for Accessories Included in One or More CBP Product Category	A weighted average of the SPAs for the item in each CBA where the item is included in more than one Product Category would be used to determine the adjusted payment amounts under methodologies 1) or 2)
5) Payment Adjustments to Northern Mariana Islands Using the National Mail Order SPAs	Fee schedule amounts adjusted to equal the SPAs under the national mail order CBP

*Note: We are also proposing to adjust the SPAs for a lower level of service item to not exceed the SPAs of a higher level of service item prior to applying the methodologies in 1) and 2) above in instances where the SPA for the lower level of service item exceeds the higher level of service item.

VI. Proposed Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished under the Competitive Bidding Program

A. Background

The payment rules for DME have changed significantly over the years since 1965, resulting in the replacement of the original monthly rental payment methodology with lump sum purchase and capped rental payment rules, as well as separate payment for repairs, maintenance and servicing, and replacement of expensive accessories for beneficiary-owned equipment. In our experience, these payment rules have been burdensome to administer and have added program costs associated with expensive wheelchair repairs and payment for loaner equipment, and have significantly increased costs associated with frequent replacement of expensive accessories at regular intervals for items such as CPAP devices. We estimate that separate payments for CPAP accessories have increased annual expenditures by approximately $200

million. In some cases, the costs associated with maintaining DME owned by beneficiaries equals or exceeds any savings that might be generated from capping rental payments. In the case of repairs, suppliers are not mandated to service the equipment they furnish once title transfers to the beneficiary – any supplier can provide these services. This could create a hardship for the beneficiary since they must find a supplier willing to repair the equipment and their separate coinsurance payments could be substantial if the repair services are extensive. According to § 414.408(h)(3) of our regulations, payment on a capped rental basis also results in the restart of periods of continuous use for capped rental items, and according to § 414.408(i)(2) of our regulations, an extension in the rental cap periods for oxygen equipment when a beneficiary transitions from a non-contract supplier to a contract supplier at the start of a new CBP. These issues were discussed in the February 26, 2014, ANPRM noted above (79 FR 10758). It is not clear, however, the extent to which the capped rental requirement, combined with separate payments for supplies, accessories, repairs, and program administration, overall results in net savings or net costs to the Medicare program, particularly if we examine the effects of the policy on specific DME items and services.

Under the Social Security Amendments of 1965 (P.L. 89-97) enacted on July 30, 1965, Medicare Part B covered only rental of DME items. The Social Security Amendments of 1967 (P.L. 90–248), approved January 2, 1968, revised the statute to provide authority for making payment for DME on a purchase basis as well as on a rental basis. On May 12, 1972, the Government Accountability Office (GAO) issued a report to the Congress entitled "Need for Legislation to Authorize More Economical Ways of Providing Durable Medical Equipment under Medicare" (B-164031(4), May 12, 1972) that led to Social Security Amendment (section 245) in 1972. Section 245 of the Social Security Amendments of 1972 (Public Law 92-603)

enacted on October 30, 1972, modified the payment provisions for specific equipment items to LCL of reasonable charges to contain the costs of DME. This law allowed the Department of Health and Human Services (HHS) to experiment with reimbursement approaches and implement any purchase approach found to be feasible and economical in order to avoid prolonged rental payments for expensive DME. Furthermore, section 16 of the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Public Law 95-142), enacted on October 25, 1977, amended section 1833(f) of the Act to read as follows:

> In the case of durable medical equipment to be furnished an individual as described in section 1861(s)(6), the Secretary shall determine, on the basis of such medical and other evidence as he finds appropriate (including certification by the attending physician with respect to expected duration of need), whether the expected duration of the medical need for the equipment warrants a presumption that purchase of the equipment would be less costly or more practical than rental. If the Secretary determines that such a presumption does exist, he shall require that the equipment be purchased, on a lease-purchase basis or otherwise, and shall make payment in accordance with the lease-purchase agreement (or in a lump sum amount if the equipment is purchased other than on a lease-purchase basis); except that the Secretary may authorize the rental of the equipment notwithstanding such determination if he determines that the purchase of the equipment would be inconsistent with the purposes of this title or would create an undue financial hardship on the individual who will use it.

This law required HHS to make lease-purchase decisions on a case-by-case basis based on whether purchase would be less costly or more practical than rental and reimburse on the basis of a lump-sum purchase or a lease/purchase arrangement. To implement the change in the

law, HHS issued final regulations (45 FR 44287) on July 1, 1980. This regulation provided that the purpose of the lease purchase payment arrangement for new and used DME was to reduce program costs caused by long and costly rentals of the equipment and reduce beneficiary expenses for annual deductibles and coinsurance for unnecessarily long rentals. However, the regulations were not implemented until 1985 because of uncertainty as to whether they would result in program savings. During the same time period, amidst growing concerns by the agency about prolonged and excessive rentals, Williams College under a grant administered by HCFA (now CMS) issued a report entitled "Determinants of Current and Future Expenditures on Durable Medical Equipment by Medicare and its Program Beneficiaries" on April 1983. This report estimated the excess rentals at about 14 percent of rental payments. Following this report, a GAO report titled "Procedures for avoiding excess rental payments for durable medical equipment should be modified" issued on July 30, 1985, showed that excess rentals represented about 54 percent of the amounts allowed for lower cost items ($120 or less) and 34 percent for higher cost items. In the GAO report, excess rental payments represented the difference between total Medicare rental payments for an item of equipment and Medicare reimbursement for the item if it had been purchased. GAO data showed substantially fewer short-term rentals than Williams' data (22 percent versus 64 percent for episodes lasting 1 or 2 months) and substantially more long-term rentals (33 percent. versus 8 percent for episodes lasting more than 12 months).

GAO concluded that savings would result for reimbursing low-cost items on a purchase basis because about two-thirds of the rented items in its study costing $100 or less would have been cheaper to buy. GAO also found that sufficient data was not available to reliably predict when purchasing a high cost item would be less costly than renting it. The report indicated that purchase price was reached by about month 7, with additional monthly rental payments beyond

month 7 resulting in excess rental payments cost thereafter. Because of the uncertainty with respect to the high-cost items, GAO recommended alternative reimbursement approaches such as adjustment of the rental rate and requirements that suppliers accept whatever percentage is adopted.

The report further discussed HHS and supplier comments on the GAO report draft. HHS also commented that the cap proposal did not address the issues associated with ownership of DME after the maximum amount of the cap had been reached. The supplier comments included recommendations from National Association of Medical Equipment Suppliers (NAMES) proposal for considering alternative methods that limited rental payments after a specified number of months such as 24 months for non-oxygen-related DME items (wheelchairs and hospital beds). At the end of the 2-year period, any item still being rented would be subject to a monthly maintenance fee in lieu of rental based on 30 percent of the latest allowable rental charge. Title to the items would remain with the supplier, and the item would be returned when no longer needed.

Section 4062 of the Omnibus Budget Reconciliation (OBRA) Act of 1987 (Public Law 100-203), was enacted on December 22, 1987. This legislation added section 1834 (a) to the Act, which mandated payment categories and rules for DME that dictated whether payment would be made on a rental and/or purchase basis for items in each category. These changes were intended to align payment rates and achieve savings in the Medicare program. The new payment categories mandated by section 1834(a) of the Act were promulgated via regulation at §414.210. Sections 1834(a) (2) through (a) (5) and 1834(a) (7) of the Act set forth separate payment categories of 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 or capped rental items.

Section 13543 of the Omnibus Budget Reconciliation Act (OBRA) of 1993 (Public Law 103-66), was enacted on August 10, 1993, and amended section 1834 (a) to reclassify nebulizers, CPAP devices, aspirators or suction pumps, and intermittent assist or respiratory assist devices from the category of items requiring frequent and substantial servicing to the capped rental payment category. It also mandated separate payment for accessories used in conjunction with these items. Section 4315 of the Balanced Budget Act of 1997 (P.L. 105-33), enacted on August 5, 1997, added section 1842(s) to the Act, to authorize a fee schedule for PEN, which was promulgated via regulations at § 414.100 (66 FR 45173, August 28, 2001). In 42 CFR Part 414, Subpart C of the regulations, govern payment on a fee schedule basis for PEN nutrients, equipment and supplies. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

Section 1847 of the Act establishes the Medicare DMEPOS Competitive Bidding Program (CBP) ("Competitive Bidding Program"). Under the CBP, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in 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 competitively bid items and services is made on an assignment-related basis equal to 80 percent of the applicable SPA amount, less any unmet Part B deductible.

Payment errors and increased costs can occur as a result of paying separately for equipment, repairs, accessories, and routine maintenance and servicing associated with

beneficiary ownership of DME after the 13-month capped rental period or initial lump sum purchase, which have increased the risk for improper payments. The findings published in the August 2010 OIG report (OEI-07-08-00550) titled "A review of claims for capped rental durable medical equipment" reveal that from 2006 to 2008, Medicare erroneously paid separately for these services. Medicare paid $2.2 million for routine maintenance and servicing of capped rental DME; from 2006 to 2008, Medicare erroneously allowed nearly $4.4 million for repairs for beneficiary-owned capped rental DME that failed to meet payment requirements; and in 2007, Medicare allowed nearly $27 million for repair claims of beneficiary-owned capped rental DME that failed to meet payment requirements.

Based upon our experience, the ownership of equipment by beneficiary after lump sum purchase or after the end of 13 months capped rental period leads to complicated administrative procedures. The program must keep track of separate payment, coverage, medical necessity, and other rules for a number 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 edits for processing millions of claims for these items and services. 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 necessary for the effective use of DME.

B. Proposed Provisions

We believe that we have general authority under section 1847(a) and (b) of the Act to

establish payment rules for DME and enteral nutrition equipment that are different than the rules established under section 1834(a) of the Act for DME, section 1842(s) for enteral nutrients, supplies, and equipment, and, section 6112(b) of Omnibus Budget Reconciliation (OBRA) Act of 1989 (Public Law 101-239) for enteral pumps. We believe that lump sum purchase and capping rentals for certain DME and enteral nutrition may no longer be necessary to achieve savings under the program when competitive bidding can be used to establish a reasonable monthly payment. We also believe that payment on a continuous rental basis – that is, ongoing monthly payments not subject to a cap – could help to ensure that medically necessary DME and enteral nutrition equipment is kept in good working order for the entire duration of medial need and would make it easier for beneficiaries to change from one supplier to another since the new supplier would not be faced with a finite number of rental payments. Currently, there is no requirement that a supplier take responsibility for repairing equipment once it is owned by a beneficiary, which may cause difficulties for the beneficiary to find a supplier to undertake such services. We believe that continuous rental payment would eliminate such issues because the supplier of the rented equipment would always be responsible for keeping the equipment in good working order. We do not believe that continuous monthly rental payments for DME and enteral nutrition would negatively impact access to items and services and could potentially be implemented in a manner that does not increase program expenditures since suppliers would be paid based on bids for furnishing the same general items and services they would otherwise provide. In addition, since Medicare payment for rental of DME and enteral nutrition equipment include payment for maintenance and servicing of the rented equipment, the suppliers would be directly responsible for meeting the monthly needs of the beneficiary in terms of keeping the rented equipment in good working order.

As indicated in section IV above, CMS issued an ANPRM: Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information From Competitive Bidding Programs on February 26, 2014 (79 FR 10754). As part of this ANPRM, comments were solicited on whether payment on a bundled, continuous rental basis for DME and enteral nutrition should be adopted under the DMEPOS CBP. Some commenters were concerned that services such as replacement of CPAP masks and equipment repairs would not be provided if they were not paid for separately. Some commenters supported bundling payments for oxygen and enteral nutrition. Some commenters suggested that the bundling methodology be tested first before it is utilized on a wide scale basis. Thirteen commenters that included beneficiaries, beneficiary advocacy organizations, occupational therapists, and physical therapists raised concerns that access to items such as highly configured wheelchairs and speech generated devices might be disrupted under a continuous monthly bundled rental payment that includes equipment rental, replacement accessories and repairs. They felt that payment on a rental basis would result in patients losing access to these devices when they entered institutions such as hospitals and skilled nursing facilities where separate payment for DME is prohibited by section 1861(n) of the Act.

For items that continue to be paid for on a lump sum purchase basis or a capped rental basis where ownership of equipment transfers to the beneficiary following the capped rental period, we solicited comments on whether the supplier of the equipment should be responsible for repairing the equipment following transfer of title. Some commenters were opposed to the idea of making contract suppliers of purchased equipment responsible for ongoing repairs of equipment following transfer of title to the beneficiary. They stated that it would be a significant

burden on suppliers to provide ongoing maintenance of equipment they furnished on a purchase basis, especially if the beneficiary moved out of the area.

After carefully considering comments received in response to the ANPRM, we are proposing to update the regulations to include proposed special payment rules described below that would be utilized in paying claims for certain DME or enteral nutrition under a limited number of CBPs. As explained in more detail in the sections that follow below, we propose to revise the regulation by adding a new section at 42 CFR § 414.409 with special payment rules to replace specific payment rules at § 414.408 for these items and services in these CBPs. We also propose to revise § 414.412 regarding submission of bids for furnishing items and services paid in accordance with these special payment rules. We seek comments on these proposals.

We propose to phase-in the special payment rules described in sections 1 and 2 below in a limited number of areas for a limited number of items initially to determine whether it is in the best interest of the Medicare program and its beneficiaries to phase these rules in on a larger scale based on evaluation of the rules' effects on Medicare program costs, and quality of/access to care. In order to monitor the impact of phasing in the special payment rules in no more than 12 CBAs, we propose that, at a minimum, we would utilize evaluation criteria that are consistent with the current evaluation criteria for monitoring the impact of the CBP on utilizers of items and services in CBAs. To evaluate the quality of care for beneficiaries affected by the special payment rules, we propose that, at a minimum, we would utilize health status outcomes based criteria that would measure specific indicators such as mortality, morbidity, hospitalizations, emergency room and other applicable indicators unique to each product category. To evaluate beneficiary access to necessary items and services we propose that, at a minimum, we would monitor utilization trends for each product category and track beneficiary

complaints related to access issues. To evaluate the cost of the program, we propose that, at a minimum, we would analyze the claims data for allowed services and allowed cost for each product category and the associated accessories, supplies and repair cost in the 12 CBAs and the comparator CBAs. We propose to analyze the effect of the proposed payment rules on beneficiary cost sharing.

We propose that in any competition where these rules are applied, suppliers and beneficiaries would receive advance notice about the rules at the time the competitions that utilize the rules are announced. The combined, total number of CBAs where the proposed rules in either section 1 or 2 would apply would be limited to twelve. In other words, it would not be twelve CBAs for the rules in section 1 and an additional twelve CBAs for the rules in section 2, but 12 CBAs total. In addition, we propose that the PCs listed below would be phased in to include one or more of the CBAs that would number no more than twelve total. In addition, if a determination is made to phase-in these rules on a larger scale in additional areas and for additional items based on program evaluation results regarding cost, quality, and access, the process for phasing in the rules and the criteria for determining when the rules would be applied would be addressed in future notice and comment rulemaking. This rulemaking would also address how the methodology for using these SPAs to adjust fee schedule amounts would need to be revised.

The Affordable Care Act (Patient Protection and Affordable Care Act of 2010, P.L. 111-148 (March 23, 2010), Sec. 3021) establishes the Center for Medicare and Medicaid Innovations (CMMI) which is authorized to test models to reduce Medicare and Medicaid expenditures while preserving or improving quality for beneficiaries of those two programs. The provision includes appropriations of $10 billion for fiscal years 2011 through 2019. We solicit comments on the

option for testing the above special payment rules for DME and enteral nutrition using the CMMI demonstration authority in no more than 12 CBAs that would allow us to test and evaluate the special payment rules on a wider scale and determine whether the special payment rules reduce Medicare expenditure while preserving or improving the quality for Medicare beneficiaries. Regardless of the authority used to phase in or test these special payment rules, we would undertake rigorous evaluation to determine the rules' effects on program costs, quality, and access.

We seek comments on the specific proposals below.

1. Payment on a continuous rental basis for select items

We propose to revise the regulation at 42 CFR § 414.409 to allow for payment on a continuous monthly rental basis under future competitions in no more than 12 CBAs for one or more of the following categories of items and services: enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory assist devices, and hospital beds. We believe that 12 CBAs represents a limited number of CBAs yet would allow testing in different regions of the country. We propose that the SPAs established under the special payment rules would be based on bids submitted and accepted for furnishing rented DME and enteral nutrition on a monthly basis. We propose that the SPAs would represent a monthly payment for each month that rented DME or enteral nutrition is medically necessary. The SPA for the monthly rental of DME would include payment for each item and service associated with the rental equipment including the ongoing maintenance and servicing of the rental equipment, and replacement of supplies and accessories that are necessary for the effective use of the equipment. In the case of enteral nutrition, we propose that the monthly SPA would include payment for all nutrients, supplies and equipment. Suppliers would

be responsible for furnishing all items and services in the applicable CBA needed each month based on the physician's order. For example, in addition to furnishing the CPAP device, the supplier would be responsible for furnishing the accessories used with the device such as masks, tubing, headgear, humidifiers, etc., as well as all maintenance and servicing of the equipment. For wheelchairs, the supplier would be responsible for furnishing the type of wheelchair and all options and accessories used with the wheelchair that are needed by the patient, as well as well as all maintenance and servicing of the equipment. For hospital beds, the supplier would be responsible for furnishing the type of hospital bed and all accessories used with the hospital bed (for example, mattresses, side rails, trapeze bars, etc.) needed by the patient, as well as all maintenance and servicing of the equipment. As discussed in more detail below, phasing in these rules would help us determine the impact on Medicare expenditures as well as beneficiary access to items and services and other possible costs and benefits.

We seek comments on this proposal.

a. Enteral nutrition

We propose to implement future competitions for enteral nutrition in no more than 12 CBAs, where payment would be based on bids submitted for furnishing all enteral nutrients, supplies, and equipment needed on a monthly basis. We propose that the suppliers would submit a single bid for each CBA for furnishing all items and services related to furnishing such enteral nutrients, supplies, and equipment in the applicable CBA needed by a beneficiary on a monthly basis. We are soliciting comments on whether alternatives to submitting a single bid for enteral nutrition should be considered, such as having separate categories based on mode of delivery (syringe fed, pump fed, or gravity fed) or separate categories based on the type of nutrients delivered. We selected the category of enteral nutrition because we believe that payment on a

separate, piecemeal basis for daily supplies, calories of nutrients furnished, and monthly rental of equipment the pumps is unnecessary and overly complex. For example, for a pump-fed patient, the beneficiary must choose whether they wish to rent the pump or purchase the pump. If the beneficiary chooses to rent the pump, the supplier is required to continue furnishing the pump until the capped rental period is over, but then is allowed to bill for maintenance and servicing of the pump once every 6 month, but only if maintenance and servicing is needed and furnished. The supplier must also submit claims for daily supply kits as well as feeding tubes furnished in addition to billing for every 100 calories of enteral nutrient furnished. Finally, the supplier must bill for the pole used to hold the pump; however, the monthly rental payments for the pole are not subject to the cap on rentals that the statute specifically requires for the pump and this is confusing. In addition, issues have been raised regarding replacement parts and supplies for beneficiary-owned enteral nutrition infusion pumps when the manufacturer elects to discontinue the brand and model of pump owned by the beneficiary. Neither the beneficiary nor the supplier is able to obtain supplies that the manufacturer no longer sells and the Medicare rules would generally not allow for the purchase of a new pump since this would be duplicate equipment. We seek comments on this proposal.

b. Oxygen and oxygen equipment

We propose to implement future competitions for oxygen and oxygen equipment in no more than 12 CBAs, where payment would be based on bids submitted for furnishing all oxygen and oxygen equipment needed on a monthly basis. We propose that the suppliers would submit a single bid for each CBA for furnishing all items and services needed on a monthly basis, including all rented equipment and related accessories such as regulators, flowmeters, nasal cannulas, masks, tubing, humidifier bottles, tank stands and carts, and transtracheal catheters, as

well as well as all maintenance and servicing of the equipment and delivery of oxygen contents. We selected the category of oxygen and oxygen equipment because we believe the rental cap for oxygen equipment generates very little savings under CBPs. A small percentage of beneficiaries, approximately 25 percent based on our review of Medicare claims, reach the 36-month cap, which is extended by as much as 9 months at the start of a CBP, and the SPAs for oxygen contents furnished after the cap are roughly the same as the SPAs for furnishing oxygen and oxygen equipment during the 36-month rental cap period. In addition, recent issues related to suppliers abandoning beneficiaries after the rental cap has resulted in the need to pay for lost oxygen and oxygen equipment, eliminating any savings the rental cap might have achieved. Although section 1834(a)(5)(F)(ii)(I) of the Act mandates that the supplier receiving payment for the 36th month of continuous use must continue to furnish the oxygen and oxygen equipment for any period of medical need for the duration of the reasonable useful lifetime of the equipment, certain suppliers have failed to continue providing oxygen and oxygen equipment despite this requirement.

Section 414.226 provides that for oxygen and oxygen equipment, Medicare payments are modality neutral, with the exception that the portable oxygen equipment add-on payment for oxygen generating portable equipment (OGPE) is higher than the add-on payment for liquid and gaseous portable oxygen equipment. The Medicare monthly payment for oxygen and oxygen equipment includes payment for stationary equipment (concentrators, liquid, or gaseous stationary equipment) as well as payment for oxygen contents (stationary and portable). The add-on payment is only for the portable oxygen equipment and does not include payment for the portable oxygen contents. This fact is often confused and the portable oxygen add-on payment is erroneously viewed as a payment for portable oxygen contents as well as portable oxygen

equipment. In a majority of cases, beneficiaries receive both stationary oxygen and oxygen equipment and portable oxygen and oxygen equipment, so having a separate add-on payment for portable oxygen equipment only seems unnecessary. Under our proposal, for oxygen and oxygen equipment payment under the select CBPs, we propose to eliminate the 36-month cap on equipment payments and eliminate separate add-on payments for portable equipment and separate payment for oxygen contents. Under our proposal, the contract suppliers would continue to be responsible for furnishing equipment consistent with the requirements in §414.420.

We seek comments on this proposal.

c. Standard manual wheelchairs

We propose to implement future competitions for standard manual wheelchairs in no more than 12 CBAs, where payment would be based on bids submitted for furnishing standard manual wheelchairs and all accessories used in conjunction with the wheelchairs on a monthly basis. We propose that the suppliers would submit a single bid for each HCPCS code describing the wheelchair for each CBA for furnishing the wheelchair and all accessories and services needed on a monthly basis. We are soliciting on this proposal as well as comments on whether all standard manual wheelchairs should be described under one HCPCS code in order to simplify bidding and claims processing procedures. The current HCPCS codes for standard manual wheelchairs include standard, hemi (low seat), lightweight, high strength lightweight, heavy duty, and extra heavy duty wheelchairs described by codes K0001 thru K0004, K0006, and K0007 in the HCPCS. In view of comments to the ANPRM expressing concern regarding beneficiary impact of bundled arrangements for users of highly configured manual wheelchairs, we are requesting comment on what safeguards and monitoring approaches we should use to

ensure that access to these items is not disrupted for individuals transitioning between settings and/or residing in remote areas. We seek comments on this proposal.

d. Standard power wheelchairs

We propose to implement future competitions for standard power wheelchairs in no more than 12 CBAs, where payment would be based on bids submitted for furnishing standard power wheelchairs and all accessories used in conjunction with the wheelchairs on a monthly basis. We propose that the suppliers would submit a single bid for each HCPCS code describing the wheelchair for each CBA for furnishing the wheelchair and all accessories (including batteries) and services needed on a monthly basis. We are soliciting comments on whether all standard power wheelchairs should be described under one HCPCS code in order to simplify bidding and claims processing procedures. The current HCPCS codes for standard power wheelchairs include all group 1 and group 2 power wheelchairs that cannot accommodate rehabilitative accessories and features described by codes K0813 thru K0829 in the HCPCS. In view of comments to the ANPRM expressing concern regarding beneficiary impact of bundled arrangements for users of highly configured manual wheelchairs, we are requesting comment on what safeguards and monitoring approaches we should use to ensure that access to these items is not disrupted for individuals transitioning between settings and/or residing in remote areas.

We selected the categories of standard manual and power wheelchairs because we believe that payment on a separate, piecemeal basis for hundreds of various wheelchair options and accessories is unnecessary and overly complex. In addition, issues have been raised regarding access to repair of beneficiary-owned wheelchairs following the 13-month capped rental period. For example, there are hundreds of codes for various wheelchair accessories and separate payment for each of these items in addition to the payment for the wheelchair. The separate

billing, processing and payment of these claims would not be necessary given that the supplier can factor the costs of accessories into their bid for furnishing the rented equipment. In addition, the beneficiary's needs may change such that the beneficiary needs a different type of accessory from the one that was initially furnished by the supplier. Under the current rules, the accessory may not be covered if it is similar to the one that was already paid for by Medicare. If payments for all types of accessories are included in an ongoing, monthly rental amount for the wheelchair, the beneficiary can receive other accessories included in the program, provided such accessories are medically necessary.

We seek comments on this proposal.

e. CPAP and respiratory assist devices

We propose to implement future competitions for CPAP and respiratory assist devices in no more than 12 CBAs, where payment would be based on bids submitted for furnishing the CPAP or respiratory assist device and supplies, accessories, and services needed on a monthly basis. We propose that the suppliers would submit a single bid for each device for each CBA for furnishing all items and services needed on a monthly basis. We are soliciting comments on our proposal as well as whether all CPAP and respiratory assist devices should be described under one HCPCS code in order to simplify bidding and claims processing procedures. We selected the category of CPAP and respiratory assist devices because we believe the cost of paying separately for the expensive accessories used with these devices may exceed the amount of savings achieved from capping the rental payments for the equipment. We seek comments on this proposal.

f. Hospital beds

We propose to implement future competitions for hospital beds in no more than 12

CBAs, where payment would be based on bids submitted for furnishing hospital beds and all accessories used in conjunction with the hospital beds on a monthly basis. We propose that the suppliers would submit a single bid for each HCPCS code describing the hospital bed for each CBA for furnishing the hospital bed and all accessories and services needed on a monthly basis. We are soliciting comments on whether all hospital beds should be described under one HCPCS code in order to simplify bidding and claims processing procedures. We selected the category of hospital beds to allow us to determine the impact of the continuous monthly rental payment rule under CBP on beneficiary access, utilization rate and cost for an item that currently does not have beneficiary access issues or issues related to excessive cost for repair and accessories. We seek comments on this proposal.

g. Transition rules

We propose to revise the regulation at 42 CFR §414.409 to the include supplier transition rules for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory assist devices, and hospital beds that would be paid in accordance with the rules proposed in this section. We also propose to revise the regulation at 42 CFR §414.408 to provide a cross reference to proposed §414.409. We propose that changes in suppliers from a non-contract supplier to a contract supplier at the beginning of the CBP where the proposed payment rules would apply would simply result in the contract supplier taking on responsibility for meeting all of the beneficiary's monthly needs while receiving payment for each month of service. We developed these proposed rules based on that fact that for capped rented DME and oxygen and oxygen equipment, since rental caps would not apply under the proposed rules, there would be no need to restart or extend capped rental periods when a beneficiary transitions from a non-contract supplier to a contract supplier. We propose that

supply arrangements for oxygen and oxygen equipment, and rental agreements for standard manual wheelchairs, standard power wheelchairs, CPAP devices, respiratory assist devices, and hospital beds entered into before the start of a CBP and application of the payment rules proposed in this section would be allowed to continue so long as the supplier agrees to furnish all necessary supplies and accessories used in conjunction with the rented equipment and needed on a monthly basis. We propose that non-contract suppliers in these cases would have the option to continue rental agreements; however, we propose that as part of the process of allowing the rental agreements to continue, the grandfathered supplier would be paid based on the payment rules proposed in this section and based on the SPAs established under the CBPs incorporating the proposed rules.

We solicit comments on this proposed process.

We propose that in the event that a beneficiary relocates from a CBA where the rules proposed in this section apply to an area where rental cap rules apply, that a new period of continuous use would begin for the capped rental item, enteral nutrition equipment, or oxygen equipment as long as the item is determined to be medically necessary. We believe these rules that would result in a new period of continuous use are necessary to safeguard beneficiary access to covered items and services and plan to closely monitor the impact these rules have on beneficiary cost sharing before phasing in these rules in more than a limited number of CBAs.

We seek comments on these proposals.

h. Beneficiary-owned equipment

We propose that separate payment for all repairs, maintenance and servicing, and replacement of supplies and accessories for beneficiary-owned DME or enteral nutrition equipment would cease in the CBAs where the payment rules proposed under this section are in

effect. We propose that if the beneficiary has a medical need for the equipment, the contract supplier would be responsible for furnishing new equipment and servicing that equipment. This option would ensure that beneficiaries continue to receive medically necessary equipment, including the supplies, accessories, maintenance and servicing that may be needed for such equipment. Please note that this would not apply to items which are not paid on a bundled, continuous rental basis. We propose to revise the regulations at § 414.409 to specify that any beneficiary who owns DME or enteral nutrition equipment and continues to have a medical need for the items should these rules take effect in a CBA where they reside, would have the option to obtain new equipment, if medically necessary, and related servicing from a contract supplier. We are requesting comment as to whether a transitional process should be considered when claims are selected for review to determine whether they are reasonable and necessary and other safeguards are required to ensure timely delivery of the replacement DME so that individuals' mobility and ability to live independently is not adversely impacted by delays. While this could potentially increase beneficiary cost sharing, it would eliminate issues associated with repair of beneficiary-owned equipment. We plan to closely monitor the impact of this proposed provision, should it be finalized.

We seek comments on this proposal, including issues related to the ability of low income beneficiaries to afford additional cost sharing, and how best to monitor beneficiary impact within the 12 CBAs in which these new rules would be phased in.

2. Responsibility for repair of beneficiary-owned power wheelchairs furnished under CBPs

We propose to revise the regulation at 42 CFR § 414.409 to add a new payment rule that would apply to future competitions for standard power wheelchairs in no more than 12 CBAs where payment is made on a capped rental basis and not on the basis of the rules proposed under

§1 above. In these CBPs, we propose that contract suppliers for power wheelchairs would be responsible for all necessary repairs and maintenance and servicing of any power wheelchairs they furnish during the contract period under the CBP, including repairs and maintenance and servicing of power wheelchairs after they have transferred title to the equipment to the beneficiary. We propose that this responsibility would end when the reasonable useful lifetime established for the power wheelchair expires, medical necessity for the power wheelchair ends, the contract period ends, or the beneficiary relocates outside the CBA. We propose that the contract supplier would not receive separate payment for these services and would factor the costs of these services into their bids. We believe that based on existing maintenance and servicing requirements, suppliers could project the cost of continuing to repair and service equipment of various ages once title to the equipment has transferred to the beneficiary. As indicated above, under existing rules, the supplier that transfers title to the equipment to the beneficiary after the 13 month period of continuous use is not held responsible for repairing the equipment they furnish after the beneficiary takes over ownership of the equipment. Therefore, we believe the propose rule would safeguard the beneficiary and better ensure that the beneficiary continues to have equipment in good working order to meet their needs. We propose that the contract supplier would not be responsible for repairing power wheelchairs they did not furnish. We propose that services to repair beneficiary-owned equipment furnished prior to the start of the contract period would be paid in accordance with the standard payment rules at § 414.210(e).

We seek comments on this proposal.

3. Phasing in the proposed payment rules in CBAs

We propose that the CBAs where the proposed rules in §§ 1 or 2 above would be applied would be for MSAs with a general population of at least 250,000 and a Medicare Part B enrollment population of at least 20,000 that are not already included in Round 1 or 2. Based on 2012 population estimates from the Census Bureau and 2011 Medicare enrollment data, there are approximately 80 MSAs that would satisfy this criteria. Selecting MSAs not already included in Round 1 or 2 would allow competitions and rules associated with these competitions to begin after the final rule would take effect in areas that are comparable to existing CBAs. We propose that the boundaries of the CBAs would be established in accordance with the rules set forth at §§ 414.406 and 414.410. We propose that additional CBPs for the items identified in §§ 1 and 2 above be established in "comparator" CBAs concurrent with CBPs where the proposed rules would be applied. Payment for items and services in the comparator CBAs would be made in accordance with the existing payment rules in § 414.408. We propose that these additional comparator CBAs and CBPs be established to facilitate our analysis of the effect of the payment rules proposed in sections 1 and 2 above compared to the effect of the existing payment rules in § 414.408. We propose that for each CBP where either the rules in section 1 or 2 above are implemented, a comparator CBA and CBP would be established. We propose that the comparator CBAs be selected so that they are located in the same state as the CBA where the special payment rules would apply and are similar to the CBAs in which the proposed payment rules would be implemented based on a combination of factors that could include geographic location (region of the country), general population, beneficiary population, patient mix, and utilization of items. We are proposing to establish the comparator CBAs and CBPs to enable us to review the impact of the proposed payment rules on expenditures, quality, and access to items

and services in order to determine whether to pursue future rulemaking to expand the proposed payment rules to additional areas and or items.

We seek comments on this proposal.

4. Submitting bids for items paid on a continuous rental basis

In accordance with section 1847(b)(2)(A)(iii) of the Act, before contracts can be awarded, a determination must be made that the total amounts to be paid to contract suppliers under a CBP are expected to be less than the total amounts that would otherwise be paid. In accordance with §414.414(f) of the regulations, under the DMEPOS CBP, bids amounts for an item or service are limited to the fee schedule amount that would otherwise be paid for the item or service. We propose that in order to apply the proposed rental payment rules, we would establish the bid limits for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds that would be paid in accordance with the proposed payment rules in sections 1 and 2 above based on average monthly expenditures per beneficiary in an area for the items and services related to furnishing the DME. For example, the bid limit for the continuous monthly rental of a standard manual wheelchair in a CBA would be based on the total payment amounts per month in the area for the wheelchair, repair, maintenance and servicing of the wheelchair, and accessories used with the wheelchair, divided by the unduplicated number of beneficiaries receiving these items and services. We propose to revise § 414.412 to specify that the supplier's bid for furnishing enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds on a continuous monthly rental basis could not be higher than the average monthly payment made in the area for the items and services prior to the start of the competition. In the case of CPAP devices and respiratory assist devices, these items were paid on a bundled,

continuous rental fee schedule basis from 1989 thru 1993, based on the rules mandated by section 4062(b) of OBRA 87, prior to the change by section 13543 of OBRA 93 that moved them from the payment class for items requiring frequent and substantial servicing to the payment class for capped rental items. Payment on a bundled, continuous rental fee schedule basis was mandated by OBRA 87 from 1989 thru 1993. The fee schedule for 1993 is the most current fee schedule where payment was based on a bundled, continuous rental basis. We propose to revise § 414.412 to specify that the supplier's bid for furnishing CPAP devices and respiratory assist devices on a continuous monthly rental basis could not be higher than 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. We seek comments on this proposal.

We seek public comments on phasing in the proposed rules described in section 1 through 4 above.

VII. Scope of Hearing Aid Coverage Exclusion

A. Background

Section 1862(a)(7) of the Act states notwithstanding any other provision of title XVIII, no payment may be made under part A or part B for any expenses incurred for items or services "where such expenses are for . . . hearing aids or examinations therefor. . . ." This policy is codified in the regulation at 42 CFR 411.15(d), which specifically states that hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from Medicare coverage. At the time of passage of the Social Security Amendments of 1965 (Public Law 97, 89th Congress), which added the Medicare coverage exclusion for hearing aids at section 1862(a)(7) of the Act, all hearing aids utilized functional air and/or bone conduction pathways to facilitate hearing.

In general, to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. With regard to section 1862(a)(7) of the Act, we consider that a hearing aid provides assistance or "aid" to hearing that already exists via a functioning ear. Cochlear implants were the first hearing device that was not considered a hearing aid and met the benefit category of a prosthetic device. Prosthetic devices are a Medicare benefit category defined at section 1861(s)(8) of the Act which, in part, states a "prosthetic devices (other than dental) which replace all or part of an internal body organ." A cochlear implant is considered a prosthetic device primarily because it replaces the function of the cochlea. A cochlear implant device differs from a hearing aid in that it is an electronic instrument, part of which is implanted surgically to directly stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze and code sound. Both cochlear devices and brain stem implants, which function in a similar manner, create the perception of sound rather than aid hearing that already exists. We interpret the statute as excluding devices that provide aid to extant hearing (or hearing aids) rather than devices that create the perception of sound and hearing, given that devices with technology that utilize either air or bone conduction via mechanical stimulation to aid extant hearing were primarily utilized when the statute was written. Moreover, we believe that prosthetic hearing devices are not “hearing aids” given that such devices do more than “aid” in hearing and instead replace the function of an internal body organ (i.e., a part of the ear).

Historically, CMS has periodically addressed the scope of the Medicare hearing aid coverage exclusion through program instructions and national coverage policies or determinations. We briefly discuss the relevant changes that have occurred over time with regard to Medicare coverage and payment of hearing devices.

Cochlear implants were the first device covered for Medicare payment for adult beneficiaries in October 1986, when no other hearing device was being covered under Medicare, and such coverage was supported by the Office of Health Technology Assessment's "Public Health Service Assessment of Cochlear Implant Devices for the Profoundly Hearing Impaired", dated June 30, 1986 found at https://archive.org/stream/cochlearimplantd00feig/cochlearimplantd00feig_djvu.txt. Medicare coverage was restricted to cochlear implants that treated patients with post lingual, profound, bilateral, sensorineural deafness who are stimulable and who lack the unaided residual auditory ability to detect sound.

Effective January 1, 2003, we clarified that the hearing aid exclusion broadly applied to all hearing aids that utilized functional air and/or bone conduction pathways to facilitate hearing (see section 15903, Hearing Aid Exclusion, Medicare Carriers Manual, Part 3 – Claims Process (HCFA-Pub. 14-3), which was later moved to section 100, Hearing Aids and Cochlear Implants, of Chapter 16, of the Medicare Benefit Policy Manual, CMS-Pub. 100-02). Any device that does not produce at its output an electrical signal that directly stimulates the auditory nerve is a hearing aid for purposes of coverage under Medicare. Devices that produce air conduction sound into the external auditory canal, devices that produce sound by mechanically vibrating bone, or devices that produce sound by vibrating the cochlear fluid through stimulation of the round window are considered hearing aids and excluded from Medicare coverage.

Effective April 4, 2005, Medicare's national coverage policy for cochlear implants was modified through the NCD process (see section 65-14 of the Medicare Coverage Issues Manual (HCFA-Pub. 6), which was later moved to section 50.3, Cochlear Implantation, of Chapter 1, Part 1 of the Medicare National Coverage Determinations Manual (CMS-Pub. 100-03)). Our

findings under the NCD, in part, state that "CMS has determined that cochlear implants fall within the benefit category of prosthetic devices under section 1861(s)(8) of the Social Security Act." Medicare is a defined benefit program. An item or device must not be statutorily excluded and fall within a benefit category as a prerequisite to Medicare coverage. We believe that prosthetic hearing devices are not “hearing aids” given that such devices do more than “aid” in hearing and instead replace the function of an internal body organ (i.e., a part of the ear). Additional changes, regarding coverage criteria, have been made to NCD 50.3 over time, however, the NCD decision regarding benefit category and Medicare coverage for cochlear implantation has remained consistent. The NCD states that a cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

The regulations at 42 CFR §419.66 were revised to add new requirements, effective January 1, 2006, for transitional pass-through payments for medical devices. The auditory osseointegrated device, referred to as a bone anchored hearing aid (BAHA), was determined to be a new device category according to the new requirements for transitional pass-through payment. Medicare coverage was also expanded to cover auditory osseointegrated and auditory brainstem devices as prosthetic devices. Currently, section 100 of Chapter 16 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) reads as follows:

> Hearing aids are amplifying devices that compensate for impaired hearing. Hearing aids include air conduction devices that provide acoustic energy to the cochlea

via stimulation of the tympanic membrane with amplified sound. They also include bone conduction devices that provide mechanical energy to the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

Certain devices that produce perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be utilized due to congenital malformations, chronic disease, severe sensorineural hearing loss or surgery.

The following are considered prosthetic devices:

• Cochlear implants and auditory brainstem implants, that is, devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.

• Osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer.

B. Current Issues

We have received several benefit category determination requests in recent years for the consideration of non-implanted, bone conduction hearing aid devices for single-sided deafness, as prosthetic devices under the Medicare benefit. We have received similar requests for several other types of implanted and non-implanted devices as well. In response to these requests, we have re-examined the scope of the statutory hearing aid exclusion. Currently, we consider all air or bone conduction hearing devices, whether external, internal, or implanted, including, but not

limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea, as hearing aids. All of these devices provide traditional "aid" to hearing and are excluded in accordance with section 1862(a)(7) of the Act. In order for an item to be covered by Medicare, it must fall into a Medicare benefit category and not be statutorily excluded. Not only are these devices statutorily excluded they do not fall in a benefit category. Specifically, they do not meet the statutory definition of a prosthetic device found at section 1861(s)(8) of the Act which, in part, states a "prosthetic devices (other than dental) which replace all or part of an internal body organ." They do not replace the function of an internal body organ and thus are not considered prosthetic devices under Medicare payment policy. In regard to BAHA, it is a bone conduction hearing aid device that is osseointegrated. There are currently only two hearing devices that are not statutorily excluded and are a covered Medicare item that fall into the prosthetic benefit category; namely, the cochlear implant and the auditory brainstem device. These two devices meet the definition of a prosthetic device in that they replace the function of the inner ear consistent with the definition of prosthetic devices described in section 1861(s)(8) of the Act .

C. Proposed Provisions

After further considering the statutory Medicare hearing aid exclusion under section 1862(a)(7) of the Act, and re-examining the different types of external and implanted devices, we propose to interpret the term “hearing aid” to include all types of air or bone conduction hearing aid devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea. We believe, based on

our understanding of how such devices function, that such devices are hearing aids that are not otherwise covered as prosthetic devices, in that they do not replace all or part of an internal body organ. Therefore, we propose to modify the regulation at §411.15(d)(1) to specify that the hearing aid exclusion encompasses all types of air conduction and bone conduction hearing aids (external, internal, or implanted). Osseointegrated devices such as the BAHA are bone conduction hearing aids that mechanically stimulate the cochlea; therefore, we believe that the hearing aid exclusion applies to these devices and propose that Medicare should not cover these devices, consistent with our interpretation of section 1862(a)(7) of the Act. In addition, an NCD was issued for cochlear implant devices with the result that this determination and recent requests to expand coverage of hearing devices raises serious questions about the intent and scope of the Medicare coverage exclusion for hearing aids. It is for these reasons that we are addressing the hearing aid coverage exclusion in notice and comment rulemaking, and believe that the BAHA device qualifies as a hearing aid because it functions like other bone conduction hearing aids that are subject to the Medicare statutory coverage exclusion for hearing aids.

We continue to believe that the hearing aid exclusion does not apply to brain stem implants and cochlear implants because these devices directly stimulate the auditory nerve, replacing the function of the inner ear rather than aiding the conduction of sound as hearing aids do. Therefore, we are not proposing any changes to our current policy about brain stem implants and cochlear implants and how such implants fall outside of the hearing aid statutory exclusion (that is, such devices would fall outside the Medicare coverage exclusion for hearing aids and remain covered subject to the Medicare NCD 50.3 found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part1.pdf). We propose, however, to

modify § 411.15(d)(2) to specifically note that such devices do not fall within the hearing aid exclusion.

We seek public comment on this proposal.

VIII. Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

A. Background

Section 1847 (a)(1)(A) of the Act mandates the implementation of CBPs throughout the United States for awarding contracts for furnishing competitively priced items and services, including OTS orthotics described in section 1847(a)(2)(C) of the Act (leg, arm, back or neck braces described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h)) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. The regulation at 42 CFR §414.402 currently defines “minimal self-adjustment” as “an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual who is certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training." This current definition was proposed in the 71 FR 25669 (May 1, 2006) Notice for Proposed Rulemaking (NPRM) but did not include the term "individual with specialized training." The definition was finalized in the 72 FR 18022 (April 10, 2007) Final Rule with the term "individual with specialized training" added after receiving comments that disagreed with the May 2006 definition and pointed out that occupational therapists, physical therapists, and physicians are licensed and trained to provide orthotics.

B. Current Issues

Since adoption of the minimal self-adjustment definition there has been some concerns raised by industry and other stakeholders regarding who is considered an individual with specialized training. We have had many inquiries and comments that this term is too ambiguous and left open for interpretation. In order to identify OTS orthotics for the purpose of implementing CBPs for these items and services in accordance with the statute, we need a clearer distinction between OTS orthotics and those that require more than minimal self-adjustment and expertise in custom fitting. In doing so, we believe it is essential to identify the credentials and training a supplier needs to have in order to be considered a supplier with expertise in custom fitting; therefore, we believe the term "individual with specialized training" must be clarified. We believe these professionals must have specialized training equivalent to a certified orthotist for the provision of custom fitted orthotic devices such that these professionals satisfy requirements concerning higher education, continuing education requirements, licensing, and certification/registration requirements so that they meet a minimum professional skill level in order to ensure the highest standard of care and safety for Medicare beneficiaries.

This would also help to prevent any supplier without expertise in custom fitting orthotics from potentially circumventing the competitive bidding process by furnishing custom fitting they are not qualified to provide in the event that they are not awarded a contract for furnishing OTS orthotics in their service area as the custom fitted devices are not statutorily included in the CBP.

In addition, for claims processing and payment system purposes under the CBP, we need to identify OTS orthotics, which we accomplish with codes in the HCPCS. The HCPCS codes are used on claims to identify the items and services furnished to the beneficiary, that is, to identify orthotics that are furnished OTS and subject to the CBP and to identify orthotics that have been custom fitted by suppliers with expertise. On February 9, 2012, CMS issued initial

guidance identifying specific HCPCS codes considered OTS orthotics and provided a 60-day comment period posted at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/OTS_Orthotics.html. We received 185 comments. There was no general consistency between the various commenters on which specific HCPCS codes the commenters believed were appropriately deemed OTS. Many commenters expressed their support for the proposed list while others made numerous useful recommendations to improve the OTS list. We considered each comment and performed a thorough review of the individual HCPCS codes and devices included in the codes to assess appropriate orthotic categorization. Through this process we identified HCPCS codes that described items that we believe are never furnished OTS, HCPCS codes that described items that are always furnished OTS, and HCPCS codes that described items that may or may not be furnished OTS, depending on whether more than minimal fitting and adjustment of a particular device by an expert is necessary for a particular patient. In order to address this issue we decided to create HCPCS codes for items that may or may not be custom fitted, depending on individual patient's needs, into separate codes that described the item when it has been furnished OTS and when it has been custom fitted. The new HCPCS codes were published and became effective January 1, 2014 and are published at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/OTS_Orthotics.html.

C. Proposed Provisions

Prefabricated orthotics are either furnished OTS or with custom fitting and are identified in the HCPCS. As noted above, with regard to minimal self-adjustment, § 414.402 in part identifies an individual with expertise in fitting as a certified orthotist or an individual with specialized training. Recently a DME Medicare Administrative Contractor (MAC) Web Site

Article entitled "Correct Coding - Definitions used for Off-the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces) – Revised," was published March 27, 2014, and included: a physician, a treating practitioner, , an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. The DME MAC published this article following the change in 2014 HCPCS codes for OTS and custom fitted orthotics as an education tool for Medicare enrolled DMEPOS suppliers. We believe physicians, treating practitioners, occupational therapists, and physical therapists are considered "individuals with specialized training" that possess training equivalent to a certified orthotist for the provision of custom fitted orthotic devices through their individual degree programs and continuing education requirements. In addition, physicians, treating practitioners, occupational therapists, and physical therapists possess equivalent or higher educational degrees, continuing education requirements, licensing, and certification and/or registration requirements. We believe these professionals meet a minimum professional skill level in order to ensure the highest standard of care and safety for Medicare beneficiaries. Each of these professionals has undergone medical training in various courses such as kinesiology and anatomy. For example, through coursework the named medical professionals gain a clinical understanding of the human body, proper alignment, normal range of motion, agonist and antagonist relationship, and biomechanics necessary to modify a custom fitted orthotic device properly.

Clinical providers such as assistants, fitters, and manufacturer representatives that work under the supervision of the individual with specialized training must do so as required under their governing body Code of Ethics and supervision standards as well as state licensure requirements. These individuals are not considered to have specialized training for the purposes

of providing custom fitting; therefore, orthotics adjusted by these individuals but not by individuals with specialized training would still be considered OTS.

The current regulation of orthotic provision in the U.S. is inconsistent between individual States. There are currently 17 States that require licensure in P&O. In States that do require licensure for the provision of orthotics, individual states do not all recognize certified orthotic fitters and do not provide licensure for this level of provider. This inconsistency also prompts us to provide clarification on the individuals who are recognized as having specialized training for the purposes of determining what constitutes minimal self-adjustment of OTS orthotics.

We propose to update the definition of minimal self-adjustment in § 414.402 to codify an individual with specialized training includes: a physician defined in section 1861(r) of the Act, a treating practitioner defined at section 1861(aa)(5) (physician assistant, nurse practitioner, or clinical nurse specialist), an occupational therapist defined at 42 CFR § 484.4, or physical therapist defined at 42 CFR § 484.4, who is in compliance with all applicable Federal and State licensure and regulatory requirements for reasons discussed above. We seek comments on this proposal.

IX. Revision to Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business

A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), requires the Secretary to establish and implement CBPs in CBAs throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The programs mandated by section 1847(a) of the Act are collectively referred to as the

"Medicare DMEPOS Competitive Bidding Program." The 2007 DMEPOS competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other Issues published in the **Federal Register** on April 10, 2007 (71 FR 17992)), required CBPs for certain Medicare Part B covered items of DMEPOS throughout the United States. The CBP, which was phased in over several years, utilizes bids submitted by qualified suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items for beneficiaries receiving services in designated CBAs.

CMS awards contracts to those suppliers who meet all of the competitive bidding requirements and whose composite bid amounts fall at or below the pivotal bid (the bid at which the capacity provided by qualified suppliers meets the demand for the item). These qualified suppliers will be offered a competitive bidding contract for that PC, provided there are a sufficient number of qualified suppliers (there must be at a minimum of 2) to serve the area. Contracts are awarded to multiple suppliers for each PC in each CBA and will be re-competed at least once every 3 years.

CMS specifies the duration of the contracts awarded to each contract supplier in the Request for Bid Instructions. We also conduct extensive bidder education where we inform bidders of the requirements and obligations of contract suppliers. Each winning supplier is awarded a single contract that includes all winning bids for all applicable CBAs and PCs. A competitive bidding contract cannot be subdivided. For example, if a contract supplier breaches its contract, the entire contract is subject to termination. In the Physician Fee Schedule final rule published on November 29, 2010, we stated that "once a supplier's contract is terminated for a particular round due to breach of contract under the DMEPOS CBP, the contract supplier is no longer a DMEPOS contract supplier for any DMEPOS CBP PC for which it was awarded under

that contract. This termination applies to all areas and PCs because there is only one contract that encompasses all CBAs and PCs for which the supplier was awarded a contract." (75 FR 73578)

A competitive bidding contract cannot be sold. However, CMS may permit the transfer of a contract to an entity that merges with or acquires a competitive bidding contract supplier if the new owner assumes all rights, obligations, and liabilities of the competitive bidding contract pursuant to regulations at 42 CFR §414.422(d).

For the transfer of a contract to be considered, the CHOW must include the assumption of the entire contract, including all CBAs and PCs awarded under the contract.

B. Proposed Provisions

We propose to revise § 414.422(d) to permit transfer of part of a competitive bidding contract under specific circumstances. We believe requiring a transfer of the entire contract to a successor entity in all circumstances may be overly restrictive, and may be preventing routine merger and acquisition activity. To maintain integrity of the bidding process we award one contract that includes all the CBA/PCs combinations for which the supplier qualifies for and accepts as a contract supplier. This proposed rule would establish an exception to the prohibition against transferring part of a contract by allowing a contract supplier to sell a distinct company (for example, an affiliate, subsidiary, sole proprietor, corporation, or partnership) which furnishes one or more specific PCs or serves one or more specific CBAs and transfer the portion of the contract initially serviced by the distinct company, including the PC(s), CBA(s), and location(s), to a qualified successor entity who meets all competitive bidding requirements (i.e., financial standards, licensing, and accreditation). The proposed exception would not apply to existing contracts but would apply to contracts issued in all future rounds of the program, starting

with the Round 2 Recompete. As required in § 414.422(d) we are also requiring a contract supplier that wants to sell a distinct company which furnishes one or more specific PCs or serves one or more specific CBAs to notify CMS 60 days before the anticipated date of a change of ownership. If documentation is required to determine if a successor entity is qualified that documentation must be submitted within 30 days of anticipated change of ownership, pursuant to § 414.422(d)(2)(ii). We propose that CMS would then modify the contract of the original contract supplier by removing the affected PC(s), CBA(s) and locations from the original contract. For CMS to approve the transfer, we propose that several conditions would have to be met. First, we propose that every CBA, PC, and location of the company being sold must be transferred to the new owner. Second, we propose that all CBAs and PC's in the original contract that are not explicitly transferred by CMS must remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW. Third, we propose that all requirements in 42 CFR § 414.422 (d)(2) must be met. Fourth, we propose that the sale of the company must include all of the company's assets associated with the CBA and/or PC(s). Finally, we propose that CMS must determine that transferring part of the original contract will not result in disruption of service or harm to beneficiaries. No transfer will be permitted for purposes of this program if we determine that the new supplier does not meet the competitive bidding requirements (such as financial requirements) and does not possess all applicable licenses and accreditation for the product(s). In order for the transfer to occur, the contract supplier and successor entity must enter into a novation agreement with CMS and the successor entity must accept all rights, responsibilities and liabilities under the competitive bidding contract. Part of a novation agreement requires successor entity to "seamlessly continue to service beneficiaries." We believe that these

proposed conditions are necessary for proper administration of the program, to ensure that payments are made correctly and also to ensure continued contract accountability and viability along with continuity of service and access to beneficiaries. We specifically invite comments on whether more or different conditions would be appropriate.

In addition, we are proposing to update the current CHOW regulation, § 414.422(d) to clarify the language to make it easier to comprehend. The proposed changes reformat the regulation so that the requirements applicable to successor entities and new entities are listed separately. These proposed changes to the regulation are technical, and not substantive in nature. CMS seeks comments on all changes proposed for § 414.422.

X. Proposed Changes to the Appeals Process for Termination of Competitive Bidding Contract

We propose to modify the DMEPOS CBP's appeals process for termination of competitive bidding contracts under § 414.423. First, we propose to modify the effective date of termination in the termination notice CMS sends to a contract supplier found to be in breach of contract. Currently, the regulation at 42 CFR 414.423(b)(2)(vi) indicates that the effective date of termination is 45 days from the date of the notification letter unless a timely hearing request "has been" filed or corrective action plan "has been" submitted within 30 days of the effective date of the notification letter (emphasis added). We propose to change these references to provide additional clarification. This change would emphasize that the contract will automatically be terminated if the supplier does not time file a hearing request or submit corrective action plan. This proposed change is also being addressed at 42 CFR § 414.423(l). We propose deleting the lead-in sentence, as it does not properly lead into the first paragraph. Additionally, we propose inserting language from the lead-in sentence in the second paragraph to

indicate that the contract supplier, "whose contract has been terminated," must notify beneficiaries of the termination of their contract. Second, we propose to modify the deadline by which a supplier whose competitive bidding contract is being terminated must notify affected beneficiaries that it is no longer a contract supplier. Current regulations at 42 CFR § 414.423(l)(2)(i) require a contract supplier to provide this notice within 15 days of receipt of a final notice of termination. We propose to change the beneficiary notification deadline to no later than 15 days prior to the effective date of termination. This proposed change is intended to provide beneficiaries with the protection of advanced notice prior to a contract supplier being terminated from the CBP so they have sufficient time to plan/coordinate their current and future DMEPOS needs.

XI. Technical Change Related to Submitting Bids for Infusion Drugs under the DMEPOS Competitive Bidding Program

The standard payment rules for drugs administered through infusion pumps covered as DME are located at section 1842(o)(1)(D) of the Act, and mandate that payment for infusion drugs furnished through a covered item of DME on or after January 1, 2004, is equal to 95 percent of the average wholesale price for such drug in effect on October 1, 2003. The regulations implementing section 1842(o)(1)(D) of the Act are located at 42 CFR § 414.707(a), under Subpart I of Part 414. Section 1847(a)(2)(A) of the Act mandates the establishment of CBPs for covered items defined in section 1834(a)(13), for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME. Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under a CBP unless the total amounts to be paid to contract suppliers are expected to be less than would otherwise be paid. The regulations implementing

section 1847(b)(2)(A)(iii) of the Act with respect to items paid on a fee schedule basis under Subparts C and D of Part 414 are located at 42 CFR § 414.412(b)(2), and specify that "the bids submitted for each item in a PC cannot exceed the payment amount that would otherwise apply to the item under Subpart C or Subpart D of this part." In addition, the regulations regarding the conditions for awarding contracts under the DMEPOS CBP at 42 CFR § 414.414(f) state that "a contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item under a CBP are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D." The regulations implementing of section 1847(b)(2)(A)(iii) of the Act did not address payments for drugs under subpart I, which was an oversight. We therefore propose to revise §§ 414.412(b)(2) and 414.414(f) to include a reference to drugs paid under subpart I in addition to items paid under subparts C or D. We propose to revise § 414.412(b)(2) to specify that the bid amounts submitted for each drug in a PC cannot exceed the payment limits that would otherwise apply to the drug under subpart I of part 414. This concerns certain infusion drugs with payment limits equal to 95 percent of the average wholesale price for the drug in effect on October 1, 2003, in accordance with §414.707(a)(3). See http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=7065f17b411e37b3788b6e7fcce21f89&rgn=div8&view=text&node=42:3.0.1.1.1.9.1.3&idno=42 We propose to revise § 414.414(f) to specify that a contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for infusion drugs provided with respect to external infusion pumps under a CBP are expected to be less than the amounts that would otherwise be paid to suppliers for the same drug under subpart I of part 414. We seek comments on this proposal.

XII. Accelerating Health Information Exchange

	Number of Facilities	*Number of Treatments 2013 (in millions)*	*Number of Facilities with QIP Score*	*Number of Facilities Expected to Receive a Payment Reduction*	*Payment Reduction (percent change in total ESRD payments)*
Pacific	710	5.4	703	90	-0.08%
South Atlantic	1,333	9.1	1,315	232	-0.10%
West North Central	438	2.0	426	53	-0.07%
West South Central	807	5.6	806	90	-0.07%
US Territories[2]	42	0.3	42	15	-0.25%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,086	2.7	1,032	215	-0.16%
4,000-9,999 treatments	2,226	10.5	2,225	277	-0.07%
Over 10,000 treatments	2,523	25.7	2,523	352	-0.07%
Unknown	161	0.3	128	75	-0.59%

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3]Based on claims and CROWNWeb data through December 2013.

3. DMEPOS Provisions

a. Effects of the Proposed Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs

We estimate that the proposed methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would save over $7 billion over FY 2016 through 2020. The savings would be primarily achieved from price reductions for items. Therefore, most of the economic impact is expected from the reduced prices. We estimate that approximately half of the DMEPOS items and services furnished to Medicare beneficiaries are furnished to beneficiaries residing outside existing CBAs. (See Table 45.)

TABLE 45: Impact of Pricing Items in Non-Competitive Areas Using Competitive Bidding Pricing

FY	Impact on the federal government in dollars (to the nearer ten million)	Impact on beneficiary cost sharing in dollars (to the nearer ten million)
2016	-880	-270
2017	-1,430	-470
2018	-1,520	-510
2019	-1,630	-540
2020	-1,750	-580

Although these transfers create incentives that very likely cause changes in the way society uses its resources, we lack data with which to estimate the resulting social costs or benefits.

b. Effects of the Proposed Special Payment Methodologies and Payment Rules for Durable Medical Equipment and Enteral Nutrition Furnished under the Competitive Bidding Program

We believe that the proposed special payment rules would not have a significant impact on beneficiaries and suppliers. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services does not change based on whether or not the equipment and related items and services are paid for separately under a capped rental payment method. Because the supplier's bids would reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings would be generally the same as they are under the current payment rules. Furthermore, as indicated above, we are proposing that the alterative payment rules would be phased in under a limited number of areas first to determine impact on the program, beneficiaries, and suppliers. If supported by evaluation results, a decision to expand the proposed special payment rules to other areas would be addressed in future rulemaking.

c. Effects of the Proposed Clarification of the Scope of the Medicare Hearing Aid Coverage Exclusion

This proposed rule proposes to clarify the scope of the Medicare coverage exclusion for hearing aids and proposes to no longer cover BAHAs. However, if finalized, this proposed rule would have no significant fiscal impact on the Medicare program, because Medicare program expenditures for BAHAs during the period CY2005 through CY 2013 have been insignificant. This proposed clarification would provide clear guidance about coverage of DME with regard to the statutory hearing aid exclusion. The proposed regulation, if finalized, would explicitly except cochlear implants and brain stem implants from the hearing aid exclusion, and therefore, Medicare coverage for these devices would continue.

We estimate that the proposed clarification of the scope of the Medicare hearing coverage exclusion would save Medicare approximately $80 million dollars over five years beginning in January 1, 2015 through September 30, 2019. The savings would be primarily achieved from removing coverage of the BAHA device. (See Table 46.)

TABLE 46: Clarification of the Statutory Medicare Hearing Aid Coverage Exclusion

FY	Impact to the Federal Government (rounded to the nearer $10 millions)
2015	-10
2016	-10
2017	-20
2018	-20
2019	-20

d. Effects of the Proposed Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

The proposed rule would modify the definition of minimal self-adjustment to indicate that it means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the

device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or a physician as defined in section 1861(r) of the Act , a treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in 42 CFR 484.4, or physical therapist as defined in 42 CFR 484.4 in compliance with all applicable Federal and State licensure and regulatory requirements. We estimate that the proposed clarification of the definition of minimal self-adjustment would have no significant impact on program expenditures or access to orthotics. This proposed clarification would impact suppliers furnishing custom fitted orthotics that do not have the expertise necessary to make more than minimal adjustments to an orthotic that a beneficiary or caregiver could be trained to make.

e. Effects of the Proposed Revision to Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business

This rule would clarify the change of ownership rules so as to not interfere with the normal course of business for DME suppliers. This rule would establish an exception under the CHOW rules to allow transfer of part of a competitive bidding contract when a contract supplier sells a distinct line of business to a qualified successor entity r under certain specific circumstances. This clarification would impact businesses in a positive way by allowing them to conduct everyday transactions without interference from our rules and regulations.

C. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 47 below, we have prepared an

accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

estimates of facility performance, we also estimated the impact of payment reductions on ESRD small entity facilities by comparing the total estimated payment reductions for 209 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 975 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.16 percent in PY 2018.

We expect that the proposed methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would have a significant impact on a substantial number of small suppliers. Although suppliers furnishing items and services outside CBAs do not have to compete and be awarded contracts in order to continue furnishing these items and services, the payment amounts for these items and services would be reduced using the methodology established as a result of the proposed rule. The statute requires that the methodology for adjusting payment amounts take into consideration the costs of furnishing items and services in areas where the adjustments will occur and these considerations are discussed in the preamble (refer to section IV(A)(5) of the preamble). The proposed methodology for making payment adjustments would allow for adjustments based on bids in different geographic regions to reflect regional variation in costs of furnishing items and services and the national floor for adjustments in states with unique costs. We believe that suppliers would be able to continue furnishing items and services to beneficiaries in areas outside the CBAs after the reductions in the payment amounts are applied without a significant change in the rate at which they accept assignment of Medicare claims for these items and services. Because section 1834(a)(1)(F)(ii) of the Act mandates that payment amounts for DME subject to competitive bidding be adjusted in areas where CBPs are not implemented, the only alternative we can consider other than paying based on adjusted fee schedule amounts is to implement CBPs in all areas. However, this approach

would have an even greater impact on small suppliers.

We expect the proposed special payment rules for DME and enteral nutrition would not have a significant impact on small suppliers. We believe that these rules would benefit affected suppliers since payment for rental of DME and enteral nutrition infusion pumps would no longer be capped and suppliers would retain ownership to the equipment.

We expect that the proposal to modify the definition of minimal self-adjustment of orthotics would not have a significant impact on small suppliers. According to the Medicare Pricing, Data Analysis and Coding (PDAC) Contractor from FY 2010 through FY 2013 there were approximately 6,000 DMEPOS suppliers with a provider transaction access number (PTAN) registered with the National Supplier Clearinghouse to supply orthotics. In addition, there are a limited number of applicable HCPCS codes (approximately 77) that require a skilled individual's expertise. We believe that the majority of businesses providing orthotics already employ a "skilled individual." However, for those few businesses that do not already have a skilled individual providing custom fitted orthotics they could comply with the proposed changes to the definition and requirements by hiring a skilled individual. For example, according to the Bureau of Labor Statistics Occupational Employment Statistics May 2013 the median pay for a certified orthotist was $30.27 an hour. The impact will vary according to the caseload of custom fitted orthotics provided by an individual supplier.

We expect that although the proposal which clarifies the scope of the Medicare statutory exclusion for hearing aids would withdraw the coverage for BAHAs, it would not have a significant impact on small suppliers since the volume of allowed services for bone anchored hearing aids covered by Medicare is very small (less than 2,000 nationwide) and would not account for a large percentage of any individual supplier's total revenue.

We expect that the proposed revisions to CHOW rules to allow contract suppliers to sell specific lines of business provision would have a positive impact on suppliers and no significant negative impact on small suppliers.

Therefore, the Secretary has determined that this proposed rule would have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 145 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 145 rural hospital-based dialysis facilities will experience an estimated 0.1 percent decrease in payments. As a result, this proposed rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

XVII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year $100 million in 1995 dollars, updated annually for

11. The heading for subpart D is revised to read as set forth above.

12. Section 414.202 is amended by:

A. Adding the definition of "Frontier state".

B. Revising the definition of "Region".

C. Adding the definition of "Rural State".

The additions and revision read as follows:

§ 414.202 Definitions.

* * * * *

Frontier state means a state where at least 50 percent of counties in the state have a population density of 6 people or less per square mile.

* * * * *

Region means, for the purpose of implementing § 414.210(g), geographic areas defined by the Bureau of Economic Analysis in the United States Department of Commerce for economic analysis purposes, and, for the purpose of implementing § 414.228, those contractor service areas administered by CMS regional offices.

Rural State means a state where more than 50 percent of the population is rural as determined through census data.

13. Section 414.210 is amended by revising paragraph (a) and adding paragraph (g) to read as follows:

§ 414.210 General payment rules.

(a) General rule. For items furnished on or after January 1, 1989, except as provided in paragraphs (c) , (d), and (g) of this section, Medicare pays for durable medical equipment,

prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232

* * * * *

(g) Application of Competitive Bidding Information and Limitation of Inherent Reasonableness Authority**.** For items furnished on or after January 1, 2011, the fee schedule amounts may be adjusted based on information on the payment determined as part of implementation of the programs under subpart F, of this part, excluding information on the payment determined in accordance with the special payment rules at § 414.409. In the case of such adjustments, the rules at § 405.502(g) and (h) of this chapter shall not be applied

(1) Payment adjustments for areas within the contiguous United States using information from competitive bidding programs. For an item or service subject to the programs under subpart F, that payment amount for such item or services for areas within the contiguous United States shall be established as follows:

(i) CMS determines a regional price for each state in the contiguous United States and the District of Columbia equal to the un-weighted average of the single payment amount for an item or service established in accordance with § 414.416 for competitive bidding areas that are fully or partially located in the same region where the state or District of Columbia is located.

(ii) CMS determines a national average price equal to the average of the regional prices determined under paragraph (g)(1)(i) of this section.

(iii) A regional price determined under paragraph (g)(1)(i) of this section cannot be greater than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section nor less than 90 percent of the national average price determined under paragraph (g)(1)(ii) of this section. In addition, a regional price determined under paragraph (g)(1)(i) of this section for a state designated as a rural or frontier state cannot be less than 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) Payment adjustments for areas outside the contiguous United States using information from competitive bidding programs. For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States are adjusted based on the greater of—

(i) The average of the single payment amounts for the item or service for CBAs outside the contiguous United States.

(ii) 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section.

(3) Payment adjustments for items and services included in no more than ten competitive bidding programs. Notwithstanding paragraph (g)(1) of this section, for an item or service that is included in ten or fewer competitive bidding programs as defined at § 414.402, the fee schedule amounts applied for all areas within and outside the contiguous United States are adjusted based on 110 percent of the un-weighted average of the single payment amounts for the item or service.

(4) Payment adjustments using data on items and services included in competitive bidding programs no longer in effect. In the case where adjustments to fee schedule amounts are made using any of the methodologies described, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the adjusted

fee schedule amounts shall be increased on an annual basis using the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect. Following the initial adjustment to the fee schedule amounts, the adjusted fee schedule amounts would continue to be updated every 12 months using the percentage change in the CPI-U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

(5) Adjusted payment amounts for accessories used with different types of base equipment. In situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA under competitive bidding, a weighted average of the single payment amounts for the code is computed for each CBA, weighted based on national allowed services for the code when used with different equipment. The weighted average single payment amount per code per CBA would then be used in applying the payment adjustment methodologies proposed in this section.

(6) Payment adjustments consistent with items and services furnished. In the case where payment amounts are established under subpart F of this part for an item or service that are greater than the payment amounts established under subpart F of this part for a higher level item or service (i.e., one with additional features or functionality), the payment amounts for the lower level of service are adjusted so that they are no greater than the payment amounts for the higher level of service before making payment adjustments using any of the methodologies above.

(7) Payment adjustments for mail order items furnished in the Northern Mariana Islands. The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana

Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program.

(8) Updating adjusted fee schedule amounts. The adjusted fee schedule amounts are revised each time a single payment amount for an item or service is updated following one or more new competitions and as other items are added to programs established under subpart F of this part.

14. Section 414.402 is amended by revising the definition of "Minimal self-adjustment" to read as follows:

§414.402 Definitions.

* * * * *

Minimal self-adjustment means an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification), or a physician as defined in 1861(r) of the Act, a treating practitioner which means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in §484.4 of this chapter, or physical therapist as defined in §484.4 of this chapter who are in compliance with all applicable Federal and State licensure and regulatory requirements.

* * * * *

15. Section 414.408 is amended by adding paragraph (l) to read as follows:

§ 414.408 Payment rules.

* * * * *

(l) Exceptions for certain items and services paid in accordance with special payment rules. The payment rules in paragraphs (f) thru (i), (j)(2), (j)(3), (j)(7), and (k) of this section do not apply to items and services paid in accordance with the special payment rules at § 414.409.

16. Section 414.409 is added to read as follows:

§ 414.409 Special payment rules.

(a) Payment on a bundled, continuous rental basis. (1) In no more than 12 CBAs, in conjunction with competitions that begin on or after January 1, 2015, payment is made on a bundled, continuous monthly rental basis for enteral nutrients, supplies and equipment, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, CPAP and respiratory assist devices, and hospital beds. The CBAs and competitions where these payment rules apply are announced in advance of each competition, with the payment rules in this section used in lieu of the payment rules at §414.408(f) thru (i), (j)(2), (j)(3), (j)(7), and (k). The single payment amounts are established based on bids submitted and accepted for furnishing rented DME and enteral nutrition on a monthly basis for each month of medical need during the contract period monthly single payment amount would include payment for all nutrients, supplies and equipment.

(2) Payment is made on a continuous monthly rental basis for DME. The single payment amount for the monthly rental of DME includes payment for the rented equipment, maintenance and servicing of the rented equipment, and replacement of supplies and accessories necessary for 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 circumstances.

(3) Payment is made on a monthly basis for enteral nutrition. The single payment amount includes payment for all nutrients, supplies and 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 circumstances.

(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 and enteral nutrition 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 or enteral nutrition. 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, enteral nutrition equipment, or oxygen equipment 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 on or 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.

17. Section 414.412 is amended by revising paragraph (b)(2) and adding paragraphs (b)(3) through (5) to read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(2) The bids submitted for each item or drug in a product category cannot exceed the payment amount that would otherwise apply to the item under Subpart C, Subpart D, or Subpart I of this part.

(3) The bids submitted for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, and hospital beds 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 C or subpart D of this part.

(4) The bids submitted for continuous positive airway pressure (CPAP) devices and respiratory assist 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.

* * * * *

18. Section 414.414 is amended by revising paragraph (f) to read as follows: --

§414.414 Conditions for awarding contracts.

* * * * *

(f) Expected savings. A contract is not awarded under this subpart unless CMS determines that the amounts to be paid to contract suppliers for an item or drug under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D or the same drug under subpart I based on 95 percent of the average wholesale price in effect on October 1, 2003.

* * * * *

19. Section 414.422 is amended by revising paragraph (d) to read as follows:

§414.422 Terms of contracts.

* * * * *

(d) Change of ownership. (1) A contract supplier must notify CMS if it is negotiating a change in ownership no later than 60 days before the anticipated date of the change.

(2) CMS may transfer a contract to an entity that merges with, or acquires, a contract supplier if the entity meets the following requirements:

(i) A successor entity---

(A) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(B) Submits to CMS the documentation described under § 414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not need to make a financial determination. This documentation must be submitted no later than 30 days prior to the anticipated effective date of the change of ownership; and

(C) Submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(ii) A new entity ---

(A) Meets the requirements of (d)(2)(i)(A) and (B) of this section; and

(B) Contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement as described in paragraph (d)(2)(iii) of this section for CMS review. The new entity submits to CMS, within 30 days after the effective date of the change of ownership, an executed novation agreement acceptable to CMS.

(3) Except as specified in paragraph (d)(4) of this section, CMS transfers the entire contract, including all product categories and competitive bidding areas, to a new entity.

(4) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company, (e.g., an affiliate, subsidiary, sole proprietor, corporation, or partnership) that furnishes a specific product category or services a

specific CBA, CMS may transfer the portion of the contract performed by that company to a successor, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the new qualified owner who meets all competitive bidding requirements; i.e. financial, accreditation and licensure;

(iii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iv) All requirements of paragraph (d)(2) of this section are met; and

(v) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(vi) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

* * * * *

20. Section 414.423 is amended by revising paragraphs (b)(1)(vi), (l)(2) introductory text, and (l)(2)(i) to read as follows:

§ 414.423 Appeals Process for Termination of Competitive Bidding Contract.

* * * * *

(b) * * *

(1) * * *

(vi) The effective date of termination is 45 days from the date of the notification letter unless a timely hearing request is filed or a corrective action plan (CAP) is submitted within 30

days of the date on the notification letter.

* * * * *

(l) * * *

(2) A contract supplier whose contract has been terminated must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(i) The notice to the beneficiary from the supplier whose contract is terminated must be provided no later than 15 days prior to the effective date of termination.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: June 24, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: June 27, 2014.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2014-15840 Filed 07/02/2014 at 4:15 pm; Publication Date: 07/11/2014]