This document is a condensed version of CMS 1614-F, the "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" final rule released by CMS on October 31, 2014. This condensed version was prepared by AAHomecare and includes the relevant portions of the final rule for HME.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 405, 411, 413, and 414
[CMS-1614-F]
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Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

CONDENSED VERSION RELATED TO HME

This final rule sets 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); makes alternative payment rules for certain DME under the Medicare DMEPOS CBP; clarifies the statutory Medicare hearing aid coverage exclusion and specifies devices not subject to the hearing aid exclusion; will not update the definition of minimal self-adjustment; clarifies the

Change of Ownership (CHOW) and provides for an exception to the current requirements; revises the appeal provisions for termination of a CBP contract, including the beneficiary notification requirement under the Medicare DMEPOS CBP, and makes a technical change to the regulation related to the conditions for awarding contracts for furnishing infusion drugs under the Medicare DMEPOS CBP.

I. Executive Summary

A.Purpose

3. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

This final rule finalizes a methodology for making national price adjustments to payments for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) paid under fee schedules based upon information gathered from the DMEPOS competitive bidding programs (CBPs) and finalizes the phase-in of special payment rules in a limited number of competitive bidding areas (CBAs) under the CBP for certain specified DME at 42 CFR 414.408 and 414.409. This final rule clarifies the statutory Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act and the regulation at §411.15(d) to further specify the scope of this exclusion. In addition, this final rule will not finalize the definition of minimal self-adjustment at § 414.402 to identify certain individuals with specialized training with regard to off-the-shelf (OTS) orthotics under the CBP. This final rule revises the Change of Ownership (CHOW) policy in the current regulations to allow a product category to be severed from a competitive bidding contract and transferred to a new contract when a contract supplier sells a distinct line of business to a new qualified owner. This rule amends § 414.423 to clarify the effective date for terminations of competitive bidding contracts, and the deadline for contract

suppliers notifying its beneficiaries of its contract termination. Finally, this rule includes a technical change related to submitting bids for infusion drugs under the CBP.

B. Summary of the Major Provisions

3. DMEPOS

• The methodology for making national price adjustments based upon information gathered from the DMEPOS CBPs: As required by the MIPPA, this rule finalizes methodologies for using information from the DMEPOS CBP to adjust the fee schedule amounts for DME in areas where CBPs are not implemented. The rule finalizes the same methodologies to adjust the fee schedule amounts for enteral nutrition and off-the shelf (OTS) orthotics in areas where CBPs are not implemented.

• Phase-in of special payment rules in a limited number of CBAs under the CBP for certain, specified DME: This rule finalizes a phase-in of special payment rules for certain DME at 42 CFR 414.408 and 414.409 under the DMEPOS CBP in a limited number of CBAs.

• Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act: This rule modifies the regulation at § 411.15 to address the scope of the statutory hearing aid exclusion and note the types of devices that are not subject to the hearing aid exclusion.

• Definition of minimal self-adjustment at § 414.402: This rule will not finalize changes to the "minimal self-adjustment" definition to specify certain "individuals with specialized training" with regard to the definition of OTS orthotics under the CBP.

• Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of

Business: This rule establishes an exception under the CHOW rules to allow CMS to sever a product category from a contract, incorporate the product category into a new contract, and transfer the new contract to a qualified new owner under certain specific circumstances.

- Appeals Process for Termination of a Competitive Bidding Contract: This rule amends §414.423 to clarify the effective date for terminations of competitive bidding contracts, and the deadline for contract suppliers notifying its beneficiaries of its contract termination.

C. Summary of Costs and Benefits

3. Impacts for DMEPOS

a. Final methodology for making national price adjustments to DMEPOS fee schedule amounts based upon information gathered from the CBPs.

The final regulation adjusts Medicare fee schedule amounts for items subject to DMEPOS CBPs beginning January 1, 2016, using information from the DMEPOS CBPs to be applied to items in non-competitive bidding areas. It is estimated that these adjustments would save over $4.4 billion in gross payments for the 5-year period beginning January 1, 2016, and ending December 30, 2020. The estimated gross savings are primarily derived from price reductions for items. It is expected that most of the economic impact would result from reduced payment amounts. The ability of suppliers to furnish items is not expected to be impacted.

b. Phase-in of special payment rules under the CBP for certain DME and enteral nutrition in certain CBAs

We believe that the special payment rules we are finalizing for certain DME under the DMEPOS CBPs 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 to generally be the same as they are under the current payment rules. Furthermore, the final special payment rules would be phased in under a limited number of areas first to evaluate their impact on the program, beneficiaries, and suppliers, including costs, quality, and access. Expanded use of the special payment rules in other areas or for other items would be addressed in future rulemaking.

c. Clarification of the statutory Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act

This final rule clarifies the scope of the Medicare coverage exclusion for hearing aids. This rule will not have a fiscal impact on the Medicare program because there will be no change in the devices that are currently covered for Medicare payment purposes. This rule provides further guidance about coverage of DME with regard to the statutory hearing aid exclusion.

d. Definition of minimal self-adjustment at 42 CFR 414.402

This final rule will not finalize the definition of minimal self-adjustment at this time.

e. Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business This rule finalizes changes to the CHOW rules in order to limit disruption to the normal

course of business for DME suppliers. This final rule establishes an exception under the current CHOW rules to allow CMS to sever a product category from a contract, incorporate the product category into a new contract, and transfer the new contract to a qualified new owner under

certain specific circumstances. This change would impact businesses in a positive way by allowing them to conduct everyday transactions with less disruption from our rules and regulations.

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

A. Background

1. Fee Schedule 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 the Medicare DMEPOS Competitive Bidding Program (CBP), as authorized under section 1847(a)(2)(B) of the Act. Additional background discussion about DMEPOS items subject to section 1834 of the Act, rules for calculating reasonable charges, and fee schedule payment methodologies for PENs and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings, was provided in the proposed rule (79 FR 40275 through 40277).

2. 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 competitive bidding areas (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.

3. 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. 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."

B. Summary of the Proposed Provisions and Responses to Comments on the Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs

The proposed rule for implementing section 1834(a)(1)(G) of the Act to establish a methodology for using information from CBPs to adjust the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii) of the Act was published on July 1, 2014 (79 FR 40208). We proposed applying the methodology proposed in this rule in making adjustments to the payment amounts for enteral nutrition as authorized by section 1842(s)(3)(B) of the Act (79 FR 40281). We received 89 public comments on the proposed rule, including comments from patient organizations, patients, manufacturers, health care systems, and DME suppliers. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received, our responses to the comments, and the policies we are finalizing for DMEPOS furnished under section 1834 of the Act. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

We proposed establishing three methodologies for adjusting DMEPOS fee schedule amounts in areas where CBPs have not been established for these items and services based on single payment amounts SPAs established in accordance with the payment rules at § 414.408 (79 FR 40281). We stated that the use of SPAs that may be established in accordance with the payment rules proposed in section VI of the proposed rule 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. The first methodology we proposed is summarized in subsection V. B. 1 below and would utilize regional adjustments limited by national parameters for items bid in more than 10 CBAs throughout the country. The second methodology we proposed is summarized 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. The third methodology we proposed is summarized in subsection 5 and would be used for mail order items furnished in the Northern Mariana Islands. We also proposed rules that would apply to all of these proposed methodologies, which are discussed in sections V.B.3, V.B.4, and V.B.6 below.

1. Proposed Regional Adjustments Limited by National Parameters

CBPs are currently in place in 100 of the largest metropolitan statistical areas (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 that are fully or partially located within a given state range from one to twelve. One CBA is for a non-contiguous area of the United States (Honolulu, Hawaii) and 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 proposed 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 (79 FR 40281).

Under the proposed methodology, adjusted fee schedule amounts for areas within the contiguous United States would be determined based on regional SPAs or regional single payment amounts (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 average of the RSPAs established for all states. This limits the range in the regional fee schedule amounts from highest to lowest to no more than 20 percent, 10 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 proposed 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 (79 FR 40284). 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 proposed 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 proposed 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.

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 proposed 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 (79 FR 40284). 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.

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 proposed 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 above.

We proposed 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 (79 FR 40284). 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 proposed 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 (79

FR 40284). 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 we proposed 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 solicited 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 proposed that the designation of rural and frontier states could change as the U.S. Census information changes. We proposed 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 proposed 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 (79 FR 40285). We proposed 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 proposed 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 proposed 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 proposed 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.

We indicated in the proposed rule (79 FR 40285) that some of the comments received on the advance notice of proposed rulemaking 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. In summary, we proposed 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 solicited public comments on whether payment in rural areas of states that are not designated as rural or frontier states should be set differently. For the purpose of ensuring access to necessary items and services in states that are more rural or sparsely populated than others, we proposed 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.

In addition, we proposed that the adjustments to the fee schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we proposed 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 (79 FR 40285). These proposals were made in consideration of 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 proposed that any SPAs from programs in these areas be excluded from the calculation of the RSPAs in section a. In addition, we proposed that the adjustments to the fee schedule amounts for areas outside the contiguous United States would not be based on the RSPAs. Rather, we proposed 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 proposed 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 (79 FR 40285).

For the purpose of establishing the boundaries for the regions, we proposed using 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce (79 FR 40282). Research and analysis conducted by the

BEA indicated 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 proposed to revise the definition of region in § 414.202 to mean a region developed for economic analysis purposes by the 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 the proposed rule are listed in Table 31 below.

Further information can be obtained at http://www.bea.gov/

TABLE 31: 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 solicited public comments on whether different regional boundaries should be considered that would better reflect potential regional differences in the costs of furnishing items and services subject to the DMEPOS CBP. The comments on these proposals and our responses are set forth below.

Comment: Many commenters stated that the DMEPOS CBP and the SPAs established under the program are flawed because the bids they are based on are not binding and therefore result in the submission of non-bona fide bids and because the SPA is based on the median of supplier bids for an item rather than the maximum bid resulting in some suppliers being paid less than the amount they bid. The commenters therefore believe that the SPAs should not be used to adjust payment amounts for items and services furnished in other areas of the country.

A few commenters said that no decisions should be made before future Office of the Inspector General (OIG) reports on competitive bidding are published because these reports might validate their claims that the SPAs are flawed.

Response: We do not agree that the DMEPOS CBP and the SPAs established under the program are flawed because the bids they are based on are not binding and therefore result in the submission of non-bona fide bids or because the SPA is based on the median of supplier bids for an item rather than the maximum bid resulting in some suppliers being paid less than the amount they bid. Bids are screened to ensure that they are bona fide. Suppliers that submit the lowest bids are required to provide invoices and other information to validate the bid and bids that are not validated are rejected. Regarding calculation of the SPA using the median rather than maximum bid, suppliers offered contracts under the program do not have to accept these amounts, but if they do, they are accepting the payment amounts in the contract and suppliers have successfully furnished items at these amounts with no impact on access. Over 90 percent of suppliers accept contracts they are offered, indicating that the SPAs are appropriate. We therefore do not agree with the commenters that the SPAs should not be used to adjust payment amounts for items and services furnished in other areas of the country and we do not agree that waiting for an OIG evaluation of this issue is necessary. Section 1834(a)(1)(F)(ii) of the Act mandates use of information on the payment determined under CBPs to adjust the payment amount that would otherwise be made for DME for an area that is not a CBA by no later than January 1, 2016, therefore, we believe it is appropriate to establish the methodology in rulemaking so that it takes effect on January 1, 2015, allowing time for calculation and implementation of the adjusted fee schedule amounts on January 1, 2016.

Comment: Some commenters suggested that a survey of supplier costs in areas outside

of CBAs should be conducted to determine whether the costs in these areas are greater than the costs in CBAs or to otherwise provide information on how the payment amounts in areas outside CBAs should be adjusted.

Response: We disagree with this comment. The statute requires CMS to use CBP information (as opposed to survey data of supplier costs as the commenters suggest).

Comment: Many commenters suggested that as an alternative to using SPAs to adjust payment amounts, the methodology should use either the highest bid submitted for each item under the competition or the highest bid submitted for the item by the suppliers in the winning range.

Response: We disagree with this suggestion. We believe that the median bid is a better reflection of the costs of furnishing items by suppliers as whole as reflected in their bids than either the lowest bid or the highest bid. Medicare payment methods at 42 CFR 405.502 used in the past for DME have relied on customary charges from suppliers based on the median of their charges as well as fee schedule amounts based on average reasonable charges. In no case have the highest supplier charges or highest reasonable charges been used to establish Medicare allowed amounts for DME in the past, and in no case has use of median or average charges in establishing Medicare allowed payment amounts resulted in significant problems related to obtaining access to items and services in the past.

Comment: Some commenters stated that bids submitted by suppliers unable to fulfill the terms of their contract, for example, due to problems associated with meeting State licensure requirements, should be excluded and SPAs should be recalculated before they are used to determine the adjusted fee schedule amounts.

Response: We disagree with this comment. We have observed no significant negative impacts on access to items and services under the CBPs since they were initially phased in on January 1, 2011. In the limited situations where bids used in the calculation of the SPAs were from suppliers that later were determined to be ineligible, these bids did not impact access to items and service.

Comment: One commenter indicated that the boundaries for the regions based on the 8 regions developed for economic analysis purposes by the Bureau of Economic Analysis (BEA) within the Department of Commerce are too broad and are not representative of current regional economic characteristics.

Response: We disagree. The BEA regional designations have been evaluated and have evolved over the years to continue to encompass socio-economic patterns.

Comment: Many commenters stated that the proposed methodology does not adequately address the costs of furnishing items and services in areas of the country where CBPs have not been established, particularly for rural areas, non-contiguous areas, or remote areas where suppliers must incur extraordinary delivery expenses. Some commented that the SPA-based pricing is too low for a supplier to stay in business and for the beneficiaries to receive equipment. Some commenters believe that the quality of items and services furnished will be compromised by the proposed methodology for adjusting payment amounts. Many commenters did not agree with the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor for rural states and frontier states and suggested varied ways to adjust prices in rural areas, including raising the national ceiling to 120 or 150 percent, or having rural and low population density areas add-on payments at the ZIP code or county level similar to the add-on payments allowed for rural areas under the ambulance fee

schedule. Commenters believe that considerations should be made for all rural areas within states regardless of whether the state meets the proposed definitions of rural or frontier state. Some commenters stated that the SPAs

do not account for unique costs of delivering items to extremely remote locations and should not be used to adjust payments in these areas.

Response: We agree that the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor for rural states and frontier states should be applied to all rural areas and on a statewide basis depending on whether or not the state meets the proposed definitions for rural or frontier state. We believe the proposed methodology for using the national ceiling or 110 percent of the average of the RSPAs as a payment floor should be applied, at least initially, in other areas within a state that are designated as rural areas rather than entire states in order to ensure access to items and services in these areas. Although we do not have direct evidence that cost in rural areas are higher than costs in urban areas or vice versa or that the SPAs do not cover costs in rural areas, we believe it is prudent for the sake of ensuring access to items and services in these areas to proceed cautiously in adjusting fee schedule amounts in these areas. Therefore, in response to comments that considerations should be made for all rural areas within states regardless of whether the state meets the proposed definitions of rural or frontier state, we are finalizing a definition for rural area at §414.202 to mean a geographic area represented by a postal zip code of at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any metropolitan area (MSA). The definition of rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of

the Act at the time the rules at § 414.210(g) are applied. As part of the methodology we are finalizing for adjusting fee schedule amounts using information from CBPs, we are finalizing a provision that the adjusted fee schedule amounts for any area meeting the definition of rural area will be no lower than the national ceiling amount. We are not finalizing the proposed definitions of rural state and frontier state because we have decided to apply provisions proposed for these areas (79 FR 40284) to all rural areas based on comments received and as explained in more detail below. Lastly, we note that Medicare program guidance at section 60 of chapter 20 of the Medicare Claims Processing Manual (Pub. 100-04) allows for payment of separate charges for delivery expenses in rare and unusual circumstances in order to meet the needs of beneficiaries living remote areas that are not served by a local supplier.

Comment: Some commenters recommended a 4 year phase-in of the adjusted fees by payment amounts or regions so suppliers have time to adjust to the change in payment amounts.

Response: We agree that phasing in the adjustments to the payment amounts would allow time for suppliers to adjust to the new payment rates and would allow time to monitor the impact of the change in payment rates on access to items and services; however, we do not believe that a phase in period of 4 years is necessary. We believe that time frame is excessive. Therefore, we are finalizing a phase in of 6 months, which we believe provides suppliers with an adequate amount of time to make adjustments to their businesses in light of the reduced payment amounts and is more than enough time to determine if the payment amounts are impacting access to items and services in any part of the country. CMS will monitor access and health outcomes using real time claims data and analysis. Therefore, in this final rule at § 414.210(g)(9), we finalizing the adjustments to the fee schedule amounts for use in paying claims with dates of service from January 1 2016, thru June 30, 2016, based on 50 percent of

the un-adjusted fee schedule amount and 50 percent of the adjusted fee schedule amount. For example, if the fee schedule amount that would have gone into effect on January 1, 2016, without any adjustments would have been $100.00, and the amount resulting from the methodology established in this rule would have been $75.00, the fee schedule amount taking effect on January 1, 2016, will be $87.50. Beginning on July 1, 2016, the fully adjusted fees will apply.

Comment: Many commenters urged CMS to monitor patient access, utilization, and satisfaction levels after the implementation of the adjusted fees. Commenters also recommended adding a methodology to adjust prices if access problems develop.

Response: We concur with the recommendation to closely monitor the impact of the reductions in payment on access to items and services and health outcomes. We do not believe that the reductions in payment will negatively impact access to items and services, so we do not find it necessary to adopt an additional methodology to account for access problems; however, we can address the matter in future rulemaking, if necessary.

After consideration of the public comments, and for the reasons we discussed in the proposed rule and above, we are finalizing the proposed provisions summarized above and in the proposed rule (79 FR 40208), with the exception of the proposed definitions for rural state and frontier state and the proposed provision to use the national ceiling or 110 percent of the average of the RSPAs as a payment floor for adjusting the fee schedule amounts for these states. We are finalizing a definition of rural area and revising the definition of “Region” as described above at

§ 414.02. We are finalizing the proposed § 414.210(a) and (g), except we have amended 42 CFR 414.210(g) to note the application of competitive bidding information and limitation of

inherent reasonableness authority, and the payment adjustments for areas within and outside the contiguous United States using information from CBPs.

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 proposed 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 (79 FR 40285). 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 proposed 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.

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 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 proposed 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 proposed 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 proposed 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 9 Round 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 proposed 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 9 Round 1 areas where CBPs are implemented (79 FR 40285). 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 109 CBAs 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 proposed 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 (79 FR 40286). 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. The comments and our responses are set forth below.

Comment: Several commenters suggested that in the instances where the items and services included in limited number of CBPs, the adjusted fee schedule amounts for rural, frontier and non-contiguous areas should be greater than 110 percent of the average of the SPAs because the commenters believe that the cost of furnishing DMEPOS items in these areas are more than 10 percent higher than the cost of furnishing DMEPOS items in the CBAs. The commenters suggested using greater than 110 percent of the average of the SPAs to adjust the fee schedule amounts for rural, frontier, and non-contiguous areas.

Response: We disagree with this comment because we do not have direct evidence that the cost of furnishing DMEPOS items in rural, frontier, or non-contiguous areas is greater than the costs of furnishing the items in CBAs. In some cases, the cost of furnishing DMEPOS items in the CBAs may be greater than the costs of furnishing the items in rural, frontier, or non- contiguous areas, but we have no direct evidence of this either. Our proposal struck a balance by using 110 percent of the average of the SPAs rather than 100 percent of the average of the SPAs to account for the possibility that there may be slightly higher costs for furnishing items and

services in certain areas than the cost of furnishing the items in the CBAs. Absent additional evidence, we believe that paying more than 110 percent of the average of the SPAs for the CBAs is not appropriate. However, we can consider making changes in the future if new information is made available.

Comment: Some commenters stated that that items that were excluded from CBP after initially being in the program should be excluded from the adjustment of fees One commenter argued that the SPAs for items only included in CBPs during the Round 1 Rebid are no longer reflective of the true and current cost of the items. Also, one commenter argued that if CMS included items in CBPs and then decides not to include the items in subsequent CBPs, this is an indication that CMS believes the items are not well-suited for competitive bidding.

Other commenters stated that data from less than 10 CBPs is not enough data to determine what the payment amounts should be for the items on a national basis.

Response: We disagree with these comments. We believe that SPAs based on supplier bids from CBPs established in recent years are far more reflective of the true and current cost of the items than fee schedule amounts based on supplier charges from 1986 and/or 1987. There may be reasons why items are not included in subsequent CBPs, such as the fact that the item is a low volume item such as one of the hundreds of HCPCS codes for wheelchair options and accessories that is not included in subsequent CBPs to reduce the burden and cost of suppliers submitting bids for a product category (for example, wheelchairs) that already includes over a hundred higher volume items (HCPCS codes). It does not mean that CMS believes that the item is not suitable for competitive bidding. We believe that recent data from less than 10 CBPs is enough data to determine what the payment amounts should be for the items on a national basis, especially for those items that are furnished on a limited basis to a small number of

beneficiaries throughout the United States yet are items for which implementation of CBPs or adjustments to payment amounts using information from CBPs is mandated by the statute. Using pricing from 10 or fewer CBPs allows for implementation of the statutory requirement to implement competitive bidding for the item.

After consideration of the public comments, we are finalizing the rule in § 414.210(g)(3) to include payment adjustments for items and services included in no more than ten competitive bidding programs reduced to 110 percent of the unweighted average of the single payment amounts. We added technical changes to the final regulation text from the proposed regulation text by adding the term "ten or fewer" for added clarification. We are also finalizing the rule in § 414.210(g)(4) for payment adjustments using data on items and services included in competitive bidding programs no longer in effect and specify that we will be updating the payment amounts prior to adjusting the fee schedule amounts as described above.

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 proposed (79 FR 40286) 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 sought 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 proposed 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 proposed methodology, national allowed services would be used to compute a weighted average of the SPAs for code Exxx1 in each of the CBAs. So, rather than having 2 different SPAs for the same HCPCS 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 proposed to use the SPAs for the item from that PC in applying the payment adjustment methodologies proposed above (79 FR 40287). The comments and our responses are set forth below.

Comment: Several commenters argued that accessories used with different base equipment have higher service costs. They pointed out cases where CMS established different SPAs for the same accessories when used with different base equipment included in different PCs. The commenters do not believe that SPAs established for a HCPCS code describing an accessory used with one type of base item (for example, standard power wheelchair) should be used to adjust the fee schedule amounts for the HCPCS code that would govern payment for the accessory when it is used with a different type of base item (for example, complex rehabilitative power wheelchair).

Response: We disagree. We believe that using the weighted average of the SPAs established for accessories used with different base equipment takes into account any difference in the cost of furnishing the accessories with different types of base equipment in setting the overall rate for the accessories. We believe it is administratively burdensome and unnecessary to have more than one fee for the same item.

Comment: Some commenters suggested that composite bids and items weights make some accessories under-bid when they have a low weight relative to other items in the PC or relative to the same item in a different PC. For example, a HCPCS code describing a wheelchair accessory included in two different PCs, one for power wheelchairs and one for manual wheelchairs might be underbid in one PC if the item weight for the item is very low relative to the item weight for the item in the other PC. The commenter argued that, creating a weighted payment amount from the SPAs for the item from the manual and power wheelchair PCs distorts the true cost of the item if the item was under-bid in one PC because it had a low weight.

Response: We disagree. Suppliers are required to submit a bona fide bid for every item in every product category and the bids are screened to ensure that they are all bona fide. In addition, we believe that the costs of the accessories described by a single HCPCS code do not vary depending on what type of base equipment the item is used with. To the extent that the costs do vary, combining the SPAs for the accessories from different product categories results in payment amounts that reflect the average costs of the accessory when used in conjunction with various types of base equipment. If an item was underbid due to its low volume, that bid would not be considered for a contract.

After consideration of the public comments, we are finalizing the rule as proposed in

§414.210(g)(5) for adjusted payment amounts for accessories used with different types of base equipment, when 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 based on the total number of allowed services for the item on a national basis for the code from each product category prior to applying the payment adjustment methodologies under the section. We also made an additional change to the regulation from the proposed rule for added clarification by specifying that "the total number of allowed services for the item on a national basis for the code from each product category" is completed "prior to applying the payment adjustment methodologies under the section."

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). 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 product category (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. In the proposed rule (79 FR 40287), we identified the case where unbalanced bidding resulted in higher SPAs for enteral infusion pumps without alarms than enteral infusion pumps with alarms, even though pumps without alarms have become virtually obsolete. In this case, the alarm is the hierarchal feature. Only 0.3 percent of beneficiaries using

enteral infusion pumps received a pump without an alarm in 2012 according to Medicare claims data. Clearly, separately identifying pumps with alarms and pumps without alarms is no longer necessary, yet the codes for both types were included in the CBPs, resulting in a case of unbalanced bidding that could have been avoided if only one code for enteral infusion pumps existed. Likewise, in 2006, codes were added for portable power wheelchairs and power wheelchairs with less functionality (Group 1) than those commonly used by beneficiaries (Group 2). All of the codes for standard power wheelchairs meet the same needs for power wheelchairs used in the patient's home. The features of being more expensive, sturdier non-portable power wheelchairs or higher performing power wheelchairs are the hierarchal features for the standard

power wheelchairs. Although the codes for portable power wheelchairs and Group 1 power wheelchairs were added in order to provide a less expensive alternative for power wheelchairs used in the home, beneficiaries did not take advantage of the lower priced, alternative equipment. Only 0.9 percent of beneficiaries using standard power wheelchairs received a portable or Group 1 power wheelchair in 2012 according to Medicare claims data. The goal of creating savings for beneficiaries by having codes for economy power wheelchairs did not materialize, yet the codes for these types of power wheelchairs were included in the CBPs, resulting in a case of unbalanced bidding that could have been avoided if the codes for the economy power wheelchairs did not exist. 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 proposed 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 (79 FR 40287). We sought public comments on this issue and our proposed provision to address this issue. The comments and our responses are set forth below.

Comment: A commenter suggested that "hierarchal feature" be better defined. Another commenter suggested that weighing based on utilization rates ignores whether there were supply issues that affected the utilization rates. One commenter also suggested that balanced bidding does not reflect SPA cost differences based on the features of equipment.

Response: We agree that hierarchal features should be clearly identified for the purpose of implementing the proposed rule. We will limit the final policy by identifying two specific scenarios where the hierarchal features involved are additional features or features with additional functionality. In the future, we will either add other scenarios or develop a definition of "hierarchal features." Therefore, the final policy will only apply to the specific cases of unbalanced bidding that were identified in the proposed rule that clearly show that certain equipment has features that exceed that of other equipment.

After consideration of the public comments, we will limit the final policy by identifying two specific scenarios where the hierarchal features involved are additional features or features with additional functionality. In the future, we will either add other scenarios or develop a way to define "hierarchal features" in general, or in a way that would identify various scenarios, which we expect to address in future rulemaking. Therefore, the final policy will only apply to the specific cases of unbalanced bidding that were identified in the proposed rule (79 FR 40287) that clearly show that certain equipment has features that exceed that of other equipment. Specifically, we are adding § 414.210(g)(6) and requiring that adjusted fee schedule amounts for Group 1 power wheelchairs or Group 2 portable power wheelchairs cannot exceed the

adjusted fee schedule amounts for Group 2, non-portable power wheelchairs in order to avoid situations where Medicare allowed payment amounts for power wheelchairs with less functionality are established that are higher than fee schedule amounts for power wheelchairs with more functionality. We are also finalizing a rule at § 414.210(g)(6) that adjusted fee schedule amounts for enteral infusion pumps without alarm cannot exceed the adjusted fee schedule amounts for enteral infusion pumps with alarm. We believe that wheelchairs that can go farther, faster, can climb over higher obstacles, or are not portable and more sturdy have features that exceed wheelchairs that travel shorter distances, go slower, climb over lower obstacles, or are portable and less sturdy. Payment amounts for shorter distance, slower, smaller obstacle climbing, less sturdy, power wheelchairs should not be higher than the payment amounts for longer distance,

faster, higher obstacle climbing, sturdy, power wheelchairs. An enteral feeding pump with a safety alarm includes additional features than a pump without such an alarm. Payment amounts for enteral feeding infusion pumps without an alarm should not be higher than the payment amounts for pumps with an alarm. We will consider whether to add a definition of hierarchal feature, or to apply the rule we proposed to other items not identified above through future notice and comment rulemaking.

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

proposed 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 (79 FR 40287). We proposed that the adjusted fee schedule amounts would be equal to 100 percent of the amounts established under the national mail order CBP (79 FR 40287).

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: A few commenters recommended waiting for the second round of bidding for the national mail-order CBP before applying the payment amount in order to allow more time to determine if the competitive bidding payment amounts allow access to items and services and acquire more pricing points over an extended period of time. They further recommended increasing payment amounts for the national mail order SPA for the Northern Mariana Islands to

limit any access or pricing complications.

Response: We disagree with these suggestions. The national mail order SPAs currently apply to items shipped to various remote areas of the United States and have not resulted in any problems with access to mail order items in these areas. Therefore, we believe these amounts can be used to adjust the mail order fee schedule amounts for the Northern Mariana Islands effective January 1, 2016.

After consideration of the public comments and for the reasons we previously articulated, we are finalizing the proposal regarding the National Mail Order Program and the Northern Mariana Islands at § 414.210 (7) to provide that the fee schedule amounts for mail order items furnished 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 program.

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 proposed 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 (79 FR 40287). 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 proposed 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 proposed to use these SPAs to adjust payment amounts using the methodologies described above and we proposed to do so following application of inflation adjustment factors. We proposed 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 (79 FR 40288).

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 total payments made to contract suppliers in the CBA are expected to be 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. 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 (79 FR 40288).

We solicited comments on these proposals. The comments and our responses are set forth below.

Comment: Some commenters suggested updating adjusted fees yearly with CPI-U and not freeze it for 3 years until the next.

Response: We disagree. Contracts and SPAs are replaced at least once every 3 years, following one or more new competitions and as other items are added to programs established under Subpart F of this part, and increased costs in doing business are factored into the bids with each new competition. In addition, suppliers submitting bids under the CBPs are educated that their bids will be used in establishing SPAs that will be in effect for the entire duration of the contract period. Therefore, we believe that suppliers take increased costs and prices into

account when developing their bids. In addition, because section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under a CBP if the total amounts paid to contract suppliers are expected to be more than the total amounts that would otherwise be paid, we believe that the intent of competitive bidding is to product a reduction in payment amounts rather than an increase in payment amounts. In lieu of establishing a CBP in an area, the authorities under the statute for adjusting fee schedule amounts based on information from CBPs must be used; however, in no case should it result in an increase in the amounts that would otherwise be paid. If an inflation adjustment factor is applied to fee schedule amounts that are adjusted by the methodologies we are adopting in this final rule, it could result in an amount that is greater than the fee schedule amount that would otherwise be paid, and we believe that this is contrary to the intent of the statute.

After consideration of the public comments, for the reasons we set forth above, we are finalizing the proposals and are adding § 414.210(g)(8) to indicate that adjusted fee schedule amounts are revised each time an SPA 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.

Table 32 provides a summary of the final methodologies intended to achieve savings by adjusting fee schedule amounts using information from CBPs. With regard to all methodologies in this final rule that are intended to achieve savings by adjusting fee schedule amounts using information from CBPs, we are adding a provision specifying that in any case where application of these methodologies results in an increase in the fee schedule amount, the adjustment to the fee schedule amount is not made.

TABLE 32 - Summary of Final Methodologies for Adjusting Payment in Non-Bid Areas

Proposed Methodology	Calculations
1) Adjustments for Items Included in More than 10 CBAs*	
(a) 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 average of the RSPAs calculated for each of the 48 contiguous states and District of Columbia (national average RSPA).
(b) Adjustments for Rural Areas	-Adjusted payment for areas designated as rural areas based on 110 percent of the national average RSPA
(c) 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 average RSPA 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.
Proposed Methodology	**Calculations**
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 effect.
4) Adjustments for Accessories Used with Different Types of Base Equipment	
(a) 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)
(b) 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

VI. Final 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 continuous positive airway pressure (CPAP)

devices.

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 explained in more detail below, we proposed to revise the regulation by adding a new section at 42 CFR 414.409 with special payment rules to replace existing payment rules at § 414.408 for certain items and services in no more than 12 CBPs where these rules are applied. We also proposed to revise § 414.412 to address the submission of bids for furnishing items and services paid in accordance with these proposed special payment rules.

B. Summary of the Proposed Provisions and Responses to Comments on the Payment

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

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

We proposed to update the regulations to include proposed special payment rules for paying claims for certain DME or enteral nutrition under a limited number of CBPs. We proposed 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 CBPs where the special rules are applied. We also proposed to revise § 414.412 regarding submission of bids for furnishing items and services paid in accordance with these special payment rules.

We believe that alternative payment models for certain DME and enteral nutrition may 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. We sought comments on these proposals.

We proposed (79 FR 40291 through 40292) to phase-in the special payment rules described in sections VI.B.1 and VI.B.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, quality of care, and access to items and services. In order to monitor the impact of phasing in the special payment rules in no more than 12 CBAs, we proposed 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 proposed 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 proposed 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 proposed 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 proposed to analyze the effect of the proposed payment rules on beneficiary cost sharing.

We proposed 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 proposed 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.

We proposed 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 proposed 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 proposed 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 requested 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.

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. We solicited 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 proposed to undertake rigorous evaluation to determine the rules' effects on program costs, quality, and access.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

We received 28 public comments on this proposal from manufacturers, DMEPOS suppliers, coalitions, and beneficiaries. The comments and our responses are set forth below.

1. Payment on a continuous rental basis for select items

Under our general authority under section 1847(a) and (b) of the Act to establish payment rules for DME and enteral nutrition equipment, we proposed (79 FR 40292) 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 (RADs), and hospital beds. We proposed 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 proposed 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.

Comment: Several commenters indicated that CMS does not have the authority to use bundled payments under the CBP.

Response: We do not agree with this comment. The existing payment rules under section 1834 of the Act govern DMEPOS paid under the various fee schedules and do not directly apply to the CBP; therefore, CMS is not explicitly required to apply such rules to the CBP. Section 1847 of the Act mandates the implementation of CBPs throughout the United States for the purpose of awarding contracts for furnishing competitively priced items and services described under section 1847(a)(2) of the Act. As discussed in the proposed rule (79 FR 40290), we believe we have broad authority under section 1847 to establish payment rules for the CBP. In particular, consistent with section 1847(a)(6), the general payment rules for the CBPs are governed by section 1847(b) which mandates payment based on bids submitted and accepted by Medicare for the competitively priced items and services. Therefore, we believe that we have discretion to establish rules on whether covered items are paid for on a purchase or rental basis as long as total payments to contract suppliers are expected to be less than the total amounts that would otherwise be paid.

Comment: Several commenters felt that CMS has not demonstrated that a CBP that includes bundling meets the criteria for a demonstration under the CMMI.

Response: We thank the commenters for their comments. If a decision is made to use CMMI demonstration authority to implement and evaluate payment on a bundled, continuous

rental basis for DME and/or enteral nutrition, it would only be after CMMI has determined that a particular payment model meets the criteria established for such a demonstration.

Comment: Many commenters expressed concerns that monthly bundled payments for DME and enteral nutrition would reduce quality and access to care. For example, they believe that if separate payments are not made for certain items, such as the ongoing replacement of CPAP accessories, contract suppliers will not have an incentive to replace the items when they need to be replaced. Other commenters suggested that specific parameters or guidelines for replacement of such items, such as the usual maximum number of accessories needed as provided in DME MAC local coverage policies, be established under the programs. Commenters were particularly vocal about the fact that these rules should not be phased in for enteral nutrition and that enteral nutrition is not a suitable product category for bundled monthly payments.

Response: We do not agree. The rules are not being phased-in in limited areas due to concerns that suppliers contracted to provide items and services under these rules will not provide those items and services. The rules are being phased in to gauge whether rental caps are necessary in order to save money for items used on a longer term basis and whether the rules can address problems associated with repair of beneficiary-owned equipment. Suppliers awarded contracts under the programs must be in compliance with DMEPOS quality standards and supplier standards in order to remain a contract supplier and in order to continue to be an enrolled DMEPOS supplier under Medicare. As always, we will closely monitor contract suppliers and real time claims data and health outcomes data to ensure that suppliers are in compliance with the standards. Guidelines for the usual maximum amount of accessories expected to be medically necessary have already been established under local

DME MAC policies, and suppliers will be educated to take the cost of replacing these accessories into account when establishing their bids. Suppliers submitting bids under the program will be educated that they cannot receive payment for furnishing DME without furnishing everything the patient needs each and every month they continue to need and use the equipment. As stated in the proposed rule, the impact of the rules on program expenditures, beneficiary cost sharing, access to items and services, and quality of care will be closely monitored and compared to impacts under comparator areas. However, in light of concerns regarding the impact of the rules on access to quality items and services, we are further limiting the scope of the phase in to CPAP devices and standard power wheelchairs, and we are not finalizing the remaining categories of items at this time. These two categories of items generate the greatest amount of separate payments for accessories and repair compared to enteral nutrition or any other category of DME described in section 1847(a)(2) of the Act.

We will apply a focused and intense monitoring program to these two categories of items to evaluate quality of care and access to items and services, including specific accessories prescribed for beneficiaries under the programs to these two categories. Using real time claims analysis and health outcomes data, we will quickly identify potential problems and take action to ensure that contract suppliers are providing access to quality items and services under the programs. We believe these two DME categories will provide sufficient information in order to determine the overall effect of the special payment rules on program and beneficiary costs, quality, and access to items and services.

Comment: Some commenters supported bundling for enteral nutrition. They noted that the beneficiary would not be responsible for maintaining the pump and temporary cessation of

therapy would not occur while the pump is being repaired if it is not owned. Other commenters believed that bundled payment for enteral nutrition would be beneficial for short term nutritional therapy because the patient would no longer own a pump that is not needed. However, other commenters argued that CMS should exclude enteral nutrition from the bundled initiative because of the wide variation in cost of the enteral nutrients. Some commenters recommended establishing a monthly rental bundled payment based upon mode of delivery. Other commenters recommended establishing a separate bundled payment amount that would only cover the supplies and equipment used for each mode of delivery (syringe, gravity and pump) and would exclude enteral formulas from the bundle because of wide variation in cost and treatment.

Response: We thank the commenters for their support and input. After careful consideration of the comments received on this topic, we will not be finalizing the proposal to phase in bundled, continuous monthly rental payment for enteral nutrition at this time.

Comment: One commenter made suggestions for calculating the bundled payment rates for oxygen and oxygen equipment.

Response: We thank the commenter for their input. We will not be finalizing the proposal to phase in bundled, continuous monthly rental payment for oxygen at this time.

Comment: Many commenters opposed bundling monthly payment for all standard manual wheelchair bases with accessories or all standard power wheelchair bases with accessories or all standard and power wheelchair bases with accessories because they feel the different types are wheelchair bases are unique and should not be bundled together. Some recommended a bundled bid approach for standard manual or standard power wheelchairs and only those accessory items that are tied to the same medical necessity as the wheelchair.

Some suggested bundling only 3 codes or 6 accessory codes with each base code for wheelchairs based on utilization in order to simplify billing. Some suggested excluding repair and replacement items from the bundle. Commenters believed that bundling of multiple HCPCS codes into a single code for payment will further decrease access and quality of products and services and is complex. The commenters believes that a single bid code cannot accommodate the characteristics of the various technologies and varying manufacturing costs for standard manual or power wheelchairs. The commenters believe that there will be no mechanism to track utilization to ensure the beneficiaries still have access to the range of medically necessary technology. If base codes are combined then distinguishing coverage policies that reflect the medical and functional needs of beneficiaries cannot be developed. It provides a disincentive to suppliers to avoid high risk or complex beneficiaries and decreases beneficiary choices.

Response: We will not be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for standard manual wheelchairs at this time. The specific power wheelchair items and HCPCS codes included in competitions where special payment rules are applied will be announced to suppliers and beneficiaries in advance of the competitions with an explanation of why wheelchair bases are bundled together to the extent that they are under the competition.

Comment: Many commenters were opposed to applying bundled monthly continuous rental payment rules to CPAP devices and RADs. Some commenters recommended enforcing the current replacement schedule for CPAP and RAD accessories as outlined in DME MAC local coverage policies under the CBPs that utilize the special payment rules. Other commenters stressed that the CPAP supply replacement schedules should be factored

into the development of any bundled payment data and should be used to determine bundles and their respective amounts. In addition, commenters were concerned that bundling of CPAP removes all ability of CMS and providers to ensure that beneficiaries receive medically necessary equipment because they will not see claims for the items to know how often they are being replaced. For CPAP, some commenters urged CMS to craft policies integral to bundling such as a minimum service/contract level requirement for the provider to maintain with the beneficiary. Some commenters suggested that we require suppliers to check in on supply requirements with the beneficiaries.

Response: After consideration of the public comments we received, we will not be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for respiratory assist devices. But we will be finalizing the proposal to phase in competitions for bundled, continuous monthly rental payment for CPAP devices. We note that Medicare paid on a bundled, continuous monthly rental basis for CPAP devices under the fee schedules from 1989 thru 1993 and did not encounter any problems related to access to necessary items and services during this time. The tables in the DME MAC local coverage policies listing the usual maximum amount of CPAP accessories expected to be reasonable and necessary are not tables that indicate how often these items need to be replaced. They represent how often claims for the accessories would be paid without the need to have additional medical documentation in the patient's record. They can be used as guidelines for the usual maximum amount that are typically needed, but under a bundled, continuous rental payment method for CPAP devices, the supplier would be expected to replace the accessories as often as necessary for the effective use of the CPAP device. If the usual number of masks needed is once every 6 months, the masks may need to be replaced less often in the case of some

beneficiaries and more often than once every 6 months in the case of other beneficiaries. In any case where a replacement of an accessory is needed during a month, the contract supplier would be responsible for furnishing the necessary accessory, just as they would be responsible for repairing rented equipment whenever necessary. We will closely monitor contract suppliers to ensure that they are doing so.

Comment: Two commenters opposed our proposal that the bids submitted for furnishing CPAP devices on a bundled, continuous monthly rental basis 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. The commenters contended that equipment features developed since the establishment of the base year fees, such as a heated humidifier, would not be encompassed in the bid limits and instead suggested using a more recent base period for these items. Other commenters noted that the proposal to set bid limits for CPAP to 1993 fee schedule is inconsistent with the proposed methodology for the other bundled product categories which would use recent expenditures per beneficiary.

Response: We do not agree with these comments. Historical bundled, monthly rental fee schedule amounts are available for CPAP devices and reflect a bundled monthly rental payment that was previously mandated and established for these items under the Medicare program. We believe that separate payment for CPAP accessories has led to overutilization of the accessories based on complaints received from beneficiaries over the years about suppliers shipping unnecessary quantities of accessories. Therefore, we believe that the average payment per beneficiary for equipment and accessories could result in a bid limit that is artificially high when compared to historic Medicare bundled monthly rental fees for CPAP devices that were in place for 5 years and did not result in any problems with access to

necessary items and services. The 1993 fee schedule amounts for CPAP devices are based on historic reasonable charges that are representative of payment made to a supplier for furnishing these items on a bundled, continuous rental basis over a period of 5 years. The application of the covered item updates for DME in general, in section 1834(a)(14) of the Act, account for changes in the costs of furnishing covered items and services. Historic continuous bundled fee schedule amounts are not available to use to set the bid limit for the standard power wheelchair bundled category, therefore, current expenditure data would be used to set bid limits for the standard power wheelchair product category.

Comment: Many commenters believed that continuous monthly rental payments for DME would increase the financial burden of the beneficiaries because instead of being limited to paying coinsurance for no more than 13 months of continuous use, they would be required to make coinsurance payments for as long as they use the equipment.

Response: Our analysis strongly suggests that the benefits associated with paying on a continuous monthly rental basis outweigh the potential of increased copayments for the beneficiary. For items that are paid on a capped rental basis where title to the item transfers to the beneficiary after conclusion of the 13-month rental period, beneficiaries are responsible for maintaining and repairing the item after title transfer. Under the special payment rules that provide for payment on a continuous rental basis, beneficiaries will no longer be responsible for repair and maintenance of equipment because they will not own the equipment. The supplier will retain the title to the equipment and will be responsible for repair and maintenance. Although beneficiaries who use a CPAP device or power wheelchair for more than 13 months of continuous use will pay coinsurance payments for additional rental months beyond 13 months of continuous use, the monthly payments include payment

for ongoing costs such as replacement of accessories and repair and maintenance of equipment, which are also ongoing costs that exist under the current capped rental payment methodology. The cost of furnishing items and services is the same regardless of whether payment is made on a capped rental basis for equipment with separate payment for accessories, maintenance and servicing or on a bundled, continuous rental basis.

Most importantly, the statute prohibits the awarding of contracts under a CBP if the total payments to contract suppliers under the CBP are expected to be more than what would otherwise be paid and we would confirm that this requirement is met prior to implementing prices established under these special payment rules.

Comment: Some commenters were concerned that beneficiaries would not have the choice of opting out of the program although they would be notified about the alternative payment initiative.

Response: We proposed to phase-in the special payment rules because we believe they will have a positive impact on beneficiary access to quality equipment that continues to remain in good working order, while lowering the administrative costs of the program, and eliminating the need for beneficiaries to locate suppliers willing to repair equipment they own. In order to receive payment for equipment subject to this program, beneficiaries do not have the option to opt out. The programs will be closely monitored.

Comment: Most commenters were supportive of phasing in or testing the continuous rental bundled payment methodology on select products in limited areas. Some stakeholders suggested that bundled payment should be pilot tested first with a small subset of items and exclude complex items. Many commenters agreed that bundling will simplify complex

administration procedures.

Response: We agree with commenters that a phase-in limited to only a few select categories would be the best way to evaluate the impact of the special payment rules at this time. As such, we are not finalizing bundled, continuous payment rules for the following categories of items: enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, respiratory assist devices and hospital beds. The special payment rules would only be phased in initially for the following categories of DME items: CPAP devices and standard power wheelchairs. We selected the category of CPAP devices because we believe the cost of paying separately for the expensive accessories used with these devices exceeds the amount of savings achieved from capping the rental payments for the equipment. We selected the category of power wheelchairs because we believe that payment on a separate, piecemeal basis for hundreds of various power wheelchair options and accessories is unnecessary and overly complex. In addition, power wheelchairs are the most frequently repaired DME item and we believe that phasing in payment on a continuous monthly rental basis would ensure access to power wheelchairs that are in good working order. As discussed in our proposal (79 FR 40291), the CBPs would be phased in as early as 2017, and would be closely monitored. Subsequent rulemaking would be necessary to adopt special payment rules for other items or in more than 12 CBAs.

Comment: Some commenters recommended a bundled bid approach comprised of products associated with a single medical necessity or single coverage and payment policy. Some suggested accessories that are included in a bundle with the base equipment must be tied to the same medical necessity as the base equipment. One commenter suggested that beneficiaries meeting medical necessity for a support surface may also meet the medical

necessity for a hospital bed; however, support surfaces and hospital beds should never be included in the same bundle.

Response: These are issues that would be addressed in Medicare program guidance.

Comment: Some commenters were concerned that CMS has not provided information about how the Agency will administer a bundled bid program so the lack of information violates the Administrative Procedure Act (APA). The commenter's claim the proposed rule only gives general outline of the bundling program but does not explain what makes up a bundle, how bids will be evaluated or pivotal bids will be selected to establish payment amounts. These commenters stated that CMS must publish a new proposed rule soliciting comments on the elements of the biding program.

Response: We disagree. We have issued rules concerning the general dictates of the CBP and this competition would be consistent with those rules. We would evaluate suppliers and bids consistent with those provisions except that the bids and the SPAs established based on those bids would be for the monthly rental of DME and all items and services necessary for the effective use of the DME (that is, all related supplies, accessories, maintenance and servicing, etc.). Bids would not be submitted for purchase of any item or for separate payment for accessories used with base DME items. Under the existing CBP, CMS specifies certain parameters, but then through the Request for Bids (RFB) and competitive bidding process, further addresses certain details. Similar to other CBPs that do not employ the special payment rules, we intend to conduct extensive education outreach programs prior to implementing competitions that apply the bundled continuous rental methodology so that suppliers are educated about the rules and understand what is required of the bidding suppliers. This includes advance notice of bidding and comparator areas and defining the

bundled categories. We believe that our proposed rules were sufficiently detailed to enable the public to provide meaningful comments on them.

Comment: Many commenters urged CMS to share the bundled bidding methodology with stakeholders and establish quality metrics before beginning the program. Some commenters suggested that to facilitate accurate bidding CMS must give suppliers per patient utilization and expenditures data by HCPCS codes. Some commenters argued that CMS states in the proposed rule that it will monitor and evaluate the quality and success of bundled payments but no metrics have been determined or shared by CMS. Some suggested that submitted claims data versus paid claims data must be used. Those commenters stated that bid limits must take into account all repairs, accessories, and rental payments divided by number of patients to create a monthly per patient allowable. Commenters stated that bids must include only patients with active rental periods in calculating the bid limit. Commenters also stated that CMS must identify the data parameters from which it will take data. Many commenters recommended that CMS establish quality metrics before implementing the bundled payment. Some commenters recommended providing safeguards for Medicare beneficiaries, setting proper expectations with providers and evaluating the feasibility of the bundled payment methodology by creating methods to identify beneficiaries not identified in claims data, establishing minimum standards of quality and quantity of services, tracking products provided to the beneficiaries furnished with equipment paid on a bundled continuous rental basis as compared to all other Medicare beneficiaries to ensure quality care is being provided and beneficiaries have access to most innovative products. Commenters suggested we conduct a long term longitudinal study to determine comorbidity costs and access to care with bundled payments.

Response: We thank the commenters for their input. Consistent with the current CBP monitoring and oversight, CMS will employ a wide range of monitoring techniques before beginning any competition that applies the special payment rules. We will provide advance notice of the areas and comparator areas, defining bundles, verifying bona fide bids, and setting up monitoring techniques before beginning the competition. As we proposed in the proposed rule (79 FR 40291), in any competition where these final special payment rules are applied, we will provide advance notice of the rules at the time the competitions that utilize the rules are announced.

In order to monitor the impact of phasing in the special payment rules in the no more than 12 CBAs we are finalizing, we will 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 will at a minimum, 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 will monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we intend to 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 will also analyze the effect of the proposed payment rules on beneficiary cost by analyzing number of monthly rental payments made compared to reductions in coinsurance payments. Medicare has established quality standards, supplier standards, local medical review policies and other requirements that currently address

furnishing medically necessary items and services, and CMS monitors whether these requirements have been met by suppliers, as applicable. Submitted charge data is not used to establish Medicare allowed payment amounts and therefore would not be a good bid limit or a limit used to ensure that payments under the programs are less than what would otherwise be paid.

Comment: Some commenters argued that CMS did not provide information on how bids will be evaluated, what constitutes a bundle or how the pivotal bid will be selected to establish payment amounts. Commenters also indicated that CMS did not identify CBAs and comparator areas. Commenters also stated that there is no baseline for what constitutes a bundle in a product category so suppliers will not know what to bid. Commenters raised concerns that CMS has no way to compare bids because there is no consensus on what it takes to service patients who receive the bundle. Without an assessment tool and a baseline tool, those commenters believe that CMS has no way of comparing bids, or determining pivotal bids or verifying bona fide bids because there is no consensus on what is in the bundle or the intensity of the services patients who receive the bundle need. It would be difficult for suppliers to determine the appropriate amount to bid under a bundled payment method because there are many factors that would influence the cost associated with supplies, maintenance and repairs. Some expressed concerns about supplier challenges in determining the appropriate amount to bid because of factors such as case mix, variable cost of different types of base equipment and accessories and the variable cost associated with supplies, maintenance, repairs and frequency of replacement parts. Suppliers will have to guess the type of equipment and frequency of services different patients may need. Under a bundled bid, commenters were concerned that CMS will not be able to track utilization patterns that

could be harmful to the beneficiaries.

Response: We thank the commenters for their input. Although specific CBAs were not identified in the proposed rule, we will be identifying the areas and comparator areas, defining the bundles, and setting up monitoring techniques before beginning the competition as we have done during the previous rounds. As we proposed in the proposed rule (79 FR 40291), in any competition where these final special payment rules are applied, we will provide advance notice of implementation at the time the competitions that utilize the rules are announced. This notice could take the form of the competitive bidding request for bids or a CMS web posting or programs instructions or listserv messages and would define the related products and services included in a category's single bundled grouping. The process for setting the SPA and determining the pivotal bid in competitions where the special payment rules are applied would follow the existing process that is in place for a product category and outlined in sections 42 CFR 414.414 and 414.416 of our regulations. Using the CPAP and standard power wheelchair bid limits, which we will announce in advance of the competitions and calculate, consistent with what we proposed in the proposed rule (79 FR 40291) and are finalized in this rule, as well as past CBA utilization data for these bundled items, we believe bidding suppliers can use their experience in furnishing these items to develop a monthly bundled rental bid that would be reflective of their costs and profit for all items identified in the bundle. In competitions where the single bundled bid rules apply, CMS would continue to employ the wide range of resources used to monitor the CBP including use of real-time claims analysis to monitor the health outcomes status of groups in CBAs. Suppliers are responsible for providing all items and services to beneficiaries in accordance with the orders of their physicians. This responsibility does not change depending

on whether one payment is made for the monthly rental of DME and all related supplies, accessories, and services or whether piece meal payments are made for each individual item or service. For example, a supplier furnishes a CPAP device and accessories in accordance with the physician's order and replaces the accessories and services the rented equipment for up to 13 months of continuous use for individual beneficiaries.

As stated in the proposed rule, the impact of the rules on program expenditures, beneficiary cost sharing, access to items and services, and quality of care will be closely monitored and compared to impacts under comparator areas. To evaluate the quality of care for beneficiaries affected by the special payment rules, we will at a minimum, 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 will monitor utilization trends for each product category and track beneficiary complaints related to access issues. To evaluate the cost of the program, we intend to 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 will also analyze the effect of the proposed payment rules on beneficiary cost by analyzing number of monthly rental payments made compared to reductions in coinsurance payments.

Comment: Some commenters contended that payment on a continuous rental basis for select bundled items instead of on a capped rental basis would result in additional administrative burden for suppliers because they would have to submit more than 13 claims for rental of equipment to a beneficiary. Commenters reacted unfavorably to repeated billings for monthly rental claims for as long as the item is medically necessary.

Response: While suppliers may need to submit additional claims for the monthly rental of CPAP devices and power wheelchairs, they would no longer have to submit separate claims for accessories and repairs and would no longer have to keep track of periods of continuous use or when a rental cap is approaching. In addition, suppliers would no longer have to transfer title to equipment after 13 months of continuous use, and would therefore need to replace items in their inventory less often.

Comment: Numerous commenters requested a delay in the implementation of payment on a continuous rental basis for select bundled items. One commenter stated that more time is needed to educate practitioners, suppliers, and patients along with receipt of adequate program guidance. Several commenters stated CMS should convene advisory groups to study bundling payment methods and bidding factors. Another comment from a manufacturer's association requested CMS establish an additional HCPCS Advisory Panel to review and revise current HCPCS codes for improved bundling.

Response: The final rule does not set forth an exact timeframe for when the special payment rules will be implemented. CMS will be providing additional guidance and education, if needed.

Comment: Various commenters expressed concern that our proposal did not include a listing of existing HCPCS base codes along with HCPCS accessory codes that may comprise a bundled item code. As a result, several commenters submitted recommended coding bundles of existing HCPCS codes for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, power wheelchairs, CPAP, RADs, and hospital beds.

Response: CMS will follow the HCPCS coding process. We appreciate these comments and

thank the commenters for their helpful suggestions for coding bundles. When further steps for implementing a continuous rental basis for select bundled items are developed, we will review the submitted information to ensure compliance with the Medicare coverage and coding guidelines. As noted in an earlier response, specific information on the items that comprise a bundled bid for the CPAP category or standard power wheelchairs category will be announced

well in advance of a competition that would use the continuous rental payment methodology.

Comment: Commenters stated that the proposed change in payment rules will be adopted by payers other than Medicare and therefore should not be adopted.

Response: Such issues are beyond the scope of this rulemaking and we have not taken such things into consideration when finalizing our policies for the Medicare program. We appreciate that changes in Medicare policy may affect other insurers who choose to base their payments on Medicare payment rules; however, it is our obligation to set our policies based upon the needs of Medicare and its beneficiaries.

Comment: One commenter asked for clarification on how CMS will establish coverage criteria for a bundle of HCPCS codes consisting of a base and all options and accessories including what data will be used to establish the coverage criteria that will identify whether or not a beneficiary qualifies for a bundle of equipment, services, and supplies.

Response: These comments are outside the scope of the proposed rule, and therefore are not addressed in this final rule. The process for reviewing coverage for an item or bundle of items is not addressed in this payment rule.

We received many additional comments that were out of the scope of this rule.

In this final rule we are finalizing our proposal for only two items, CPAP devices and standard power wheelchairs. This rule finalizes the phase-in of special payment rules for CPAP and power wheelchairs as noted previously in the proposed rule (79 FR 40293) under the DMEPOS CBP in no more than 12 CBAs at 42 CFR 414.408, 414.409, and 414.412.

Comment: Some commenters noted that making payments for DME on a bundled, continuous rental basis will not eliminate repair issues and will increase financial burden on the beneficiaries. Some commenters noted that the ability for a beneficiary to switch to another

provider should he/she feel the service is not appropriate would drive competition for better care but bundling would not eliminate the need for patients to requalify for equipment when they change suppliers. Beneficiaries would still need to re-establish medical necessity when changing suppliers. Some suggested allowing beneficiaries to switch suppliers without restarting documentation. Some commented that mandating suppliers repair will not solve beneficiary's inability to obtain repairs for beneficiary-owned equipment.

Response: Contract suppliers paid for furnishing DME paid for on a bundled, continuous rental basis would be responsible for all necessary repairs, maintenance and servicing needed to keep the rental equipment in good working order or for replacing rental equipment that no longer functions and cannot be repaired. The process for documenting medical necessity for items would be addressed outside the rulemaking process.

We proposed 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 proposed to

revise the regulation at 42 CFR 414.408 to provide a cross reference to proposed § 414.409. We proposed 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 proposed 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 proposed that non-contract suppliers in these cases would have the option to continue rental agreements; however, we proposed that as part of the process of allowing the rental agreements to continue, the grandfathered supplier would be paid based on existing rules at § 414.408. We solicited comments on this proposed process. We did not receive any specific comment for this section and therefore, for the reasons we discussed previously, we are finalizing the proposed transition rules. This rule finalizes the transition rules as noted previously in the proposed rule (79 FR 40293, 40294) under the DMEPOS CBP at 42 CFR 414.409.

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

CBPs We proposed (79 FR 40294) 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. In these CBPs, we proposed 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 proposed 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 proposed that the contract supplier would not receive separate payment for these services and would factor the costs of these services into their bids. We proposed that the contract supplier would not be responsible for repairing power wheelchairs they did not furnish. We proposed 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 sought comments on these proposals. The comments and our responses are set forth below.

Comment: Some commenters argued that adding a requirement specifying that contract suppliers are responsible for repairing power wheelchairs they furnish will not eliminate problems beneficiaries are experiencing related to obtaining repairs for beneficiary-owned equipment.

Response: We agree that this requirement would not address situations where a beneficiary owns a power wheelchair in need of repairs that they received prior to the start of the CBP or

prior to moving into the CBA where the proposed rule would be in effect. It would also not address situations where a beneficiary owns a power wheelchair in need of repairs that they received prior to enrolling in Medicare part B. As stated in our proposal (79 FR 40294) we proposed that a contract supplier would not be responsible for repairing power wheelchairs they did not furnish. As a result, we proposed 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), which allows any Medicare enrolled DME supplier to perform this service and receive payment.

We also proposed 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 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 sought comments on these proposals, did not receive any specific comment for these proposals, and are therefore, for the reasons we discussed previously, we are finalizing these proposals. This rule finalizes the sections Beneficiary-Owned Equipment and Responsibility for Repair of Beneficiary-Owned Power Wheelchairs furnished under CBPs as noted previously in the proposed rule (79 FR 40294) under the DMEPOS CBP at 42 CFR 414.409

We proposed that the CBAs where the proposed rules in (79 FR 40294) 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 proposed that the boundaries of the CBAs would be established in accordance with the rules set forth at §§ 414.406 and 414.410. We proposed that additional CBPs for the items identified in sections 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 proposed 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 proposed 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 proposed 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 proposed 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 sought comments on this proposal, did not receive any specific comment for this proposal, and are therefore finalizing

this proposal.

We proposed that 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). We sought comments on this proposal, did not receive any specific comment for this proposal, and are therefore finalizing this proposal.

We are finalizing a change to add special payment rules at §414.409 that will be phased in. In no more than 12 CBAs, payment is made on a bundled, continuous monthly rental basis for standard power wheelchairs and CPAP devices. In addition, in no more than 12 CBAs, payment for power wheelchairs is made on a continuous rental basis, for power wheelchairs furnished in conjunction with competitions that begin 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. In accordance with § 414.408(c), 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.

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) proposed rule 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 addition, questions were raised regarding when it is appropriate for a supplier to bill for a prefabricated orthotic as having been custom fitted versus one furnished OTS. In order to address this specific question, the DME MACs issued a policy article on March 27, 2014, which details what custom fitting of an orthotic involves and indicating that furnishing custom fitted orthotics "requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements." The DMEPOS quality standards have been updated to reflect this requirement and we decided to revise the definition of minimal self-adjustment in the regulation to address this issue as well.

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 believed it was 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 believed the term "individual with specialized training" must be clarified in regulations as well as in contractor policies and DMEPOS quality standards. In addition, we believed that suppliers who are not certified orthotists should not be allowed to furnish custom fitted orthotics unless they have specialized training equivalent to a certified orthotist for the provision of custom fitted orthotic devices. We believed that these suppliers must 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 appropriate care and safety for Medicare beneficiaries.

C. Summary of the Proposed Provisions and Responses to Comments on the Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding

For reasons discussed above, we proposed that 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. We proposed these types of practitioners because we believe physicians, treating practitioners, occupational therapists, and physical therapists possess equivalent or higher educational degrees, continuing education requirements, licensing, and certification and/or registration requirements. Each of these professionals has undergone medical training in various courses such as kinesiology and anatomy.

Specifically, we proposed to update the definition of minimal self-adjustment in §414.402 to recognize as an individual with specialized training: 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.

At this time, we have decided not to finalize any changes to the definition of minimal self-adjustment in § 414.402 to recognize as an individual with specialized training. We may address this provision in future rulemaking.

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 competitive bidding programs (CBPs) in competitive bidding area (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 Change of Ownership (CHOW) must include the assumption of the entire contract, including all CBAs and PCs awarded under the contract.

B. Summary of the Proposed Provisions and Responses to Comments on the Revision to Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business

In this final rule, we provide a summary of each proposed provision, a summary of the public

comments received and our responses to them, and the policies we are finalizing for the DMEPOS CBP. We received 1 public comment on this proposal from a manufacturer and supplier. Comments related to the paperwork burden are addressed in the "Collection of Information Requirements" section in this final rule. Comments related to the impact analysis are addressed in the "Economic Analyses" section in this final rule.

Specifically, we proposed (79 FR 40298) 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 and accepts as a contract supplier. We proposed to 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 new qualified successor entity who meets all competitive bidding requirements (that is, financial standards, licensing, and accreditation) (79 FR 40299). The 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 also proposed that a contract supplier that wants to sell a distinct company which furnishes one or more specific PCs or serves one or more specific CBAs would be required 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 proposed 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 proposed that several conditions would have to be met. First, we proposed that every CBA, PC, and location of the company being sold must be transferred to the new owner. Second, we proposed 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 proposed that all requirements in 42 CFR 414.422 (d)(2) must be met. Fourth, we proposed that the sale of the company must include all of the company's assets associated with the CBA and/or PC(s). Finally, we proposed that CMS must determine that transferring part of the original contract will not result in disruption of service or harm to beneficiaries. No transfer would 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 invited comments on

whether more or different conditions would be appropriate.

We proposed to update the current CHOW regulation at § 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 sought comments on all changes proposed for § 414.422. The comment and our responses are set forth below.

Comment: One commenter recommended that CMS implement financial penalties for suppliers who sell their contracts along with selling their organizations prior to providing the product/service at the contracted payment rate, and/or remove an entity's bid from calculation of the SPA if they have failed to supply the awarded contract items for a period of time prior to re- sale. The commenters also believed that bids by suppliers who have no intention of providing services to Medicare beneficiaries should not be given the same weight as those of reputable suppliers in the community.

Response: CMS does not agree with the suggestions raised by this commenter. CMS cannot require a contract supplier to furnish a certain amount of competitive bid items. However, contract suppliers must be ready, available and willing to furnish contracted competitive bid items starting on day one of implementation to any beneficiary within a CBA. A contract supplier is not permitted to sell just its competitive bidding contract. CMS ensures that the successor entity 1) assumes all rights, obligations, and liabilities of the entire competitive bidding contract, 2) meets all requirements applicable to a contract supplier, and 3) is acquiring the assets of the existing supplier. In addition, the competitive bidding contract specifically states that CMS does not guarantee a minimum amount of business. In

response to the comment on the recalculation of the single payment amount (SPA), CMS carefully screens and evaluates bids to ensure that they are bona fide (rational and feasible) before determining the single payment amounts and offering contracts. Since only bona fide bids from qualified suppliers are included in the array of bids used to set prices, recalculating payment amounts based on contract rejections would not improve the validity of the single payment amounts. Also, the SPAs are set at the time of contract award and cannot be changed. It would not be possible for CMS to re- calculate the SPAs each time a contract supplier goes through a change of ownership. Contract offers include the SPAs applicable throughout the duration of the contract period for each HCPCS code in each CBA. Therefore, it is not possible for CMS to re-compute the SPAs whenever there is a change in contract suppliers as this would require continued re-contracting.

Therefore, for the reasons CMS stated above, CMS is finalizing the proposed changes to § 414.422(d) of the regulation and making one additional technical change to replace certain terms with "a new qualified entity," when referring to a company that is approved to purchases a contract supplier and assume the competitive bidding contract in whole or in part. We are making this technical change for purposes of consistency and to avoid possible confusion.

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

We proposed (79 FR 40299) to modify the DMEPOS CBPs appeals process for termination of competitive bidding contracts under § 414.423. First, we proposed 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 proposed to change these references to emphasize that the contract will automatically be terminated if the supplier does not file a hearing request or submit a corrective action plan.

In 42 CFR 414.423(l), we also proposed (79 FR 40299) deleting the lead-in sentence, as it does not properly lead into the first paragraph. Additionally, we proposed 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 proposed 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 proposed 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. We did not receive any comments on this proposal (79 FR 40299). For the reasons we noted previously, we are finalizing these changes to § 414.423, with two modifications to the regulation text to address errors in citation references. First, in the proposed regulation of the proposed rule (79 FR 40315), we incorrectly referenced § 414.423(b)(1) instead of §414.423(b)(2), so we are correcting that citation in this final rule. Second, although we made clear in the preamble our proposal to delete the lead-in language in § 414.423(l), we

inadvertently failed to note that deletion in the proposed regulation text. Therefore, we are making technical corrections in the final rule to reflect final decision to delete the lead-in sentence in § 414.423(l).

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 DME and medical supplies. The statute specifically states that this category includes "items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with DME." Implementation of CBPs for infusion drugs is therefore specifically mandated by the statute.

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 proposed 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 proposed 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. Infusion drugs have 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 proposed 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 sought comments on this proposal and received 4 comments. The comments and responses are set forth below.

Comment: Some commenters stated that CMS does not have authority to change payment amounts for infusion drugs using competitive bidding. One commenter stated that home infusion therapy is one of the most clinically complex therapies covered under the DME benefit and involves more than the delivery of infusion drugs to patients. The commenter believed that payment amounts for infusion drugs could be improperly reduced if

CMS sets the payment rate using bids from inexperienced providers who do not adequately account for the cost of the services.

Response: Section 1847(a)(2)(A) of the Act includes infusion drugs in the list of items subject to the DMEPOS Competitive Bidding Program. Therefore, we are finalizing our proposal to modifying § 414.414(f) of the regulations, with an additional modification to make a general reference to Subpart I. We note, however, that at this time there are no CBPs in effect that include infusion drugs. The phase-in of infusion drugs would occur under a future CBP(s).

XII. Accelerating Health Information Exchange

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange)." The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: 1) alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies, 2) adoption of common standards and certification requirements for interoperable health IT, 3) support for privacy and security of patient information across all HIE-focused initiatives, and 4) governance of health information networks. These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs

and those who are not eligible for the EHR Incentive programs, and are designed to improve care delivery and coordination across the entire care continuum. For instance, to increase flexibility in the Office of the National Coordinator for Health Information Technology's (ONC) regulatory certification structure Health IT Certification Program, ONC expressed in the 2014 Edition Release 2 final rule (79 FR 54472 through 54473) an intent to propose future changes to the program that would permit the certification of health IT for other health care settings, such as long-term and post-acute care and behavioral health settings.

We believe that HIE and the use of certified EHRs can effectively and efficiently help ESRD facilities and nephrologists improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures (eCQMs).

XIII. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

C. Additional Information Collection Requirements

XIV. Economic Analyses

A. Regulatory Impact Analysis

This final rule establishes a methodology for adjusting DMEPOS fee schedule amounts using information from the Medicare DMEPOS CBP. The final rule phases in special payment rules for certain DME in a limited number of areas under the Medicare DMEPOS CBP. This rule also clarifies the Medicare hearing aid coverage exclusion under section 1862(a)(7) of the Act. Finally, this final rule modifies the rules for a CHOW under the Medicare DMEPOS CBP.

3. Overall Impact

We estimate that the final methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs would save over $4.4 billion in gross payments over FYs 2016-2020. The gross savings would be primarily achieved from the reduced payment amounts for items and services.

We estimate the special payment rules at § 414.409 would not have a negative impact on beneficiaries and suppliers, or on the Medicare program. Contract suppliers are responsible for furnishing items and services needed by the beneficiary, and the cost to suppliers for furnishing these items and services generally would 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 fiscal impact generally would be the same as is under the current payment rules. Furthermore, as indicated above, the special payment rules would be phased in under a limited number of areas to gradually determine effects on the program, beneficiaries, and suppliers, including their effects on cost, quality, and access before expanding to other areas after notice and comment rulemaking, if supported by evaluation results. We believe that the special payment rules will give beneficiaries more choice and flexibility in changing suppliers. We estimate the clarification of the statutory Medicare hearing aid coverage exclusion will not have a significant fiscal impact on the Medicare program because we are not changing the current coverage for devices for Medicare payment purposes. This regulation at § 411.15(d) will provide guidance as to coverage of DME with regard to the statutory exclusion.

We estimate finalizing a change to the CHOW rules under the Medicare DMEPOS CBP will have no significant impact to DMEPOS suppliers.

B. Detailed Economic Analysis

3. DMEPOS Provisions

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

We estimate that the final methodology for adjusting DMEPOS payment amounts using information from DMEPOS CBPs will save over $4.4 billion in gross payments over FY 2016 through 2020. The gross savings will 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 40.)

TABLE 40: Impact of Pricing Items in Non-Competitive Areas Using Competitive Bidding Pricing*

FY	Impact on the gross impact in dollars (to the nearer ten million)	Impact on beneficiary cost sharing in dollars (to the nearer ten million)
2016	-550	-130
201	-	-
201	-	-
201	-	-
202	-	-

b. Effects of the Final Special Payment Methodologies under the Competitive Bidding Program We believe that the final special payment rules will 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 will reflect the cost of furnishing items in accordance with the new payment rules, we expect the overall savings will be generally the same as they are under the current payment rules. Section 1847(b)(2)(A)(iii) prohibits the awarding of contracts under a CBP unless total payments made to contract suppliers in the CBA are expected to be less than the payment amounts that would otherwise be made. Furthermore, as indicated above, we are finalizing a phase-in of the special payment rules under a limited number of areas to gradually determine effects on the program, beneficiaries, and suppliers. If supported by evaluation results, a decision to expand the special payment rules to other areas will be

addressed in future rulemaking.

This final rule clarifies the scope of the Medicare coverage exclusion for hearing aids. This rule will not have a fiscal impact on the Medicare program because there will be no change in the coverage of devices for Medicare payment purposes. This clarification will provide clear guidance about coverage of DME with regard to the statutory hearing aid exclusion.

d. Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding The final rule will not finalize a modification to the definition of minimal self-adjustment.

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

This final rule modifies the change of ownership rules to reduce interference with the normal course of business for DME suppliers. This rule establishes 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 under certain specific circumstances. This change impacts 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 41 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

XV. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

We expect the final methodologies for adjusting DMEPOS fee schedule amounts using information from DMEPOS CBPs will 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 fee schedule amounts for these items and services will be reduced using the methodology established as a result of the final rule. The statute requires that the methodology for adjusting fee schedule 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 V.A.5.). The final methodology for making payment adjustments will allow for adjustments based on bids in different geographic regions to reflect regional costs of furnishing items and services or the national limits for adjustments in areas with costs outside of MSAs and areas subject to section 1847(a)(3)(A) of the Act. We believe that suppliers will 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 final special payment rules for certain DME will not have a significant impact on small suppliers. We believe that these rules will benefit affected suppliers since payment for rental of certain DME would no longer be capped and suppliers would retain ownership to the equipment.

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

Therefore, the Secretary has determined that this final rule will have a significant economic impact on a substantial number of small entities. We solicited comment on the RFA analysis provided. The comments and our responses are set forth below.

Comment: Some commenters noted that CMS has not considered the economic and regulatory flexibility analysis under the proposed rule for applying special payment rules for certain DME in competitive bidding areas and the final Methodology for Adjusting DMEPOS Payment Amounts using Information from Competitive Bidding Programs.

Response: We thank the commenters for their input. The continuous rental bundled payment methodology will be phased in for only two items, CPAP device and power wheelchairs in no more than 12 CBAs at this time. Our analysis indicates that establishing single payment amounts based upon bids submitted by suppliers using the continuous rental bundled methodology instead of capped rental methodology for these two items in no more than 12 CBAs will not have a significant impact because the bid limits for power wheelchairs will be based upon current utilization and expenditure in the 12 CBAs. The updated 1993 fee schedule amounts would be the bid limits for CPAP. The 1993 fee schedule represents a

fairly accurate bundled rental payment amount for the CPAP and the covered item update factor would cover for improvements in technology. The CPAP fees from 1993 were based on average reasonable charges from July 1986 through June 1987 for rental of the device with no separate payment for the accessories; we believe the historic amounts fairly reflect the utilization and payment for accessories used with the device. We expect that the final special payment rules will not have a significant impact on small suppliers because of the limited scope of the program. The phase-in of the special payment rules would be limited to only two product categories; Power Wheelchairs and CPAP devices in no more than 12 CBAs.

We expect the final methodologies for adjusting DMEPOS fee schedule amounts using information from DMEPOS CBPs will have a significant impact on a substantial number of small suppliers. However, 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, therefore, the only alternative we can consider other than paying based on adjusted fee schedule amounts is to implement CBPs in all areas, however, our analysis indicates that this approach would have an even greater impact on small suppliers. The statute requires that the methodology for adjusting fee schedule amounts take into consideration the costs of furnishing items and services in areas where the adjustments will occur and we have considered these factors in developing the final methodology, thereby reducing the extent of impact on small suppliers. We believe that suppliers will 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.