

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice-and-comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in Section II.B of this document, including the basis for that finding.

IV. Statutory Authority

The statutory authority for this action is provided by sections 110, 126 and 307 of the CAA as amended (42 U.S.C. 7410, 7426 and 7607).

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practices and procedures, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone.

Dated: May 3, 2018.

E. Scott Pruitt,
Administrator.

[FR Doc. 2018-09892 Filed 5-8-18; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 414**

[CMS-1687-IFC]

RIN 0938-AT21

Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period makes technical amendments to the regulation to reflect the extension of the transition period from June 30, 2016 to December 31, 2016 that was mandated by the 21st Century Cures Act for phasing in fee

schedule adjustments for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In addition, this interim final rule with comment period amends the regulation to resume the transition period's blended fee schedule rates for items furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and United States territories) not subject to the CBP from June 1, 2018 through December 31, 2018. This interim final rule with comment period also makes technical amendments to existing regulations for DMEPOS items and services to reflect the exclusion of infusion drugs used with DME from the DMEPOS CBP.

DATES:

Effective date: The provisions of this interim final rule with comment period are effective on June 1, 2018.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 9, 2018.

ADDRESSES: In commenting, please refer to file code CMS-1687-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1687-IFC, P.O. Box 8010, Baltimore, MD 21244-8010.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1687-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT: Laurence Wilson, 410-786-4602 and DMEPOS@cms.hhs.gov.

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

Table of Contents

- I. Executive Summary
 - A. Purpose
 - B. Summary of the Major Provisions
 - C. Summary of Costs and Benefits
- II. Durable Medical Equipment, Prosthetics, Orthotics Supplies (DMEPOS) Fee Schedule and Competitive Bidding Program (CBP)
 - A. Background for Payment Revisions for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
 - 1. Fee Schedule Payment Basis for Certain DMEPOS
 - 2. DMEPOS CBP
 - a. Payment Basis
 - b. Geographic Areas Designated Under the DMEPOS CBPs
 - B. Background on the Methodology for Adjusting Payment Amounts for Certain DMEPOS Using Information From DMEPOS CBPs
 - C. Transition Period for Phase-In of Fee Schedule Adjustments
 - 1. Statutory Mandate To Reconsider Fee Schedule Adjustments
 - 2. Fee Schedule Adjustment Impact Monitoring Data
 - 3. Restoring Transitional Blended Fee Schedule Rates in Rural Areas and Non-Contiguous Areas
 - D. Fee Schedule Amounts for Accessories Used With Group 3 Complex Rehabilitative Power Wheelchairs
 - E. Technical Changes To Conform the Regulation to Section 5004(b) of the 21st Century Cures Act (the Cures Act): Exclusion of DME Infusion Drugs Under CBPs
- III. Provisions of the Interim Final Rule With Comment Period
 - A. Transition Period for Phase-In of Fee Schedule Adjustments
 - B. Technical Changes To Conform the Regulation to Section 5004(b) of the Cures Act: Exclusion of DME Infusion Drugs Under CBPs
- IV. Waiver of Proposed Rulemaking
- V. Collection of Information Requirements
- VI. Response to Comments
- VII. Economic Analyses
 - A. Regulatory Impact Analysis
 - 1. Introduction
 - 2. Statement of Need
 - 3. Overall Impact
 - B. Detailed Economic Analysis
 - a. Effects on the Medicare Program and Beneficiaries

- b. Impact on Beneficiaries and Other Payers
- c. Alternatives Considered
- d. Regulatory Familiarization Costs
- C. Accounting Statement
- VIII. Regulatory Flexibility Act Analysis
- IX. Unfunded Mandates Reform Act Analysis
- X. Federalism Analysis
- XI. Reducing Regulation and Controlling Regulatory Costs
- XII. Congressional Review Act

I. Executive Summary

A. Purpose

This interim final rule with comment period amends the regulation at 42 CFR 414.210(g)(9) to reflect the extension of the transition period for phasing in fee schedule adjustments for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) through December 31, 2016, mandated by section 16007(a) of the 21st Century Cures Act (the Cures Act) (Pub. L. 114–255). In addition, in light of information, the Centers for Medicare & Medicaid Services (CMS) has gathered in accordance with section 16008 of the Cures Act, this interim final rule with comment period resumes the transition period for phasing in adjusted fee schedule rates for DME items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and United States (U.S.) territories) not subject to the CBP from June 1, 2018 through December 31, 2018. It also makes technical amendments to existing regulations for DMEPOS items and services to reflect the exclusion of infusion drugs used with DME from the DMEPOS CBP, as required by section 5004(b) of the Cures Act.

B. Summary of the Major Provisions

- *Transition Period for Phase in of Adjustments to Fee Schedule Amounts:* We are amending § 414.210(g)(9)(i) to reflect the extension of the transition period to December 31, 2016 for phasing in adjustments to the fee schedule amounts for certain items based on information from the DMEPOS CBP that was required by section 16007(a) of the Cures Act. In addition, we are adding § 414.210(g)(9)(iii) to resume the fee schedule adjustment transition period in rural areas and non-contiguous areas effective June 1, 2018, in light of concerns regarding the impact of the full fee schedule adjustments in rural and non-contiguous areas, so that the 50/50 blended fee schedule rates will apply for certain items and services furnished in rural and non-contiguous areas from

June 1, 2018 through December 31, 2018. We are also amending § 414.210(g)(9)(ii) to reflect that for items and services furnished with dates of service from January 1, 2017 to May 31, 2018, and on or after January 1, 2019, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount. We are soliciting comments on the resumption of the transition period for the phase in of fee schedule adjustments.

- *Technical Change Excluding DME Infusion Drugs From the DMEPOS CBP:* Section 5004(b) of the Cures Act amends section 1847(a)(2)(A) of the Social Security Act (the Act) to exclude drugs and biologicals described in section 1842(o)(1)(D) of the Act from the DMEPOS CBP. We are making conforming changes to the regulation to reflect the exclusion of infusion drugs, described in section 1842(o)(1)(D) of Act, from items subject to the DMEPOS CBP.

C. Summary of Costs and Benefits

This interim final rule with comment period resumes the blended adjusted Medicare fee schedule amounts during the transition period for certain items and services that are furnished in rural and non-contiguous areas not subject to the CBP beginning June 1, 2018. It is estimated that these adjustments will cost \$290 million in Medicare benefit payments and \$70 million in Medicare beneficiary cost sharing for the period beginning June 1, 2018 and ending December 31, 2018.

We are unable to quantify the benefits of this interim final rule with comment period at this time; however, the goal of this interim final rule is to preserve beneficiary access to DME items and services in rural and non-contiguous areas not subject to the CBP during a transition period in which CMS will continue to study the impact of the change in payment rates on access to items and services in these areas. The alternative to this interim final rule with comment period would have been to allow the full phase in of fee schedule adjustments based on competitive bidding prices to continue in all non-competitive bidding areas (non-CBAs). We believe that resuming the fee schedule adjustment transition period in rural and non-contiguous areas promotes stability in the DMEPOS market in these areas, and enables CMS to work with stakeholders to preserve beneficiary access to DMEPOS.

II. Durable Medical Equipment, Prosthetics, Orthotics Supplies (DMEPOS) Fee Schedule and Competitive Bidding Program (CBP)

A. Background for Payment Revisions for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

1. Fee Schedule Payment Basis for Certain DMEPOS

Section 1834(a) of the Act governs payment for 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 are 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).
- 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 under the Part B benefit for prosthetic devices defined at section 1861(s)(8) of the Act. The Medicare allowed amount for DMEPOS items and services paid on a fee schedule basis is equal to the lower of the supplier’s actual charge or the fee schedule amount. We refer readers to the November 6, 2014 calendar year (CY) 2015 ESRD PPS final rule entitled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies” (79 FR 66223 through 66233) for additional background discussion about DMEPOS items subject to section 1834 of the Act, rules for calculating reasonable charges, and fee schedule payment methodologies for PEN and for DME prosthetic devices, prosthetics, orthotics, and surgical dressings.

2. DMEPOS CBP

a. Payment Basis

The DMEPOS CBP is mandated by section 1847(a) of the Act and requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement CBPs in competitive bidding areas (CBAs) throughout the U.S for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. Section 1847(a)(2) of the Act describes the items and services subject to the DMEPOS CBP:

- 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.
- 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 devices that have been classified in class III under the Federal Food, Drug, and Cosmetic Act and Group 3 or higher complex rehabilitative power wheelchairs and related accessories when furnished in connection with such wheelchairs. Although initially identified in section 1847(a)(2) of the Act, infusion drugs were excluded from the DMEPOS CBP by section 5004(b) of the Cures Act. Sections 1847(a) and (b) of the Act specify certain requirements and conditions for implementation of the Medicare DMEPOS CBP.

Under the DMEPOS CBP, Medicare sets single payment amounts (SPAs) for selected DMEPOS items and services furnished to beneficiaries in CBAs based on the median of bids submitted by winning suppliers and accepted by Medicare for each individual item and service. For competitively bid items and services furnished in a CBA, the SPAs replace the Medicare allowed amounts established using the lower of the supplier's actual charge or the payment amount recognized under sections 1834(a)(2) through (7) of the Act. Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is made on an assignment-related basis, and is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act.

B. Background on the Methodology for Adjusting Payment Amounts for Certain DMEPOS Using Information From DMEPOS CBPs

For DME furnished on or after January 1, 2016, section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs. Section 1834(a)(1)(F)(iii) of the Act requires the Secretary to continue to make these adjustments as additional covered items are phased in or information is updated as new CBP contracts are awarded. Similarly, sections 1842(s)(3)(B) and 1834(h)(1)(H)(ii) of the Act authorize the Secretary to use payment information from the DMEPOS CBP to adjust the fee schedule amounts for enteral nutrition and OTS orthotics, respectively, furnished in all non-CBAs. Section 1834(a)(1)(G) of the Act requires that in promulgating the methodology used in making these adjustments to the fee schedule amounts, the Secretary consider the costs of items and services in areas in which the adjustments would be applied compared to the payment rates for such items and services in the CBAs.

On February 26, 2014, we published an Advance Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** entitled, "Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Using Information from Competitive Bidding Programs" (79 FR 10754). In that ANPRM, we solicited stakeholder input on several factors including whether the costs of furnishing various DMEPOS items and services vary based on the geographic area in which they are furnished in relation to developing a payment methodology to adjust DMEPOS fee schedule amounts or other payment amounts in non-CBAs based on DMEPOS competitive bidding payment information.

We received approximately 185 comments from suppliers, manufacturers, professional, state and national trade associations, physicians, physical therapists, beneficiaries and their caregivers, and one state government office. Commenters generally stated that costs do vary by geographic region and that costs in rural and non-contiguous areas of the U.S. (Alaska, Hawaii, Puerto Rico, etc.) are significantly higher than costs in urban areas and contiguous areas of the U.S. One commenter representing many

manufacturers and suppliers listed several key variables or factors that influence the cost of furnishing items and services in different areas that should be considered. This commenter stated that information on all bids submitted under the CBP should be considered and not just the bids of winning suppliers. Some commenters expressed concern that the SPAs assume a significant increase in volume to offset lower payment amounts. Commenters also recommended phasing in the adjusted fee schedule amounts, allowing for adjustments in fees if access issues arise, and annual inflation updates to adjusted fee schedule amounts.

On July 11, 2014, we published the CY 2015 ESRD PPS proposed rule in the **Federal Register** entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies;" (79 FR 40208) as required by section 1834(a)(1)(G) of the Act, to establish methodologies for using information from the CBP to adjust the fee schedule amounts for items and services furnished in non-CBAs in accordance with sections 1834(a)(1)(F)(ii) and 1834(h)(1)(H)(ii) of the Act. We also proposed making adjustments to the payment amounts for enteral nutrition as authorized by section 1842(s)(3)(B) of the Act.

We received 89 public comments on the proposed rule, including comments from patient organizations, patients, manufacturers, health care systems, and DME suppliers. We made changes to the proposed methodologies based on these comments and finalized a method for paying higher amounts for certain items furnished in areas defined as rural areas. In addition, we provided a 6-month fee schedule adjustment phase in period from January through June of 2016, during which the fee schedule amounts would be based on 50 percent of the unadjusted fees and 50 percent of the adjusted fees to allow time for suppliers to adjust to the new payment rates and to monitor the impact of the change in payment rates on access to items and services. On November 6, 2014, we published the CY 2015 ESRD PPS final rule (79 FR 66223 through 66265) to finalize the methodologies at § 414.210(g) based on public comments received on the CY 2015 ESRD PPS proposed rule (79 FR 40208). A summary of the methodologies are provided below.

In order to delineate geographic areas to which adjusted fee schedule amounts for certain DMEPOS items are applied, we set forth a methodology to identify geographic areas using zip codes into 3

categories of rural, non-rural, and non-contiguous. We promulgated § 414.202 to define a rural area to mean, for the purpose of implementing § 414.210(g), a geographic area represented by a postal zip code if at least 50 percent of the total geographic area of the area included in the zip code is estimated to be outside any Metropolitan Statistical Area (MSA) (79 FR 66228). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a CBA in accordance with section 1847(a)(3)(A) of the Act at the time the rules in § 414.210(g) are applied.

In accordance with § 414.210(g)(1)(i) through (v), CMS first determines regional adjustments to the fee schedule amounts using the 8 regions of the Bureau of Economic Analysis. Also, the regional prices are determined and limited by a national ceiling (110 percent of the average of regional prices) and floor (90 percent of the average of regional prices). In addition, adjusted fee schedules for non-contiguous areas are based on the higher of the average of the SPAs for CBAs in areas outside the contiguous U.S. or the national ceiling amount in accordance with our regulations at § 414.210(g)(2)(i) through (ii). Also, § 414.210(g)(3) specifies adjustments for low volume items (that is, bid in only 10 or fewer competitive bidding programs) are based on 110 percent of the average of the SPAs. In addition, adjustments for items and services included in CBPs no longer in effect is set forth at § 414.210(g)(4). In cases where the SPAs from the DMEPOS CBP that are no longer in effect are used to adjust fee schedule amounts, § 414.210(g)(4) provides that the SPAs be updated by an inflation adjustment factor for each year from the last year when the SPAs were in effect to the year in which the adjustment would go into effect (for example, 2016) and for each subsequent year (for example, 2017 and 2018). Furthermore, § 414.210(g)(5) establishes adjustments for accessories used with different types of base equipment in situations where a Healthcare Common Procedure Coding System (HCPCS) code describing an item used with different types of base equipment is included in more than one product category in a CBA under the CBP; a weighted average of the SPAs for the code is computed for each CBA prior to applying the other payment adjustment methodologies in § 414.210(g). Finally, in accordance with § 414.210(g)(6), adjustments are made to the SPAs for certain items due to price inversions under the DMEPOS CBP (for example, the SPA for a walker without

wheels is higher than the SPA for a walker with wheels) before the SPAs are used to adjust fee schedule amounts. For groupings of similar items (for example, walkers) where price inversions have occurred, the SPAs for the items in the grouping are all adjusted to equal the weighted average of the SPAs for all of the items in the grouping. Price inversions are situations where the higher weighted and higher priced item at the time of competition becomes the lower priced item in the CBP following the competition. For a discussion regarding adjustments to SPAs to address price inversions, see the CY 2017 ESRD PPS proposed rule published in the **Federal Register** on June 30, 2016 entitled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment, and the Comprehensive End-Stage Renal Disease Care Model” (81 FR 42851).

In order to update the adjusted fee schedule amounts based on new competitions and provide for a transitional phase-in period of the fee schedule adjustments, we established § 414.210(g)(8) and (g)(9) in the CY 2015 ESRD PPS final rule (79 FR 66263). In § 414.210(g)(8), the adjusted fee schedule amounts are updated when an SPA for an item or service is updated following one or more new DMEPOS CBP competitions and as other items are added to DMEPOS CBP. The fee schedule amounts that are adjusted using SPAs are not subject to the annual DMEPOS covered item update and are only updated when SPAs from the DMEPOS CBP are updated. Updates to the SPAs may occur as contracts are recomputed. Section 414.210(g)(9)(i), specifies that the fee schedule adjustments were phased in for items and services furnished with dates of service from January 1, 2016 through June 30, 2016, so that each fee schedule amount was adjusted based on a blend of 50 percent of the fee schedule amount if not adjusted based on information from the CBP, and 50 percent of the adjusted fee schedule amount. Section 414.210(g)(9)(ii) specifies that for items

and services furnished with dates of service on or after July 1, 2016, the fee schedule amounts would be equal to 100 percent of the adjusted fee schedule amounts. Commenters recommended CMS phase in the fee schedule adjustments to give suppliers time to adjust to the change in payment amounts (79 FR 66228). Some commenters recommended a 4-year phase-in of the adjusted fees. CMS agreed that phasing in the adjustments to the fee schedule 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. We decided 6 months was enough time to monitor access and health outcomes to determine if the fee schedule adjustments created a negative impact on access to items and services. Therefore, we finalized a 6-month phase-in period of the blended rates (79 FR 66228 through 66229).

We finalized the 6-month transition period from January 1 through June 30, 2016 in the CY 2015 ESRD PPS final rule (79 FR 66223) that was published in the **Federal Register** on November 6, 2014. The Cures Act was enacted on December 13, 2016, and section 16007(a) of the Cures Act extended the transition period for the phase-in of fee schedule adjustments at § 414.210(g)(9)(i) by 6 additional months so that fee schedule amounts were based on a blend of 50 percent of the adjusted fee schedule amount and 50 percent of the unadjusted fee schedule amount until December 31, 2016 (with full implementation of the fee schedule adjustments applying to items and services furnished with dates of service on or after January 1, 2017).

C. Transition Period for Phase-In of Fee Schedule Adjustments

We have determined that the transitional period for the phase-in of adjustments to fee schedule amounts should be resumed in non-CBA rural and non-contiguous areas in order to ensure access to necessary items and services in these areas. This interim final rule with comment period amends § 414.210(g)(9) to change the end date for the initial transition period for the phase-in of adjustments to fee schedule amounts for certain items based on information from the DMEPOS CBP from June 30, 2016 to December 31, 2016, to reflect the extension that was mandated by section 16007(a) of the Cures Act. This interim final rule with comment period also amends § 414.210(g)(9) to resume the transition period for the phase-in of adjustments to

fee schedule amounts for certain items furnished in non-CBA rural and non-contiguous areas from June 1, 2018 through December 31, 2018, for the reasons discussed in this preamble.

1. Statutory Mandate To Reconsider Fee Schedule Adjustments

After we established the fee schedule adjustment methodology under § 414.210(g), Congress amended section 1834(a)(1)(G) of the Act to require that CMS take certain steps and factors into consideration regarding the fee schedule adjustments for items and services furnished on or after January 1, 2019, to ensure that the rates take into account certain aspects of providing services in non-CBAs. Specifically, section 16008 of the Cures Act amended section 1834(a)(1)(G) of the Act to require in the case of items and services furnished on or after January 1, 2019, that in making any adjustments to the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and (iii) of the Act, the Secretary shall: (1) Solicit and take into account stakeholder input; and (2) take into account the highest bid by a winning supplier in a CBA and a comparison of each of the following factors with respect to non-CBAs and CBAs:

- The average travel distance and cost associated with furnishing items and services in the area.
- The average volume of items and services furnished by suppliers in the area.
- The number of suppliers in the area.

On March 23, 2017, CMS hosted a national provider call to solicit stakeholder input regarding adjustments to fee schedule amounts using information from the DMEPOS CBP. The national provider call was announced on March 3, 2017, and we requested written comments by April 6, 2017. We received 125 written comments from stakeholders. More than 330 participants called into our national provider call, with 23 participants providing oral comments during the call. In general, the commenters were mostly suppliers, but also included manufacturers, trade organizations, and healthcare providers such as physical and occupational therapists. These stakeholders expressed concerns that the level of the adjusted payment amounts constrains suppliers from furnishing items and services to rural areas. Stakeholders requested an increase to the adjusted payment amounts for these areas. The written comments generally echoed the oral comments from the call held on March 23, 2017, whereby stakeholders claimed

that the adjusted fees are not sufficient to cover the costs of furnishing items and services in rural and non-contiguous areas and that this is having an impact on access to items and services in these areas.

The oral and written comments are organized into the following categories:

Inadequacy of Adjusted Fee Schedule Amounts: Commenters claim the adjusted fee schedule amounts do not cover the cost of furnishing the items and are not sustainable. Many commenters opposed the current adjusted payment amounts as insufficient to sustain the current cost of doing business. Some commenters stated that current reimbursement levels are below the cost of doing business. Many commenters stated they were billing non-assigned for items, or were considering billing non-assigned in the future.

Travel Distance: Commenters claim the average travel distance and cost for suppliers serving rural areas are greater than the average travel distance and cost for suppliers serving CBAs. Many commenters described farther travel distances in rural areas than in non-rural areas. For the purpose of implementing the fee schedule adjustment methodologies at § 414.210(g), the term “rural area” is defined at § 414.202 and essentially includes any areas outside an MSA or excluded from a CBA.

Volume of Services: Many commenters asserted that the average volume of services furnished by suppliers, when serving non-CBAs, are lower than the average volume of services furnished by suppliers, when serving CBAs. Many commenters stated that they do not get the same increase in volume that suppliers who obtain competitive bidding contracts get, which does not allow them to have economies of scale and obtain products at lower costs. Claims data for 2016 and 2017 indicates that the average volume of allowed services for suppliers serving CBAs is significantly higher than the average volume of allowed services for suppliers serving non-CBAs, particularly rural and non-contiguous areas.

Beneficiary Access: Many commenters stated that the adjusted fees have reduced the number of suppliers in the area, and that this has caused or will cause beneficiary access issues. Some commenters explained that they were the only supplier in the area. Claims data indicates that the number of supplier locations furnishing items and services subject to the fee schedule adjustments changed from 13,535 in 2015 to 12,617 in 2016.

Adverse Beneficiary Health

Outcomes: Commenters stated that beneficiaries are going without items and this is causing adverse health outcomes. Commenters stated that hospital readmissions and lengths of stay, falls, and fractures are increasing as a result of the fee schedule reductions.

Delivery Expenses: A few commenters provided an estimate of how much their delivery expenses cost, their estimated service radius, and the average distance traveled. Several commenters stated that they have reduced the size of their service area due to the level of reimbursement that they are receiving.

Costs in Rural and Non-Contiguous Areas: Many commenters stated rural areas have unique costs, costs that are higher than non-rural areas. Similar to comments received on our CY 2015 ESRD PPS proposed rule (79 FR 40275 through 40315) and discussed in the CY 2015 ESRD PPS final rule (79 FR 66223 through 66265), some commenters stated that a 10 percent payment increase in rural areas is not enough to cover costs in rural areas. One commenter stated that non-contiguous areas, such as Alaska and Hawaii, face unique and greater costs due to higher shipping costs, a smaller amount of suppliers, and more logistical challenges related to delivery. Some commenters stated specific costs, as well as data sources, that CMS should take into account when adjusting fees in non-CBAs. These included the following: Geographic wage index factors, gas, taxes, employee wages and benefits, wear and tear of vehicle, average per capita income, training, delivery, set up, historical Medicare home placement volume, proximity to nearby CBAs, employing a respiratory therapist, electricity charges, freight charges, 24/7 service, documentation requirements, average per patient cost, licensing accreditation, surety bonds, audits, population density, miles and time between points of service, regulatory costs, vehicle insurance, and liability insurance.

Two commenters pointed to the Ambulance Fee Schedule and one commenter pointed to the Bureau of Labor Statistic Consumer Expenditure Survey as evidence that health care costs in rural areas are higher than in urban areas. Another commenter mentioned the Internal Revenue Service Mileage Rate, the minimum wage, AAA Gallon of Gasoline prices, and the price of a loaf of white bread, to highlight how the prices of such items have increased over the years, while reimbursement for DME has not.

Using the Highest Winning Bids for the Adjusted Fee Schedule

Methodology: Five commenters suggested that the adjusted fee schedule amounts be based on maximum winning bids in CBAs rather than the median of winning bids in CBAs. One commenter suggested that the maximum winning bids should be the starting point for the adjustments and that additional payment should be added on to these amounts to pay for the higher costs of furnishing items and services in non-CBAs.

One of the factors CMS must consider when making fee schedule adjustments for items and services furnished on or after January 1, 2019, in accordance with section 16008 of the Cures Act, is the average volume of items and services furnished by suppliers in an area. A supplier recoups costs through the payments made for the items they furnish. In the case of overhead costs such as rent, utilities, salaries, and employee benefits, the more items a supplier furnishes, the more the supplier is able to recoup these overhead costs. Data for items furnished in 2016 and 2017 shows that the average volume of items furnished by suppliers in CBAs exceeds the average volume of items furnished by suppliers in rural and non-contiguous areas. The fact that the volume of items furnished per supplier in rural and non-contiguous areas is less than the volume furnished in CBAs indicates that the cost per item in rural and non-contiguous areas may be higher than the cost per item in CBAs. Because there are fewer suppliers in CBAs furnishing a higher volume of items and services, these suppliers likely have lower costs per item because they can make up their overhead costs over more items. In addition, the higher the volume of items a supplier furnishes, the larger the volume purchasing discount is likely to be when purchasing equipment from a manufacturer. This supports stakeholder input that the suppliers in rural and non-contiguous areas have an average volume of business less than that of their counterparts in CBAs, and that this difference may make it more difficult for suppliers in rural and non-contiguous areas to meet their expenses.

In addition, the adjusted fee schedule amounts for stationary oxygen equipment in non-contiguous, non-CBAs are lower than the SPA for stationary oxygen equipment in the Honolulu, Hawaii, CBA and the adjusted fee schedule amounts for stationary oxygen equipment in some rural areas are lower than the SPAs in CBAs within the same state. This is due to the combination of the fee schedule

adjustments and the budget neutrality offset that CMS applies to stationary oxygen equipment and contents due to the separate oxygen class for oxygen generating portable equipment (OGPE). In 2006, CMS established a separate payment class for OGPE (which are portable concentrators with transfilling equipment), through notice and comment rulemaking (71 FR 65884). The authority to add this payment class, located at section 1834(a)(9)(D) of the Act, only allows CMS to establish new classes of oxygen and oxygen equipment if such classes are budget neutral, which means that the establishment of new oxygen payment classes does not result in oxygen and oxygen equipment expenditures for any year that are more or less than the expenditures that would have been made had the new classes not been established. In accordance with § 414.226(c)(6), CMS reduces the fee schedule amounts for stationary oxygen equipment in non-CBAs in order to make the payment classes for oxygen and oxygen equipment budget neutral as required by section 1834(a)(9)(D) of the Act. Due to the combination of the fee schedule adjustment and the budget neutrality offset, the adjusted fee schedule amounts for stationary oxygen equipment in non-contiguous non-CBAs and some rural areas are lower than the SPAs in Honolulu, Hawaii, and CBAs within the same state, respectively. This is significant because the current methodology at 42 CFR 414.210(g) attempts to ensure that the adjusted fee schedule amounts for items and services furnished in rural areas within a state are no lower than the adjusted fee schedule amounts for non-rural areas within the same state. CBAs are areas where payment for certain DME items and services is based on SPAs established under the CBP rather than adjusted fee schedule amounts. It is worth noting that CBAs tend to have higher population densities and typically correspond with urban census tracts.

The establishment of the payment class for OGPE resulted in an increase in Medicare payments for these items and services. Therefore, each year, a budget neutrality offset is applied to the monthly payment amount for stationary oxygen equipment to ensure that the OGPE payment class does not result in oxygen and oxygen equipment expenditures that would be more or less than the expenditures that would have been made without the OGPE class. As more beneficiaries shift to using OGPE, the budget neutrality offset that is applied to the stationary oxygen equipment payment rate increases. The

budget neutrality requirement does not apply under the DMEPOS CBP because under section 1847(a) of the Act, the payment amounts for oxygen and oxygen equipment are established based on bids submitted and accepted by winning suppliers under the program, and not based on the payment rules under section 1834(a) of the Act. The budget neutrality offset has resulted in payment amounts for stationary oxygen equipment in CBAs being higher than the adjusted fee schedule amounts in some cases. Restoring the blended fee schedule rates paid in rural and non-contiguous non-CBAs during the transition period would result in fee schedule amounts for oxygen and oxygen equipment in these areas being higher than the SPAs paid in all of the CBAs. Therefore, payment at the blended rates would avoid situations where payment for furnishing oxygen in a rural or non-contiguous, non-CBA is lower than payment for furnishing oxygen in a CBA.

2. Fee Schedule Adjustment Impact Monitoring Data

Regarding adverse health beneficiary outcomes, we have been monitoring claims data from non-CBAs, some of which pre-dates the implementation of the fully adjusted fee schedule amounts. To the extent that this data pre-dates the implementation of the fully adjusted fees, it is less likely to demonstrate any adverse impacts. The data does not show any observable trends indicating an increase in adverse health outcomes such as mortality, hospital and nursing home admission rates, monthly hospital and nursing home days, physician visit rates, or emergency room visits in 2016 or 2017 compared to 2015 in the non-CBAs, overall. In addition, we have been monitoring data on the rate of assignment in non-CBAs, which reflects when suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME. More importantly, the monitoring data does not indicate the extent to which suppliers that have not already exited the Medicare program are struggling to maintain current service levels or individual cases where access or health outcomes may have been affected. We are soliciting comments on ways to improve our fee schedule adjustment impact monitoring data.

3. Resuming Transitional Blended Fee Schedule Rates in Rural and Non-Contiguous Areas

The monitoring data described in section II.C.2 of this interim final rule with comment is retrospective claims data for payment of items already

furnished. Stakeholders state that this data is of limited utility in assessing the development of adverse trends in access to items and services, or that the health of beneficiaries is being negatively affected by the fully adjusted fee schedule amounts. Claims data does not capture all of the challenges experienced by beneficiaries and suppliers, such as suppliers going out of business or timely delivery of items. Further, this claims data is also limited to a retrospective view to address potential future problems. In other words, it does not serve as a tool that can guard against the negative outcomes raised by stakeholders, as discussed elsewhere in the preamble. In fact, the Government Accountability Office (GAO) acknowledged challenges associated with the monitoring of DMEPOS and the CBP in its review of the first year of the DMEPOS CBP Round 1 Rebid, stating that the monitoring methods used by CMS in assessing the impact of competitive bidding did not directly show whether beneficiaries received the DME they needed on time.¹ We do note, however, that the Office of Inspector General (OIG) has found that the implementation of Round 2 Competitive Bidding did not appear to disrupt beneficiary access to CPAP/RAD equipment.²

Approximately 85 percent of the DME industry are considered small businesses according to the Small Business Administration's size standards. According to Medicare claims data, the number of supplier locations furnishing DME items and services subject to the fee schedule adjustments decreased by 22 percent from 2013 to 2016. In 2016 alone there was a 7 percent decline from the previous year in the number of DME supplier locations furnishing items and services subject to the fee schedule adjustments. The magnitude of this decline in DME supplier locations, from 13,535 (2015) to 12,617 (2016),³ indicates that the number of DME supplier locations serving these areas continues to decline. Based on partial year data, there was a further reduction

in supplier locations of 9 percent in 2017.⁴

There are additional factors that section 16008 of the Cures Act requires us to take into account in making adjustments to the fee schedule amounts for items and services furnished beginning in 2019. We know that the average volume of items and services furnished per supplier in non-CBAs is significantly less than the average volume of items and services furnished per supplier in CBAs. Additionally, the number of suppliers in general has been steadily decreasing over time and this trend is not abating. As the number of suppliers serving non-CBAs continues to decline, the volume of items and services furnished by the remaining suppliers is increasing. However, we do not know if the suppliers that remain will have the financial ability to continue expanding their businesses to continue to satisfy market demand. We also do not know if large suppliers serving both urban and rural areas will continue to serve the rural areas representing a much smaller percentage of their business than urban areas. We specifically address the stakeholder comments and concerns below.

Based on the stakeholder comments and decrease in the number of supplier locations, there is an immediate need to resume the transitional, blended fee schedule amounts in rural and non-contiguous areas. Resuming these transitional blended rates will preserve beneficiary access to needed DME items and services in a contracting supplier marketplace, while allowing CMS to address the adequacy of the fee schedule adjustment methodology, as required by section 16008 of the Cures Act. We recognize that reduced access to DME may put beneficiaries at risk of poor health outcomes or increase the length of hospital stays.

Suppliers have noted that they have struggled under the fully adjusted fee schedule and that they do not believe they can continue to furnish the items and services at the current rates. Stakeholders overwhelmingly have stated that the fully adjusted fee schedule amounts are not sufficient to cover supplier costs for furnishing items and services in rural and non-contiguous areas and the number of suppliers furnishing items in these areas continues to decline. Further, section 16008 of the Cures Act mandates that we consider stakeholder input and

additional information in making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished beginning in 2019. The information we have collected, however, includes input from many stakeholders indicating that the fully adjusted fee schedule amounts are too low and that this is having an adverse impact on beneficiary access to items and services, particularly in rural and non-contiguous areas. Given the strong stakeholder concern about the continued viability of many DMEPOS suppliers, coupled with the Cures Act mandate to consider additional information material to setting fee schedule adjustments, it would be unwise to continue with the fully adjusted fee schedule rates in the vulnerable rural and non-contiguous areas for 7 months. Any adverse impacts on beneficiary health outcomes, or on small businesses exiting the market, could be irreversible. It is in the best interest of the beneficiaries living in these areas to maintain a blend of the historic unadjusted fee schedule amounts and fee schedule amounts adjusted using SPAs established under the DMEPOS CBP to prevent suppliers that might be on the verge of closing from closing, as they may be the only option for beneficiaries in these areas. While our systematic monitoring in these areas has not shown problematic trends to this point, that monitoring by its nature looks backward and reflects other limitations, as discussed in section II.C.2 of this interim final rule with comment. Given the rapid changes in health care delivery that may disproportionately impact rural and more isolated geographic areas, there is concern that the continued decline of the fees and the number of suppliers in such areas may impact beneficiary access to items and services. These adjustments would maintain a balance between the higher historic rates and rates adjusted based on bidding in larger metropolitan areas where suppliers furnish a much larger volume of DMEPOS items and services and support continued access to services. In order to safeguard beneficiaries' access to necessary items and services, we should immediately resume the transition period for the phase-in of fee schedule adjustments in these areas that was in place during CY 2016. Therefore, we are revising § 414.210(g)(9) to resume the fee schedule adjustment transition rates for items and services furnished in rural and non-contiguous areas from June 1, 2018 through December 31, 2018, while we further analyze this issue. During this extended

¹ U.S. Government Accountability Office. Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid, May 2012 (GAO-12-693), <http://www.gao.gov/assets/600/590712.pdf> (accessed 4 November 2015), page 42.

² Office of Inspector General, U.S. Department of Health & Human Services. Round 2 Competitive Bidding for CPAP/RAD: Disrupted Access Unlikely for Devices, Inconclusive for Supplies, June 2017 (OEI-01-15-00040).

³ Medicare claims process through November 3, 2017

⁴ There were 12,537 supplier locations furnishing items subject to the fee reductions in 2016, based on claims processed through April 6, 2017, and 11,384 supplier locations furnishing items subject to the fee reductions in 2017, based on claims processed through April 7, 2018.

transition period, CMS will take into account the information required by section 16008 of the Cures Act in determining whether changes to the methodology for adjusting fee schedule amounts for items furnished on or after January 1, 2019, are necessary.

D. Fee Schedule Amounts for Accessories Used With Group 3 Complex Rehabilitative Power Wheelchairs

In the CY 2010 final rule (75 FR 73390) published in the **Federal Register** on November 29, 2010, entitled “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011,” we reviewed the HCPCS coding for power wheelchairs that were updated in 2006 in response to the release of the Power Mobility Device Coding Guidelines published by the DME Medicare Administrative Contractors. Codes were added to the HCPCS for various types of power wheelchair bases, differentiated based on level of performance, with group 1 being the lowest and group 3 being the highest level covered by Medicare, and the ability to accommodate complex rehabilitative power options such as power seating systems or a specialty interface, such as sip and puff controls. Codes were established at both the group 2 and 3 performance level for “complex rehabilitative” power wheelchair bases.

Section 154(a)(1)(B) of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110–275), amended section 1847(a)(2)(A) of the Act to exclude group 3 or higher complex rehabilitative power wheelchairs and related accessories when furnished in connection with such wheelchairs from competitive bidding. At the same time, section 154(a)(1)(A) of MIPPA amended section 1847(a)(1) of the Act to add paragraph (D) which terminated Round 1 and required rebidding Round 1 for the same items and services and the same areas with some changes. Since we included group 2 complex rehabilitative power wheelchairs and related accessories (including seating systems) and seat and back cushions, under Round 1 of the DMEPOS CBP, we were required to include those wheelchairs and accessories in the Round 1 Rebid of the DMEPOS CBP. The accessories (including seating systems) and cushions furnished in connection with group 2 complex rehabilitative power wheelchairs (HCPCS codes K0835 through K0843) are the same items furnished in connection with group 3 complex rehabilitative power

wheelchairs (HCPCS codes K0848 through K0864).

Single payment amounts were implemented on January 1, 2011, in the nine Round 1 Rebid areas, for group 1 and 2 standard power wheelchair bases, group 2 complex rehabilitative power wheelchair bases, and the interchangeable accessories used with the different bases (for example, batteries used with all power wheelchairs and power seating systems used with both group 2 and 3 complex rehabilitative power wheelchairs). As noted above, these items are competitively bid under section 1847 of the Act, and we did not competitively bid group 3 wheelchairs or use competitively bid prices for related accessories when used with a group 3 wheelchair in the Round 1 Rebid of the DMEPOS CBP.

Section 1834(a)(1)(F)(ii) of the Act mandates the adjustment of fee schedule amounts for items that are furnished in non-CBAs based on information from the CBPs beginning on January 1, 2016. We established a policy under § 414.210(g)(5) for adjusting the fee schedule amounts for accessories used with different types of base equipment that are included in one or more product categories under competitive bidding in the CY 2015 ESRD PPS final rule (79 FR 66223 through 66233). In that rulemaking, we stated the Agency’s belief 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, and that the costs of furnishing the accessory should not vary significantly based on the type of base equipment it is used with (79 FR 66230). We finalized § 414.210(g)(5) to adjust the fee schedule amount for a HCPCS code for an accessory for use with all types of base equipment using pricing information for the item when it is included in one or more product categories under competitive bidding. The adjusted fee schedule amounts for these common accessories became effective on January 1, 2016.

Section 2 of the Patient Access and Medicare Protection Act of 2015 (Pub. L. 114–115) delayed the adjustments to the fee schedule amounts for accessories (including seating systems) and seat and back cushions when furnished in connection with group 3 complex rehabilitative power wheelchairs until January 1, 2017. Subsequently, section 16005 of the Cures Act extended this delay in the DME fee schedule adjustments based on competitive bidding information for certain wheelchair accessories used with group

3 complex rehabilitative power wheelchairs from January 1, 2017 until July 1, 2017. Since the Congress has acted twice to address the issue, these legislative actions highlight a general concern regarding access to this specialized equipment by the vulnerable patient population that depends on this equipment and technology.

Complex rehabilitative power wheelchairs are used by patients needing functionality, such as head or sip and puff controls, power tilt or recline seating, or ventilators mounted to the wheelchair, which are not available on standard power wheelchairs. The ability and performance of the wheelchair in meeting the patients’ specialized needs is critical, and most patients use wheelchair bases with group 3 level performance to meet these needs. Far fewer use group 2 wheelchair bases, which are the bases that the accessories were included with under Round 1 of the DMEPOS CBP.

Section 1847(a)(2)(A) of the Act provides the categories of items that are subject to the CBP and excludes certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs). This statutory exclusion should inform our implementation of section 1834(a)(1)(F) of the Act such that the fee schedule amounts for wheelchair accessories and back and seat cushions used in conjunction with group 3 complex rehabilitative power wheelchairs should not be adjusted based on the methodologies set forth in § 414.210(g)(5). Therefore, as we have announced in guidance available on the CMS website in June (located at: <https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html>) the fee schedule amounts for wheelchair accessories and back and seat cushions used in conjunction with group 3 power wheelchairs continue to be based on the unadjusted fee schedule amounts updated by the covered item update specified in section 1834(a)(14) of the Act. The fee schedule amounts for all other accessories used with different types of base equipment continue to be calculated in accordance with the adjustment methodology set forth in § 414.210(g)(5) of our regulations.

E. Technical Changes To Conform the Regulations to Section 5004(b) of the Cures Act: Exclusion of DME Infusion Drugs Under CBPs

Section 5004(b) of the Cures Act amends section 1847(a)(2)(A) of the Act to exclude drugs and biologicals

described in section 1842(o)(1)(D) of the Act from the CBP. We are making conforming technical changes to the regulations text consistent with statutory requirements to exclude drugs and biologicals from the CBP. We are amending 42 CFR 414.402 to reflect that infusion drugs are not included in the CBP by revising the definition of “Item” in paragraph (2) to add the words “and infusion” after the words “other than inhalation”. The sentence will read as follows: “Supplies necessary for the effective use of DME other than inhalation and infusion drugs.” We are also removing a reference to drugs being included in the CBP by deleting the phrase “or subpart I” in § 414.412(b)(2). The sentence will read as follows: “The bids submitted for each item in a product category cannot exceed the payment amount that would otherwise apply to the item under subpart C of this part, without the application of § 414.210(g), or subpart D of this part, without the application of § 414.105. The bids submitted for items in accordance with paragraph (d)(2) of this section cannot exceed the weighted average, weighted by total nationwide allowed services, as defined in § 414.202, of the payment amounts that would otherwise apply to the grouping of similar items under subpart C of this part, without the application of § 414.210(g), or subpart D of this part, without the application of § 414.105.” Similarly, we are making a conforming technical change to § 414.414(f) in the discussion of “expected savings” so that infusion drugs are not taken into account by deleting the words “or drug” and the phrase “or the same drug under subpart I” from § 414.414(f). The “expected savings” text will read as follows: “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 competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D.”

III. Provisions of the Interim Final Rule With Comment Period

A. Transition Period for Phase-In of Fee Schedule Adjustments

We are amending § 414.210(g)(9)(i) to change the end date for the initial transition period for the phase in of adjustments to fee schedule amounts for certain items based on information from the DMEPOS CBP from June 30, 2016 to December 31, 2016, as mandated by section 16007(a) of the Cures Act. We are also amending § 414.210(g)(9)(ii) to

reflect that fully adjusted fee schedule amounts apply from January 1, 2017 through May 31, 2018, and then on or after January 1, 2019. We are also adding § 414.210(g)(9)(iii) to resume the transition period for the phase in of adjustments to fee schedule amounts for certain items furnished in rural and non-contiguous areas from June 1, 2018 through December 31, 2018. Finally, we are adding § 414.210(g)(9)(iv) to reflect that fully adjusted fee schedule amounts apply for certain items furnished in non-CBA areas other than rural and non-contiguous areas from June 1, 2018 through December 31, 2018.

As previously stated in section II.C.1 of this interim final rule with comment, stakeholders overwhelmingly have stated that the fully adjusted fee schedule amounts are not sufficient to cover supplier costs for furnishing items and services in rural and non-contiguous areas and are impacting beneficiary health outcomes. Section 16008 of the Cures Act requires CMS to consider certain factors in making fee schedule adjustments using information from the CBP for items and services furnished in non-CBAs on or after January 1, 2019. Given the limitations associated with our retrospective claims data prevent us from detecting rapidly developing beneficiary access issues, we believe we should immediately resume the blended fee schedule rates in rural and non-contiguous areas that were in place during CY 2016, while we further analyze this issue in order to safeguard beneficiaries’ access to necessary items and services in rural and non-contiguous areas. Given that additional information and factors will be considered when addressing the fee schedule adjustments for items and services furnished on or after January 1, 2019, and that these factors include differences in costs (yet to be quantified) associated with furnishing items in heavier populated CBAs versus less populated or remote rural and non-contiguous areas, we have concluded that we should adjust fee schedule amounts based on competitive bidding information prior to 2019. The volume of items furnished per supplier in rural and non-contiguous areas is far less than the volume of items furnished per supplier in CBAs, indicating that the cost per item in these areas may be higher than the cost per item in CBAs. Also, as noted earlier, our systematic claims monitoring only looks backward in time and may not detect rapidly emerging trends, particularly in isolated or rural areas. We also referenced the GAO’s acknowledgement that there are challenges associated with the

monitoring CBP. In its report regarding the first year of the DMEPOS CBP Round 1 Rebid, the GAO stated that the monitoring methods used by CMS in assessing the impact of competitive bidding did not directly show whether beneficiaries received the DME needed on time or whether adverse health outcomes were caused by problems accessing DMEPOS. As the fee schedule amounts and the number of suppliers continue to decline, we are concerned that DME access in remote areas of the country may be negatively affected by significant payment reductions put in place prior to a full analysis of the factors affecting the cost of furnishing items and services in distinctly different market areas. We are also concerned that national chain suppliers may close locations in more remote areas if the rate they are paid for furnishing items in a market where the volume of services is low does not justify the overhead expenses of retaining the locations.

Finally, because this IFC will result in a change to the 2018 fee schedule amounts for the various classes of oxygen and oxygen equipment, the annual budget neutrality adjustment for 2018, mandated by regulations at § 414.226(c)(6), will need to be recomputed. This annual adjustment to the monthly payment amount for stationary oxygen equipment and oxygen contents is mandated by section 1834(a)(9)(D)(ii) of the Act as a condition for maintaining the higher portable oxygen equipment add-on payment for portable concentrators and transfilling equipment.

B. Technical Changes To Conform the Regulations to Section 5004(b) of the Cures Act: Exclusion of DME Infusion Drugs Under CBPs

We are making conforming technical changes to the regulations text consistent with statutory requirements to exclude drugs and biologicals from the CBP. Specifically, we are amending § 414.402 to reflect that infusion drugs are not included in the CBP by revising the definition of “Item” in paragraph (2) to add the words “and infusion” after the words “other than inhalation”. We are also removing a reference to drugs being included in the CBP by deleting the phrase “or subpart I” in § 414.412(b)(2). Similarly, we are making a conforming technical change to the regulations text on “expected savings” so that infusion drugs are not taken into account in § 414.414(f) by deleting the words “or drug” and the phrase “or the same drug under subpart I”.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule take effect in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act. Specifically, section 553(b) of the APA requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. Section 553(c) of the APA further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(3)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to waive these procedures, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Section 553(d) of the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a rule from taking effect before the end of the 30-day period that begins the date that the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. In addition, the Congressional Review Act (5 U.S.C. 801(a)(3)), requires a 60-day delayed effective date for major rules. However, we can waive the delay in effective date of the rule if the Secretary finds, for good cause, that notice and public procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 808(2)).

As discussed below, and for reasons cited throughout this interim final rule with comment period, we find good cause to waive notice-and-comment rulemaking and issue this interim final rule with comment period to address fee schedule adjustments based on information from the CBP in rural and non-contiguous areas because we believe it is contrary to the public interest to go through notice-and-comment rulemaking for this provision. We also find good cause to waive the 30-day delay in effective date of this interim final rule with comment period as a delay in effective date would also be contrary to the public interest. The full fee schedule adjustments took effect on January 1, 2017, and we understand from stakeholders that some DMEPOS suppliers cannot exist at the current fully adjusted fee levels and have already had to drop out of Medicare, and even close down. Delaying the effective date of this interim final rule with comment period by 30 days could result in a further decline in the number of DMEPOS suppliers, and would pose an unnecessary risk of harm to beneficiaries in certain areas of the country that rely on one or a few suppliers to access to items and services and these suppliers are no longer able to furnish the items and services at the fully adjusted fee schedule amounts. We also note that in this interim final rule with comment period, CMS is reverting to a prior transitional payment policy that was in place from January 1, 2016 through December 31, 2016, to allow time for further engagement with stakeholders, through future notice and comment rulemaking, in the development of a long-term, more sustainable fee schedule adjustment methodology for items and services furnished in rural and non-contiguous areas.

We also find it unnecessary to undertake notice-and-comment rulemaking to make technical changes to conform the regulations to the statutory requirement under section 5004(b) of the Cures Act that infusion drugs used with DME be excluded from the DMEPOS CBP. We also find good cause to waive the delay in the effective date for this interim final rule with comment period because it would be contrary to the public interest to further delay updating the regulations to be consistent with the statute and avoid possible confusion that infusion drugs are still subject to competitive bidding, particularly given that the statutory exclusion is self-implementing and already effective.

Although we did not formally publish a notice of proposed rulemaking in the

Federal Register, we have solicited stakeholder input regarding the impact of the fee schedule adjustments as required by section 16008 of the Cures Act, through a national provider call on March 23, 2017, as well as through an accompanying written comment period. We sought feedback on section 16008 of the Cures Act, which mandates stakeholder input on the methodology for using information from the DMEPOS CBP for adjusting Medicare fee schedule amounts paid in non-CBAs.

We received numerous comments from stakeholders, such as comments that expressed how the current adjusted fee schedule is not enough to cover a DME supplier's costs of running a business and that many suppliers are not able to sustain reductions in payment of up to 60 percent on average that resulted from the full fee schedule adjustments, resulting in a number of suppliers leaving the business and many more considering leaving the business in the near future. Such a result would negatively impact beneficiaries' access to critical items and services necessary for their care. Some stakeholders commented that some of the more remote, high cost areas are served by only one or a few suppliers. In 2016, there was a 7 percent decline in the number of supplier locations furnishing items and services subject to the fee schedule adjustments in non-CBAs. The magnitude of this decline in supplier locations from 13,535 to 12,617 indicates that the number of supplier locations serving these areas continues to decline at the same time that stakeholders are indicating their expectations of additional supplier exits. In situations where there may only be one supplier serving an area, if the supplier were to stop furnishing items (for example oxygen), the beneficiaries in this area could be harmed significantly if there are no suppliers left to deliver replacement of necessary oxygen. We are concerned that national chain suppliers of oxygen may close locations in more remote areas if the rate they are paid for furnishing items in a market where the volume of services is low does not justify the overhead expenses of retaining the locations. Due to the inherent limitation associated with using retrospective claims data, our systematic monitoring in these areas has not been able to reflect problematic trends identified by numerous stakeholders. As noted, the GAO has also acknowledged challenges associated with the monitoring of DMEPOS and the CBP, stating that the monitoring methods used by CMS in

assessing the impact of competitive bidding did not directly show whether beneficiaries received the DME they needed on time or whether adverse health outcomes were caused by problems accessing DMEPOS. Given the rapid changes in health care delivery that may disproportionately impact rural and more isolated geographic areas, we are concerned that the continued decline of the fees and the number of suppliers in such areas may exacerbate the already emergent access concerns faced by beneficiaries. In general, we are concerned that beneficiaries in certain areas of the country could lose access to items and services if they rely on one or a few suppliers to furnish these items and services and these suppliers are no longer able to furnish the items and services at the fully adjusted fee schedule amounts.

Our monitoring data, by its very nature, would not alert us to the present and imminent threats to beneficiary access that stakeholders have raised in recent months. If CMS continues to pay the fully adjusted payment rates in rural and non-contiguous areas, it could further jeopardize the infrastructure of suppliers that beneficiaries rely on for access to necessary items and services in remote areas of the country. Smaller suppliers that serve remote areas may not be able to sustain larger reductions in payment because they have a limited number of ways to reduce costs. If they only have one location and a few employees to begin with, they cannot close locations or lay off employees to reduce costs. Larger suppliers that serve both remote, rural areas and urban areas may elect to close locations in the remote areas where volume of services are significantly lower because the overhead expense of maintaining the location may no longer justify retaining these locations. Therefore, we believe it is necessary to prevent future, potential access problems and adverse health outcomes for beneficiaries by resuming the fee schedule adjustment transition period in rural and non-contiguous areas. Immediately restoring the blended rates in rural and non-contiguous areas, which will cut the magnitude of the full adjustments in half, can prevent potential erosion of the supplier infrastructure that could potentially be on the verge of impacting access and health outcomes in rural and non-contiguous areas. By restoring the transition period in rural and non-contiguous areas effective June 1, 2018, this in essence extends the fee schedule adjustment phase in period by an additional 7 months and leaves a gap of

17 months from January 1, 2017 through May 31, 2018, during which suppliers have been subject to the full fee schedule adjustments in rural and non-contiguous areas. This extended phase-in period would end on December 31, 2018, since section 16008 of the Cures Act mandates that CMS consider certain factors and information in making fee schedule adjustments for items and services furnished on or after January 1, 2019. This gives suppliers serving rural and non-contiguous areas more time to adjust their businesses and may prevent the imminent closure of some supplier locations, thereby safeguarding beneficiary access to necessary items and services in rural and non-contiguous areas. It also prevents irreparable harm to businesses in rural and non-contiguous areas that would not be able to adjust to the full payment reductions, but might be able to adjust to smaller reductions in payments during an interim period until additional cost information is examined more closely by CMS to provide a more accurate reflection of the unique costs of furnishing items and services in market areas that are distinctly different from CBAs. This also allows time for CMS to receive supplier feedback and analyze the costs of furnishing DME items in rural and non-contiguous areas and other factors identified in section 16008 of the Cures Act. Resuming the fee schedule adjustment transition period for an additional 7 months in rural and non-contiguous areas seems reasonable during this interim period to allow for the more in depth analysis of the factors and information to be considered in accordance with section 16008 of the Cures Act.

In light of these concerns, while we consider broader changes to the fee schedule adjustment methodology as required by section 16008 of the Cures Act, we believe there is good cause to issue this interim final rule with comment period to revise § 414.210(g)(9) to immediately restore the fee schedule adjustment transition period in rural and non-contiguous areas. Resuming the transition period and blended rates based on adjusted and unadjusted fee schedule amounts for items and services furnished in rural and non-contiguous areas from June 1, 2018 through December 31, 2018, will allow additional time for suppliers serving rural and non-contiguous areas to adjust their businesses, prevent suppliers that beneficiaries may rely on for access to items and services in rural and non-contiguous areas from exiting the business, and allow additional time for CMS to monitor the impact of the

blended rates. We believe it is contrary to the public interest to go through notice and comment rulemaking because of the stakeholder input we have already solicited that supports this change and because any further delay in implementation risks impeding beneficiary access to DME in rural and non-contiguous areas. To further delay restoring the transitional fee schedule rates in rural and non-contiguous areas for additional months raises the access concerns described earlier in the preamble. As such, in § 414.210(g)(9)(iii), for items and services furnished in rural and non-contiguous areas on or after June 1, 2018, the payment adjustments will be based on a blend of 50 percent of the unadjusted fee schedule amount and 50 percent of the adjusted payment amount established in accordance with the methodologies in § 414.210(g)(1) through (8). We are also amending § 414.210(g)(9)(ii) to reflect that for items and services furnished with dates of service from January 1, 2017 to May 31, 2018, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount.

We note that this rule is urgent to preserve beneficiary access to DME items and services in rural and non-contiguous areas during this transition period, that CMS is continuing to study the impact of the change in payment rates on access to items and services in these areas, and that we intend to undertake subsequent notice-and-comment rulemaking for CY 2019.

Section 5004(b) of the Cures Act further amends section 1847(a)(2)(A) of the Act to exclude drugs and biologicals described in section 1842(o)(1)(D) of the Act. We are finalizing conforming regulatory changes to reflect our interpretation of these statutory requirements to exclude infusion drugs, described in section 1842(o)(1)(D) of the Act, as a covered item that could be subject to the DMEPOS CBPs. Because this is just a minor technical change to conform the language in the regulations to the statute, we believe that a notice and comment period for this change is unnecessary.

Therefore, as noted above, we find good cause to waive the notice of proposed rulemaking to address fee schedule adjustments in rural and non-contiguous areas based on information from the CBP, and to make technical changes to the regulations so they conform to the statutory requirement under section 5004(b) of the Cures Act that infusion drugs used with DME be excluded from the DMEPOS CBP. We also find good cause to waive the delay in effective date and issue this interim

final rule with comment period with an effective date of June 1, 2018. We are providing a 60-day public comment period.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this interim final rule with comment period as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. In addition, the Office of Management and Budget (OMB) has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this interim final rule with comment period, and the Departments have provided the following assessment of their impact. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

This interim final rule with comment period amends the regulation to revise the date that the initial fee schedule adjustment transition period ended and resumes the fee schedule adjustment transition period for certain DME items and services and enteral nutrition furnished in rural and non-contiguous areas not subject to the DMEPOS CBP from June 1, 2018 through December 31, 2018. This interim final rule with comment period also makes technical amendments to existing regulations for DMEPOS items and services to note the exclusion of infusion drugs used with DME from the DMEPOS CBP.

3. Overall Impact

The interim final rule with comment period resumes the transitional adjusted Medicare fee schedule amounts for certain items and services that are furnished in rural and non-contiguous areas beginning June 1, 2018 until December 31, 2018. It is estimated that these fee schedule adjustments will cost over \$290 million in Medicare Part B benefit payments and \$70 million in Medicare beneficiary cost sharing. For dual eligible beneficiaries Medicaid pays the cost sharing. The Medicaid payment is split between a Federal portion and the states’ portion, which for this rule is \$10 million and \$10 million, respectively.

B. Detailed Economic Analysis

a. Effects on the Medicare Program and Beneficiaries

This interim final rule with comment period resumes transitional adjusted Medicare fee schedule amounts for certain items and services furnished in rural and non-contiguous areas beginning June 1, 2018 until December 31, 2018. It is estimated that these adjustments will cost over \$290 million in Medicare Part B benefit payments and \$70 million in beneficiary cost sharing. The suppliers will get increased revenue from the increased fee schedule amounts. See Table 1.

TABLE 1—CASH IMPACT OF RESUMING THE ADJUSTED FEE SCHEDULE TRANSITION

FY	Impact on the benefit payments in dollars (to the nearer 10 million) ¹	Impact on beneficiary cost sharing in dollars (to the nearer 10 million) ²	Federal share of Medicaid ³	States’ share of Medicaid ³
2018	170	40	5	5
2019	120	30	5	5

¹ Does not include premium offset.

² Includes Medicaid payments.

³ Copayments made for dual eligible Medicare beneficiaries.

b. Impact on Beneficiaries and Other Payers

In order to preserve beneficiary access to DME items and services, this rule, as indicated above, will result in a \$70 million dollar Medicare cost sharing increase to the beneficiaries. For those beneficiaries who have supplemental insurance, this increase may be covered by supplemental insurance programs (for example, Medigap). This is a temporary time-limited extension of the fee schedule adjustment transition period.

For dual eligible beneficiaries, Medicaid pays the cost sharing. The Medicaid payment is split between a Federal portion and the states' portion, which for this rule is \$10 million and \$10 million, respectively.

Beneficiaries who do not have supplemental insurance or who are not dual eligible will have increased cost sharing as a result of this interim final rule with comment period.

c. Alternatives Considered

One alternative considered to address concerns about access to items and services in non-CBAs would be to apply the 50/50 blended rates in all non-CBAs, since stakeholders commented regarding problems related to access to necessary items and services in all non-CBAs. This would cost \$570 million in Medicare Part B benefit payments and \$140 million in beneficiary cost sharing. Of the \$140 million in beneficiary cost sharing, \$45 million is the Medicaid impact for dual eligibles, of which \$25

million is the Federal portion, and \$20 million is the state portion. A second alternative would be to apply the blended rates in all non-CBAs, but change the blend from 50 percent unadjusted fee and 50 percent adjusted fee to 25 percent unadjusted fee and 75 percent adjusted fee. This would cost \$290 million in Medicare Part B benefit payments and \$70 million in beneficiary cost sharing. Of the \$70 million in beneficiary cost sharing, \$20 million is the Medicaid impact for dual eligibles, of which \$10 million is the Federal portion, and \$10 million is the state portion. Table 2 compared the annual costs of these alternative rules to the annual costs of the interim final rule with comment period.

TABLE 2—COMPARISON OF THE COSTS OF ALTERNATIVE RULES WITH THE INTERIM FINAL RULE WITH COMMENT PERIOD

FY	Interim final rule	50/50 Blend in all non-CBAs	25/75 Blend in all non-CBAs
2018	170	330	170
2019	120	240	120

We did not elect either of these alternatives and chose to apply the 50/50 blended rates in rural and non-contiguous areas only to ensure access to items and services for Medicare beneficiaries in these areas.

Public comments are requested on these and any other related alternatives.

d. Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this interim final rule with comment period, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the

number of reviewers of this final rule is about the same number of commenters on similar, past rules. We acknowledge that this assumption may understate or overstate the costs of reviewing this interim final rule with comment period. Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this interim final rule with comment period is \$105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 2 hours for the staff to review this interim final rule with comment period. For each entity

that reviews this interim final rule with comment period, the estimated cost is \$210.32 (2 hours × \$105.16). Therefore, we estimate that the total cost of reviewing this interim final rule with comment period is \$21,320 (\$210.32 × 100 reviewers).

C. Accounting Statement

As required by OMB Circular A–4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 3, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this interim final rule with comment period.

TABLE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS, WITH ANNUALIZATION PERIOD 2018–2019

DME provisions	
Category	Transfers
Annualized Monetized Transfers	\$146 million (7%) or \$145 million (3%).
From Whom to Whom	Federal government to Medicare providers.
Increased Beneficiary Co-insurance Payments	\$35 million (7%) or 35 million (3%).
From Whom to Whom	Beneficiaries to Medicare providers.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

VIII. 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.

Approximately 85 percent of the DME industry are considered small businesses according to the Small Business Administration's size standards with total revenues of \$6.5 million or less in any 1 year and a small percentage are nonprofit organizations. Individuals and states are not included in the definition of a small entity. We expect the interim final rule with comment period DME provisions will have a significant impact on small suppliers. A substantial number of small suppliers will benefit from the increased fee schedule amounts. Although not legally required, this interim final rule with comment period will increase payments to small suppliers such that the beneficiaries should have improved access to items.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Our data indicates that only around 6.9 percent of small rural hospitals are organizationally linked to a DME supplier with paid claims in 2017. Thus, we do not believe this interim final rule with comment period will have a significant impact on operations of a substantial number of small rural hospitals.

IX. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. The Secretary has determined that UMRA does not apply to this rule in that this rule does not contain mandates that impose spending costs on state, local, or tribal governments in the aggregate.

X. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. The Secretary has determined that this

rule does not impose substantial direct requirement costs on state or local governments, preempt states, or otherwise have a Federalism implication.

XI. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This interim final rule with comment period is not subject to the requirements of Executive Order 13771 because it is estimated to result in no more than *de minimis* costs.

XII. Congressional Review Act

This rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

- 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

- 2. Section 414.210 is amended by revising paragraph (g)(9) to read as follows.

§ 414.210 General payment rules.

* * * * *

(g) * * *

(9) *Transition rules.* The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1, 2016 through December 31, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service from January 1, 2017, through May 31, 2018, and on or after January 1, 2019, the fee schedule amount for the area is equal to 100

percent of the adjusted payment amount established under this section.

(iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through December 31, 2018, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(iv) For items and services furnished in areas other than rural or non-contiguous areas with dates of service from June 1, 2018 through December 31, 2018, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

§ 414.402 [Amended]

- 3. Section 414.402 is amended in paragraph (2) of the definition of “Item” by removing the words “inhalation drugs” and by adding in their place “inhalation and infusion drugs”.

§ 414.412 [Amended]

- 4. Section 414.412(b)(2) is amended by removing the phrase “, or subpart I of this part”.

§ 414.414 [Amended]

- 5. Section 414.414(f) is amended by removing the words “or drug” and the phrase “or the same drug under subpart I”.

Dated: May 7, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 7, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–10084 Filed 5–9–18; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 153, 154, 155, 156, 157, and 158

[CMS–9930–F]

RIN 0938–AT12

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019; Correction

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

ACTION: Final rule; correction.