DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1738–F, CMS–1687–F, and CMS–5531–F]

RINs 0938–AU17, 0938–AT21, and 0938–AU32

Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; 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), Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule establishes methodologies for adjusting the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule amounts using information from the Medicare DMEPOS competitive bidding program (CBP) for items furnished on or after the effective date specified in the **DATES** section of this final rule, or the date immediately following the duration of the emergency period described in the Social Security Act (the Act), whichever is later. This final rule also establishes procedures for making benefit category and payment determinations for new items and services that are durable medical equipment (DME), prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B. In addition, this rule classifies continuous glucose monitors (CGMs) as DME under Medicare Part B. Lastly, this final rule finalizes certain DME fee schedule-related provisions that were included in two interim final rules with comment period (IFC) that CMS issued on May 11, 2018, and May 8, 2020.

DATES: These regulations are effective on February 28, 2022.

FOR FURTHER INFORMATION CONTACT: Alexander Ullman, 410–786–9671 or *DMEPOS@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

This final rule makes changes related to: The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule amounts to ensure access to items and services in rural areas; procedures for making benefit category and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations to prevent delays in coverage of new items and services; and classification of CGMs under the Part B benefit for DME to establish the benefit category for these items. Finally, we are finalizing provisions included in two interim final rules with comment period (IFC) that CMS issued on May 11, 2018, and May 8, 2020.

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

The purpose of this provision is to establish the methodologies for adjusting the fee schedule payment amounts for DMEPOS items and services furnished in non-competitive bidding areas (non-CBAs) on or after the effective date specified in the **DATES** section of this final rule, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. The emergency period we are referring to is the Public Health Emergency (PHE) for coronavirus disease 2019 (COVID–19). We refer readers to section III.A.6. of this rule for details regarding the DMEPOS fee schedule changes CMS has already made as a result of the PHE for COVID–19.

2. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

The purpose of this section is to finalize and address comments received on the May 11, 2018 IFC (83 FR 21912) titled ''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'' (hereinafter referred to as the ''May 2018 IFC'').

3. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, or Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

The purpose of this section of the final rule is to establish procedures for making benefit category and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations that permit public consultation through public meetings. Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) requires the Secretary to establish procedures for coding and payment determinations for new DME under Part B of title XVIII of the Act that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD–9–CM (which has since been replaced with ICD–10–CM as of October 1, 2015). We decided to expand these procedures to address all new external HCPCS level II code requests in 2005. We are finalizing procedures for making benefit category determinations and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations. Consistent with our current practices, the procedures will incorporate public consultation on these determinations.

The determination of whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Medicare. On the other hand, if the item is not excluded from coverage by the Act and is found to fall within a benefit category, we need to determine what payment rules would apply to the item if other statutory criteria for coverage of the item are met, such as the reasonable and necessary criteria under section 1862(a)(1)(A) of the Act.

Therefore, the procedures that we are finalizing for use in determining if items and services fall under the Medicare Part B benefit categories for DME, prosthetic devices, orthotics, and prosthetics, surgical dressings, splints, casts and other devices for the reduction of fractures or dislocations, or therapeutic shoes and inserts continue our longstanding practice of establishing coverage and payment for new items and services soon after they are identified through the HCPCS code application process, promote transparency, and prevent delays in access to new technologies.

4. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

The purpose of this section of this final rule is to address classification and payment for CGMs under the Medicare Part B benefit for DME.

5. DME Interim Pricing in the CARES Act

The purpose of this section is to finalize and address comments received on the ''DME Interim Pricing in the CARES Act'' section of the May 8, 2020 IFC (85 FR 27550) titled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (hereinafter referred to as the ''May 2020 COVID–19 IFC''). This provision revised § 414.210 to provide temporarily increased DME fee schedule amounts in certain areas, as required by section 3712 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020).

B. Summary of the Major Provisions

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

This rule revises § 414.210(g)(2) and (9) to establish the fee schedule adjustment methodologies for items and services furnished on or after the effective date specified in the **DATES** section of this final rule, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, in non-CBAs.

2. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

This rule finalizes the following provisions of the May 2018 IFC (83 FR 21912):

- *Transition Period for Phase in of Adjustments to Fee Schedule Amounts:* We are finalizing the amendments to § 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 DME and enteral nutrition, as required by section 16007(a) of the 21st Century Cures Act (Cures Act). In addition, we are finalizing the changes to § 414.210(g)(9)(iii), which resumed the fee schedule adjustment transition period in rural areas and non-contiguous areas effective June 1, 2018 so that the fee schedule amounts for certain items and services furnished in rural and non-contiguous areas from June 1, 2018 through December 31, 2018 were based on a 50/50 blend of adjusted and unadjusted rates. We are also finalizing changes to § 414.210(g)(9)(ii): 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 solicited 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 Act to exclude drugs and biologicals described in section 1842(o)(1)(D) of the Act from the DMEPOS CBP. We are finalizing changes to 42 CFR 414.402 to reflect the exclusion of infusion drugs from the DMEPOS CBP.

3. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, or Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

These provisions establish procedures for making benefit category and payment determinations for items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations for which a HCPCS Level II code has been requested. Specifically, the purpose of the procedure would be to determine whether the product for which a HCPCS code has been requested meets the Medicare definition of DME, a prosthetic device, an orthotic or prosthetic, a surgical dressing, splint, cast, or other device used for reducing fractures or dislocations, or a therapeutic shoe or insert and is not otherwise excluded under Title XVIII of the Act, to determine how payment for the item of service would be made, and to obtain public consultation on these determinations.

4. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

This provision classifies adjunctive CGMs as DME, and addresses comments received in response to the proposed rule. Additional determinations regarding whether a CGM is covered in accordance with section 1862(a)(1)(A) of the Act will be made by DME MACs using the local coverage determination (LCD) process or during the Medicare claim-by-claim review process.

5. DME Interim Pricing in the CARES Act

This section finalizes and addresses comments received on the May 2020 COVID–19 IFC section titled ''DME Interim Pricing in the CARES Act''. Specifically, this section finalizes the following policies that were included in the May 2020 COVID–19 IFC:

- We made conforming changes to § 414.210(g)(9), consistent with section 3712(a) and (b) of the CARES Act, omitting the language in section 3712(b) of the CARES Act that references an effective date that is 30 days after the date of enactment of the law.
- We revised § 414.210(g)(9)(iii), which describes the 50/50 fee schedule adjustment blend for items and services furnished in rural and non-contiguous areas, to address dates of service from June 1, 2018 through December 31, 2020 or through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later.
- We added § 414.210(g)(9)(v) which states that, for items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under ''this section'' (by which we mean § 414.210(g)(1) through (8)), and 25 percent of the

unadjusted fee schedule amount. For items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) (referred to as ''this section'' in the regulation text).

- In addition, we revised § 414.210(g)(9)(iv) to specify for items and services furnished in areas other than rural and noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) (''this section'' in the regulation text).

C. Summary of Cost and Benefits

1. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

We estimate that the DMEPOS fee schedule adjustment methodologies established in this final rule will increase payments an estimated $4.6 billion from the Federal Government to DMEPOS suppliers from CY 2022 to CY 2026 (for the purposes of this estimate, it is assumed the PHE ends on April 16, 2022, which is a necessary assumption for accounting purposes and is not intended to signal when the PHE will end). In CY 2022, we estimate that Medicare payments will increase about $200 million due to this provision of the final rule. Note, the Medicaid impact of this policy is explained later in this final rule.

2. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

This provision resumed the blended adjusted fee schedule amounts during the transition period for certain DMEPOS items and services that were furnished in rural and non-contiguous areas not subject to the CBP beginning June 1, 2018 and ending December 31, 2018. There is no impact assumed against the baseline, which is explained in the regulatory impact analysis section (RIA) later in this final rule, as the period during which these fee schedule adjustments were in effect has passed.

The goal of the May 2018 IFC was 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 we would continue to study the impact of the change in payment rates on access to items and services in these areas. We believe that resuming the fee schedule adjustment transition period in rural and non-contiguous areas promoted stability in the DMEPOS market in these areas, and enabled us to work with stakeholders to preserve beneficiary access to DMEPOS.

3. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, or Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

We are finalizing a process for making benefit category and payment determinations for items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations. This policy is assumed to have an indeterminable fiscal impact due to the unique considerations given to establishing payment for specific items.

4. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

We are finalizing a policy that classifies adjunctive CGMs as DME. In addition, we are addressing comments on the proposed rule. This classification is assumed to have no fiscal impact when considered against the baseline, which is further explained in the regulatory impact analysis (RIA) section of this final rule.

5. DME Interim Pricing in the CARES Act

This section finalizes the temporary increase to certain DME payment rates from March 6, 2020 through the remainder of the duration of the emergency period (PHE) for COVID–19, in accordance with section 3712 of the CARES Act. Section 3712 of the CARES Act increases Medicare expenditures and beneficiary cost-sharing by increasing Medicare payment rates for certain DMEPOS items furnished in non-rural and contiguous non-competitively bid areas.

The increase is a result of paying a blend of 75 percent of the fully adjusted payment rates and 25 percent of the unadjusted payment rates and is estimated to increase affected DME fee schedule amounts by 33 percent, on average. This provision will have a negligible fiscal impact if the emergency period for COVID–19 ends by April 2022.

II. Rulemaking Overview

In the May 11, 2018 **Federal Register** (83 FR 21912), we published an interim final rule with comment period (IFC) titled ''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''. In the May 8, 2020 **Federal Register** (85 FR 27550), we published an IFC titled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (hereinafter referred to as the May 2020 COVID–19 IFC). Subsequently in the November 4, 2020 **Federal Register** (85 FR 70358), we published a proposed rule titled ''Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)'' (hereinafter referred to as the November 2020 proposed rule).

We received 331 (208 on the May 2018 IFC, 6 on the May 2020 COVID–19 IFC, and 117 on the November 2020 proposed rule) timely pieces of correspondence containing multiple comments on the provisions of the previously mentioned IFCs and proposed rule. Comments were submitted by DMEPOS suppliers, manufacturers, trade associations, beneficiaries, the Medicare Payment Advisory Commission (MedPAC), law firms, and healthcare providers.

The provisions that we are finalizing in this final rule range from minor clarifications to more significant modifications based on the comments received. Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings. We also note that some of the public comments received for the provisions addressed in this final rule were outside of the scope of the previously mentioned IFCs and proposed rule and as such, those out-of-scope public comments are not addressed in this final rule.

Additionally, we will not be finalizing three provisions of the November 2020 proposed rule in this final rule. The provision titled ''Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the CBP'' was finalized in the FY

2022 Inpatient Rehabilitation Facility (IRF) final rule published on August 4, 2021 (86 FR 42362). Secondly, after further consideration, we will not be finalizing the proposed provisions titled ''Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process'' and ''Expanded Classification of External Infusion Pumps as DME.''

We are not finalizing any of the ''Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process'' proposals. We intend to continue to evaluate our processes, particularly as CMS and stakeholders continue to gain experience with the more frequent coding cycles.

We received 34 public comments on the HCPCS proposals. The public comments raised concerns about the HCPCS proposals. With regard to our proposed HCPCS Level II code application cycles, application resubmission, and reevaluation policies, commenters opposed the proposal for CMS to potentially delay a preliminary or final decision without placing a limit on the number of cycles a decision could be delayed.

Commenters also opposed our proposal to allow only two resubmissions of a code application for reevaluation for the same item or service particularly if new information is provided with the resubmission. While commenters mostly supported the proposals to codify more frequent coding cycles, a number of commenters requested additional process changes and increased transparency that in many cases may be infeasible within the proposed timelines for a coding cycle. Overwhelmingly, commenters responded negatively to our explanation of the term ''claims processing need'' and how it would apply throughout the HCPCS Level II code application evaluation process. Commenters also did not support CMS assessing whether a given item or service is ''primarily medical in nature'' as a threshold HCPCS Level II code application evaluation factor.

In addition, we are not finalizing the ''Expanded Classification of External Infusion Pumps as DME'' proposal because many commenters believed that the proposed rule was unclear, needed more development, raised concerns about cost-sharing and cost-shifting to the beneficiary, and raised safety concerns related to decisions regarding what drug therapies could safely be administered in a home/non-facility setting. Several commenters noted the proposed rule could increase beneficiary costs, and a commenter noted the policy would result in the use of an infusion pump as the choice of drug administration for payment purposes even if it was the less optimal method of administration. A commenter believed that the proposal would result in the beneficiary paying more for less, in light of the higher out-of-pocket costs for home administration of infusion drugs, and the home not being the highest-quality setting for infusion drug administration.

We proposed that an external infusion pump would be considered ''appropriate for use in the home'' if: (1) The Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both; (2) a qualified home infusion therapy supplier (as defined at § 486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at § 486.505); and (3) the FDA-required labeling specifies infusion via an external infusion pump as a route of administration, at least once per month, for the drug. We received 31 comments on this proposal from DME and infusion suppliers, beneficiaries, manufacturers, insurance companies, and trade associations. Many commenters supported the proposed interpretation of ''appropriate for use in the home'' and the three proposed criteria for determining when an infusion pump was ''appropriate for use in the home,'' as well as the fact that if finalized, this proposal would necessitate updates to the LCD for external infusion pumps to include additional drugs and biologicals. However serious concerns were raised about other aspects of the proposed rule. Some commenters stated that the proposal would be a very narrow policy change that would offer little in the way of expanded benefits for patients and would create administrative complexity and uncertainty regarding Medicare coverage. Some commenters supported the first criterion in our proposed standard for determining whether an external infusion pump and associated supplies could be covered under the Medicare Part B benefit for DME. However, those commenters advocated that CMS remove the requirement that the FDA-required labeling require the associated home infusion drug be ''prepared immediately prior to administration.'' They noted that this requirement is unclear, as most drugs have storage information which permits use of a drug after mixing. Some commenters supported the second criterion in our proposed standard, which required that a qualified home infusion therapy services supplier administer the drug or biological in a safe and effective manner in the patient's home.

Commenters opposed the third criterion in our proposed standard, and recommended that CMS remove the requirement that the FDA-required labeling specify an external infusion pump as a possible route of administration. Commenters stated that this requirement was too restrictive and could limit access to therapies that would otherwise be clinically appropriate for use in the home. Several commenters pointed out that not all drugs included in the LCDs for Intravenous Immune Globulin (policy number L33610) currently have labels that specify using an external infusion pump as a possible route of administration, though prescribers most often require these pumps to control the rate of infusion. Several commenters believed that the proposed rule needed more development, was unclear about which drugs could be covered under the Medicare Part B benefit for DME as supplies, and could pose safety concerns. A commenter noted the home setting is not the ideal environment for prepping sterile medications for injection or infusion. This commenter also stressed that the beneficiary may not be aware when selecting an administration site (home or outpatient) of the large difference in cost-sharing. Another commenter indicated that CMS should not be the agency to decide if home infusion was safe and appropriate. This commenter urged CMS to delay the expansion of the definition of DME to include additional external infusion pumps until CMS can gather an exact list of the drugs and biologicals that would be affected by this policy and determine whether such drugs and biologicals can be administered in the home safely and effectively under the parameters CMS proposed. We thank the commenters for their input on the HCPCS and infusion pump proposals.

III. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

A. Background

1. DMEPOS Competitive Bidding Program

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), mandates the Medicare DMEPOS CBP for contract

award purposes to furnish certain competitively priced DMEPOS items and services subject to the 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; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

Section 1847(a) of the Act 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. Section 1847(a)(1)(B)(i) of the Act mandates that the programs be phased into 100 of the largest metropolitan statistical areas (MSA) by 2011 and additional areas after 2011. Thus far, CBAs have been either an MSA or a part of an MSA. Under the Office of Management and Budget (OMB) standards for delineating MSAs, MSAs have at least one urbanized area that has a population of at least 50,000. The MSA comprises the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county or counties as measured through commuting.[1] OMB updates MSAs regularly and the most recent update can be found in OMB Bulletin No. 20–01.[2] The statute allows us to exempt rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service, from the CBP. We may also exempt from the CBP items and services for which competitive acquisition is unlikely to result in significant savings.

We refer to areas in which the CBP is not or has not been implemented as non-competitive bidding areas (non-CBAs). We use the term ''former CBAs'' to refer to the areas that were formerly CBAs prior to a gap in the CBP, to distinguish those areas from ''non-CBAs.'' More information on why there was a gap in the CBP from January 1, 2019 through December 31, 2020 can be found in the November 14, 2018 final rule titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, 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 (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS,'' (83 FR 56922) (hereinafter ''CY 2019 ESRD PPS DMEPOS final rule'').

Non-CBAs include rural areas, non-rural areas, and non-contiguous areas. A rural area is defined in 42 CFR 414.202 as 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 MSA. 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. Non-contiguous areas refer to areas outside the contiguous U.S.—that is, areas such as Alaska, Guam, and Hawaii (81 FR 77936).

2. Payment Methodology for CBAs

In the DMEPOS CBP, suppliers bid for contracts for furnishing multiple items and services, identified by HCPCS codes, under several different product categories. In the CY 2019 ESRD PPS DMEPOS final rule, we made significant changes to how we calculate single payment amounts (SPAs) under the DMEPOS CBP. Prior to these changes, for individual items within each product category in each CBA, the median of the winning bids for each item was used to establish the SPA for that item in each CBA. As a result of the changes we made in the CY 2019 ESRD PPS DMEPOS final rule, SPAs are calculated for the lead item in each product category (per § 414.402, the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition) based on the maximum winning bid (the highest of bids submitted by winning suppliers) in each CBA.

Per § 414.416(b)(3), the SPA for each non-lead item in a product category (all items other than the lead item) is calculated by multiplying the SPA for the lead item by the ratio of the average of the 2015 fee schedule amounts for all areas for the non-lead item to the average of the 2015 fee schedule amounts for all areas for the lead item.

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 fee schedule 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.

3. Fee Schedule Adjustment Methodology for Non-CBAs

Section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the Medicare DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs on or after January 1, 2016. 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 under the CBP 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 the Secretary to specify the methodology to be used in making these fee schedule adjustments by regulation, and to consider, among other factors, the costs of items and services in non-CBAs (where the adjustments would be applied) compared to the payment rates for such items and services in the CBAs.

In accordance with the requirements of section 1834(a)(1)(G) of the Act, we conducted notice-and-comment rulemaking in 2014 to specify methodologies for adjusting the fee schedule amounts for DME, enteral nutrition, and OTS orthotics in non-CBAs in 42 CFR 414.210(g). We will provide a summary of these methodologies, but also refer readers to the July 11, 2014 proposed rule titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,'' (79 FR 40208) (hereinafter ''CY 2015 ESRD PPS DMEPOS proposed rule''), and the November 6, 2014 final rule titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable

[1] OMB 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas; Notice, June 28, 2010 (75 FR 37252).

[2] *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf?#.*

Medical Equipment, Prosthetics, Orthotics, and Supplies,'' (79 FR 66120) (hereinafter ''CY 2015 ESRD PPS DMEPOS final rule'') for additional details.

The methodologies set forth in § 414.210(g) account for regional variations in prices, including for rural and non-contiguous areas of the U.S. In accordance with § 414.210(g)(1), we determine regional adjustments to fee schedule amounts for each State in the contiguous U.S. and the District of Columbia, based on the definition of region in § 414.202, which refers to geographic areas defined by the Bureau of Economic Analysis (BEA) in the Department of Commerce for economic analysis purposes (79 FR 66226). Under § 414.210(g)(1)(i) through (iv), adjusted fee schedule amounts for areas within the contiguous U.S. are determined based on regional prices limited by a national ceiling of 110 percent of the regional average price and a floor of 90 percent of the regional average price (79 FR 66225). Under § 414.210(g)(1)(v), adjusted fee schedule amounts for rural areas are based on 110 percent of the national average of regional prices. Under § 414.210(g)(2), fee schedule amounts for non-contiguous areas are adjusted based on the higher of the average of the SPAs for CBAs in non-contiguous areas in the U.S., or the national ceiling amount.

For items and services that have been included in no more than 10 CBPs, § 414.210(g)(3) specifies adjustments based on 110 percent of the average of the SPAs. In cases where the SPAs from DMEPOS CBPs that are no longer in effect are used to adjust fee schedule amounts, § 414.210(g)(4) requires that the SPAs be updated by an inflation adjustment factor on an annual basis based on the Consumer Price Index for all Urban Consumers update factors from the mid-point of the last year the SPAs were in effect to the month ending 6 months prior to the date the initial payment adjustments would go into effect.

Under § 414.210(g)(5), in situations where a HCPCS code that describes an item used with different types of base equipment is included in more than one product category in a CBA, 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). Under § 414.210(g)(6), we will adjust the SPAs for certain items prior to using those SPAs to adjust fee schedule amounts for items and services if price inversions have occurred under the DMEPOS CBP. Price inversions occur when one item in a grouping of items in a product category includes a feature that another similar item in the product category does not, and the average of the 2015 fee schedule amounts for the item with the feature is higher than the average of the 2015 schedule amounts for the item without the feature, but following a CBP competition, the SPA for the item with the feature is lower than the SPA for the item without the feature. For groupings of similar items where price inversions have occurred, the SPAs for the items in the grouping are adjusted to equal the weighted average of the SPAs for the items in the grouping.[3]

In § 414.210(g)(8), the adjusted fee schedule amounts are revised each time a SPA for an item or service is updated following one or more new DMEPOS CBP competitions and as other items are added to the 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 or, in accordance with § 414.210(g)(10), when there are temporary gaps in the DMEPOS CBP. Updates to the SPAs may occur as contracts are recompeted. In the CY 2015 ESRD PPS DMEPOS final rule, we established § 414.210(g)(9) to provide for a transitional phase-in period of the DMEPOS fee schedule adjustments. We established a 6-month transition period for blended rates from January 1 through June 30, 2016 (79 FR 66228 through 66229). In establishing a transition period, we agreed with commenters that phasing in the adjustments to the fee schedule amounts would allow time for suppliers to adjust to the new payment rates, and further noted that we would monitor the impact of the change in payment rates on access to items and services and health outcomes using real time claims data and analysis (79 FR 66228). Under § 414.210(g)(9)(i), we specified that the fee schedule adjustments for items and services furnished between January 1, 2016 through June 30, 2016 would be based on a blend of 50 percent of the unadjusted fee schedule amount and 50 percent of the adjusted fee schedule amount. Under § 414.210(g)(9)(ii), we specified that for items and services furnished with dates of service on or after July 1, 2016, the fee schedule amounts would be fully adjusted in accordance with the rules specified in § 414.210(g)(1) through § 414.210(g)(8).

[3] For further discussion regarding adjustments to SPAs to address price inversions, we refer readers to the CY 2017 ESRD PPS DMEPOS final rule, titled 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 77937 (November 4, 2016).

4. 21st Century Cures Act

Section 16007(a) of the Cures Act was enacted on December 13, 2016, and extended the transition period for the phase-in of fee schedule adjustments at § 414.210(g)(9)(i) by an additional 6 months from July 1, 2016 through December 31, 2016. In the May 2018 IFC, we amended § 414.210(g)(9)(i) to implement the 6-month extension to the initial transition period, as mandated by section 16007(a) of the Cures Act. Accordingly, the fee schedule amounts were based on blended rates 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 (83 FR 21915). Section 16008 of the Cures Act amended section 1834(a)(1)(G) of the Act to require that the Secretary take into account certain factors when making any fee schedule adjustments under sections 1834(a)(1)(F)(ii) or (iii), 1834(h)(i)(H)(ii), or 1842(s)(3)(B) of the Act for items and services furnished on or after January 1, 2019. Specifically, the Secretary was required to take into account: (1) Stakeholder input solicited regarding adjustments to fee schedule amounts using information from the DMEPOS CBP; (2) the highest bid by a winning supplier in a CBA; and (3) 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, and the number of suppliers in the area.

5. Extension of DMEPOS Fee Schedule Transition Period & Revised Methodology

In the May 2018 IFC (83 FR 21918), we expressed an immediate need to resume the transitional, blended fee schedule amounts in rural and non-contiguous areas, noting strong stakeholder concerns about the continued viability of many DMEPOS suppliers, our finding of a decrease in the number of suppliers furnishing items and services subject to the fee schedule adjustments, as well as the Cures Act mandate to consider additional information material to

setting fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019. We explained that resuming these transitional blended rates would preserve beneficiary access to needed DME items and services in a contracting supplier marketplace, while also allowing us time to address the adequacy of the fee schedule adjustment methodology, as required by section 16008 of the Cures Act. As a result, we amended § 414.210(g)(9) by adding § 414.210(g)(9)(iii) 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. We explained that resuming these transitional blended rates would 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 us to monitor the impact of the blended rates. We also amended § 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, fully adjusted fee schedule amounts would apply (83 FR 21922). In addition, we added § 414.210(g)(9)(iv) to specify that fully adjusted fee schedule amounts would apply for items furnished in non-CBAs other than rural and non-contiguous areas from June 1, 2018 through December 31, 2018 (83 FR 21920). We explained that we would use the extended transition period to further analyze our findings and consider 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 (83 FR 21918 through 21919).

In the CY 2019 ESRD PPS DMEPOS final rule, we finalized changes to bidding and pricing methodologies under the DMEPOS CBP for future competitions (83 FR 57020 through 57025). Specifically, we finalized lead item pricing for all product categories under the DMEPOS CBP, which would use the bid for the lead item to establish the SPAs for both the lead item and all other items in the product category (the non-lead items). We explained that this change would reduce the burden on suppliers since they would no longer have to submit bids on numerous items in a product category. We also finalized changes to the methodology for calculating SPAs under the DMEPOS CBP based on lead item pricing using maximum winning bids for lead items in each product category. We finalized revisions to §§ 414.414 and 414.416 to reflect our changes to the bidding and pricing methodologies, and revised the definitions of bid, composite bid, and lead item in § 414.402. We expected that these changes would have a minimal effect on savings under the DMEPOS CBP. However, during Round 2021 of the DMEPOS CBP, we observed numerous occurrences where capacity, demand, and projected savings, in concert with our policies, were incomparable to previous rounds of competition.

Also, in the CY 2019 ESRD PPS DMEPOS final rule, we established fee schedule adjustment transition rules for items and services furnished from January 1, 2019 through December 31, 2020. We decided to make these fee schedule adjustment transition rules effective for a 2-year period only, for two reasons. First, we believed that we must proceed cautiously when adjusting fee schedules in the short term in an effort to protect access to items, while we continued to monitor health outcomes, assignment rates, and other information (83 FR 57029). Second, as part of the final rule, we made significant changes to the way bids are submitted and SPAs are calculated under the CBP. We stated in the final rule these changes could warrant further changes to the fee schedule adjustment methodologies in the future (83 FR 57030).

Consistent with the requirements of section 16008 of the Cures Act, we set forth our analysis and consideration of stakeholder input solicited on adjustments to fee schedule amounts using information from the DMEPOS CBP, the highest bid by a winning supplier in a CBA, and a comparison of the various factors with respect to non-CBAs and CBAs. We noted stakeholder concerns that the adjusted payment amounts constrained suppliers from furnishing items and services to rural areas, and their request for an increase to the adjusted payment amounts for these areas (83 FR 57025). In reviewing highest winning bids, we found no pattern indicating that maximum bids were higher for areas with lower volume than for areas with higher volume (83 FR 57026). In our consideration of the Cures Act factors with respect to non-CBAs and CBAs, we found higher costs for non-contiguous areas, an increased average travel distance in certain rural areas, a significantly lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas, and a decrease in the number of non-CBA supplier locations. Based on our consideration of the foregoing, we expressed our belief that the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all rural or non-contiguous areas should be based on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g) (83 FR 57029).

We also expressed our belief that the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are non-CBAs, but are not rural or non-contiguous areas, should be based on 100 percent of the adjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g) (83 FR 57029). We finalized amendments to the transition rules at § 414.210(g)(9) to reflect these fee schedule adjustment methodologies for items and services furnished from January 1, 2019 through December 31, 2020 (83 FR 57039; 83 FR 57070 through 57071).

6. The Coronavirus Aid, Relief, and Economic Security Act

The Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116–136) was enacted on March 27, 2020. Section 3712 of the CARES Act specifies the payment rates for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs through the duration of the emergency period described in section 1135(g)(1)(B) of the Act. Section 3712(a) of the CARES Act continues our policy of paying the 50/50 blended rates for items furnished in rural and non-contiguous non-CBAs through December 31, 2020, or through the duration of the emergency period, if longer. Section 3712(b) of the CARES Act increased the payment rates for DME and enteral nutrients, supplies, and equipment furnished in areas other than rural and non-contiguous non-CBAs through the duration of the emergency period. Beginning March 6, 2020, the payment rates for DME and enteral nutrients, supplies, and equipment furnished in these areas are based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount, which results in higher payment rates as compared to the full fee schedule adjustments that were previously required under § 414.210(g)(9)(iv). We made changes to

the regulation text at § 414.210(g)(9), consistent with section 3712 of the CARES Act, in an IFC that we published in the May 8, 2020 **Federal Register** titled ''Medicare and Medicaid Programs; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency.''

B. Current Issues

In the proposed rule (85 FR 70364), we proposed to establish fee schedule adjustment methodologies for items and services furnished in non-CBAs on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. In the proposed rule (85 FR 70364), we stated that though the transition rules under 42 CFR 414.210(g)(9)(iii) and 414.210(g)(9)(v) expired on December 31, 2020, we believe that the rest of the current fee schedule adjustment rules at § 414.210(g) would continue to be in effect should the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B) (PHE) expire after January 1, 2021, and before April 1, 2021. At the time, we presumed that the PHE would expire in early 2021, and that we would finalize the proposed rule around that time. Now that April 1, 2021 has passed, but the PHE is still ongoing, and the proposed rule has yet to be finalized, we are making a technical edit to reflect the new effective date for this final rule. Consistent with our proposal, in the event that the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) expires before the effective date specified in the **DATES** section of this final rule (rather than April 1, 2021), the current fee schedule adjustment rules at § 414.210(g)(1) through (8) would be used to adjust fee schedule amounts for items and services furnished in non-CBAs and the current fee schedule adjustment rule at § 414.210(g)(10) would be used to adjust fee schedule amounts for items and services furnished in CBAs or former CBAs until the final rule takes effect on the effective date specified in the **DATES** section of this final rule.

1. Section 16008 of the Cures Act Analysis

Section 1834(a)(1)(G) of the Act requires CMS to specify by regulation the methodology to be used in adjusting DMEPOS fee schedule amounts based on information from the DMEPOS CBP. Section 16008 of the Cures Act amended section 1834(a)(1)(G) to specifically require that CMS take into account a number of factors in making any fee schedule adjustments for items and services furnished on or after January 1, 2019, including: (1) Stakeholder input we have solicited on adjustments to fee schedule amounts using information from the DMEPOS CBP; (2) the highest bid by a winning supplier in a CBA; and (3) a comparison of the factors outlined in section 16008 of the Cures Act with respect to non-CBAs and CBAs. Our analysis of the Cures Act factors focuses on the effect we believe increased payment levels have had in rural and non-contiguous non-CBAs, and the effect we believe fully adjusted fees have had in non-rural contiguous non-CBAs. We also provide our analysis of other metrics we believe are important in measuring the impacts of our payment policies.

a. Stakeholder Input Gathered in Accordancew With Section 16008 of the Cures Act

Section 16008 of the Cures Act requires us to solicit and take into account stakeholder input in making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019. On March 23, 2017, we hosted a national provider call to solicit stakeholder input regarding adjustments to fee schedule amounts using DMEPOS CBP information (83 FR 57025 through 57026). More than 330 participants called in, with 23 participants providing verbal comments during the call. We also received 125 written comments from stakeholders in response to our request for written comments. Our announcement of this call, a copy of our presentation, the audio recording of the call, and its transcript can be found at the following link on the CMS website.[4]

In general, the commenters were mostly suppliers located in MSAs, but also included manufacturers, trade organizations, and healthcare providers such as physical and occupational therapists. For additional details about the national provider call and a summary of oral and written comments received, we refer readers to the CY 2019 ESRD PPS/DMEPOS proposed rule (83 FR 57026). For a summary of public comments received on the CY 2019 ESRD PPS DMEPOS proposed rule and our responses, we refer readers to the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57030 through 57036).

While the stakeholder input from 2017 did not quantify the degree to which costs of furnishing items in CBAs versus rural areas or any other non-CBAs, the comments we received in response to our 2014 proposed rule (79 FR 40208) indicated that the adjusted fee schedule amounts for rural areas should be equal to 120 to 150 percent of the average of the regional single payment amounts (RSPAs) rather than 110 percent of the average of the RSPAs. In addition, a 2015 industry survey of suppliers of respiratory equipment indicated that the cost of furnishing respiratory equipment in ''super rural'' areas is 17 percent higher than the cost of furnishing respiratory equipment in CBAs.[5] The term ''super rural'' refers to areas identified as ''qualified rural areas'' under the ambulance fee schedule statute at section 1834(l)(12)(B) of the Act (as implemented at 42 CFR 414.610(c)(5)(ii)).

For the purposes of the fee schedule for ambulance services, rural areas are defined at 42 CFR 414.605 as areas located outside an urban area (MSA), or a rural census tract within an MSA as determined under the most recent version of the Goldsmith modification as determined by the Federal Office of Rural Health Policy at the Health Resources and Services Administration (HRSA). The most recent version of the Goldsmith Modification are the Rural-Urban Commuting Area (RUCA) codes, which are a method of determining rurality.[6] Under 42 CFR 414.610(c)(5)(ii), for ground ambulance services furnished during the period July 1, 2004 through December 31, 2022, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. We refer to this as the ''super rural'' bonus, and the areas that receive this super rural bonus as ''super rural'' areas.[7] For purposes of payment under the Medicare ambulance fee schedule, a ''super rural'' area is thus a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. DMEPOS industry stakeholders have recommended that this differential in payment between super rural areas and MSAs may be adopted in the DMEPOS fee schedule payment context as well.

[4] *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-03-23-DMEPOS.*

[5] *https://www.cqrc.org/img/CQRCCost SurveyWhitePaperMay2015Final.pdf.*

[6] *https://www.hrsa.gov/rural-health/about-us/definition/index.html.*

[7] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/afspuf.*

In general, we continue to receive feedback from industry stakeholders expressing their belief that the fully adjusted fee schedule amounts are too low and would have an adverse impact on beneficiary access to items and services furnished in rural areas if they are resumed in these areas. Industry stakeholders have also stated that the fully adjusted fee schedule amounts are insufficient to cover the supplier's costs, particularly for delivering items in rural areas.

We indicated in the November 2020 proposed rule that we have been closely monitoring beneficiary health outcomes and access to DMEPOS items. We stated that there has been no decline in allowed services for items subject to the fee schedule adjustments at any point in time, including 2017 and the first half of 2018 when payment in rural and non-contiguous areas was based on the fully adjusted fee schedule amounts. Traditional Medicare or fee-or-service allowed services for items subject to the fee schedule adjustments rose from 24,882,018 in 2015 to 25,604,836 in 2016, 26,065,601 in 2017, and 26,481,002 in 2018. This increase in allowed services occurred even though beneficiary fee-for-service enrollment dropped by 0.6 percent from 33.7 million in 2016 to 33.5 million in 2018 while Medicare Advantage beneficiary enrollment rose by 16.0 percent from 18.4 million in 2016 to 21.3 million in 2018. During this time, suppliers accepted assignment (Medicare payment in full) for most items and services (99.79 percent in 2017 and 99.81 percent in 2018). This rate of assignment remained extremely high (99.68 percent in 2017 and 99.70 percent in 2018) even after removing claims for Medicare participating suppliers and suppliers furnishing items to beneficiaries with dual (Medicare and Medicaid) eligibility, where assignment is mandatory. In addition, we stated that we continue to monitor over one thousand health metrics (emergency room visits, physician office visits, nursing home and hospital admissions, length of need, deaths, etc.) and have not detected any negative impact of the fee schedule adjustments on health outcomes. When analyzing the 2015 monthly average health outcome rates for beneficiaries in non-CBAs, which was the last year we did not make any fee schedule adjustments in non-CBAs, we noted reductions in both 2017 and 2018 in mortality rates, hospitalization rates, physician visits, SNF admissions, and monthly days in the hospital. The percentage of beneficiaries with emergency room visits increased from 3.6 to 3.9 percent and monthly days in nursing homes remained unchanged. Finally, we noted that beneficiary inquiries and complaints related to DMEPOS items and services have steadily declined since 2016 and have not increased.

b. Highest Winning Bids in CBAs Analysis

Section 16008 of the Cures Act requires us to take into account the highest amount bid by a winning supplier in a CBA when making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019. As discussed earlier, in the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57026), we found no pattern indicating that maximum bids are higher for areas with lower volume than for areas with higher volume. For additional details, we refer readers to the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34360 through 34367). Additionally, for Round 2021 of the DMEPOS CBP, SPAs were calculated for the lead item in each product category based on the maximum winning bid, and therefore the maximum winning bid is taken into account when making fee schedule adjustments based on information from the CBP for items and services included in Round 2021 and furnished on or after January 1, 2019.

c. Travel Distance Analysis

Section 16008 of the Cures Act also requires us to take into account a comparison of the average travel distance and costs associated with furnishing items and services in CBAs and non-CBAs. In the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34367 through 34371), we compared the average size of different non-CBAs nationally and found that the CBAs had much larger service areas than the non-CBAs. We also compared the average travel distances for suppliers in the different areas using claims data for items and services subject to the fee schedule adjustments. From our analysis, we found that the average distance traveled in CBAs was generally greater than in most non-CBAs. However, in reviewing certain non-CBAs, such as Frontier and Remote (FAR) areas,[8] Outside Core Based Statistical Areas (OCBSAs),[9] and super rural areas,[10] we found that suppliers generally must travel farther distances to beneficiaries located in those areas than for beneficiaries located in CBAs and other non-CBAs. For additional details on our previous travel distance analysis, we refer readers to the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34367 through 34371).

In the November 2020 proposed rule, we updated some of the travel distance data used in our previous travel distance analysis with data from 2018, which at the time was the most recent full year of CBP data. As of January 1, 2021, Round 2021 of the CBP is underway and there are currently contract suppliers furnishing OTS back and knee braces in CBAs. We did not award competitive bidding contracts to suppliers for any of the other product categories that were bid during Round 2021 of the CBP because the SPAs (calculated based on bids) did not achieve expected savings.[11]

As we indicated in the CY 2019 ESRD DMEPOS final rule (83 FR 57027), we looked at hospital beds and oxygen and oxygen equipment, as they are items that are most likely to be delivered locally by suppliers using company vehicles, as well as all items subject to the fee schedule adjustments. The last time these items were included in the CBP was in 2018, and so we believe this 2018 data is still relevant for the purposes of this analysis.

In reviewing the data from 2018, we found that the same trends we presented in the CY 2019 ESRD PPS DMEPOS proposed rule, which were based on 2016 data, apply. Similar to our previous travel distance analysis, to prevent the data from being skewed in certain ways, we only included claims where the supplier billing address is in the same or adjoining State as the beneficiary address, and we excluded claims from suppliers with multiple locations that always use the same billing address. These data restrictions left in place 96 percent of allowed claims lines when looking at hospital beds, 97 percent when looking at

[8] A Frontier and Remote (FAR) area is statistically delineated by the Health Resources and Services Administration (HRSA) based on remoteness and population sparseness. HRSA Methodology for Designation of Frontier and Remote Areas, 79 FR 25599 through 25603 (May 5, 2014).

[9] Outside Core Based Statistical Areas are delineated by OMB as counties that do not qualify for inclusion in a Core Based Statistical Area. OMB 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas; Notice, 75 FR 37245 (June 28, 2010).

[10] Under the Ambulance Fee schedule (AFS), temporary add-on payments known as the ''super rural bonus'' are available in relation to areas that are within the lowest 25 percentile of all rural areas arrayed by population density. 42 CFR 414.610(c)(5)(ii).

[11] *https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf.*

oxygen, and 92 percent when looking at all items.

TABLE 1—2018 AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY *

Beneficiary area	Hospital beds	Oxygen	All items
CBAs	28	23	30
Non-CBA MSAs	24	22	28
Non-CBA Micro Areas	22	22	27
Non-CBA OCBSA	28	31	37
Super Rural	37	37	42
FAR level 1	27	31	36
FAR level 3	40	41	47

* Includes claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

We also reviewed in the November 2020 proposed rule travel distance data updated by partial 2019 data spanning January through November 2019 (85 FR 70366). Average travel distances in former CBAs decreased, while average travel distances in rural and non-rural non-CBAs increased. Section 16008 of the Cures Act requires a comparison of average travel distance with respect to non-CBAs and CBAs. At the time of the November 2020 proposed rule, there were no CBAs due to the gap period in the DMEPOS CBP, allowing any Medicare-enrolled DMEPOS suppliers to furnish DMEPOS items and services. In the November 2020 proposed rule, we still reviewed data from former CBAs, as we believed the decrease in average travel distance in the former CBAs was additional confirmation that travel distances are generally greater in CBAs while a CBP is in effect, when compared to non-CBAs. We stated that average supplier travel distances in the former CBAs decreased for a variety of reasons. For one, CBP contract suppliers must furnish items and services to any beneficiary located in a CBA. During a gap period in the CBP, any supplier may furnish items and services to a beneficiary located in a former CBA and suppliers are no longer obligated to service a beneficiary who may be farther away from the supplier. Additionally, more suppliers can now furnish items and services to beneficiaries, so a beneficiary could also receive items and services furnished by a supplier located closer to the beneficiary. Section 16008 of the Cures Act requires us to take into account a comparison of the average travel distance and costs associated with furnishing items and services in CBAs and non-CBAs. As a result, we believe a payment methodology should account for this factor, and the increased costs suppliers may face in reaching certain non-CBAs. When we say certain non-CBAs, we are referring to non-CBAs classified as either super rural, FAR, or OCBSA. This is because although we found that the average travel distance for suppliers in non-CBAs is generally lower than the average travel distance and costs for suppliers in CBAs while the CBP was in effect, we found that suppliers generally must travel farther distances to beneficiaries located in non-CBAs that are super rural, FAR or OCBSA than for beneficiaries located in CBAs and other non-CBAs. Still, industry stakeholders have expressed their belief that the fully adjusted fee schedule amounts are too low and have an adverse impact on beneficiary access to items and services furnished in rural non-CBAs. We have not seen evidence of this, but because stakeholder input is another factor in section 16008 of the Cures Act, we are also factoring stakeholder input into our payment methodology, and therefore believe a payment methodology should result in higher payments for DMEPOS suppliers that furnish items and services to all rural areas, instead of just those areas with greater travel distance than CBAs. We believe this errs on the side of caution and may incentivize suppliers to furnish items and services to all rural areas.

d. Cost Analysis

We presented our analysis of different sources of cost data in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34371 through 34377). Overall, in comparing CBAs to non-CBAs, we found that CBAs tended to have the highest costs out of the cost data we examined. For certain cost data, we also found that Alaska and Hawaii—both non-contiguous areas—tended to have higher costs than many contiguous areas of the U.S. We stated in the November 2020 proposed rule that we updated this analysis with more recent data and did not notice any significant differences in these overall findings.

We believe these findings support a payment methodology that considers such increased costs in non-contiguous areas.

We also noted in the November 2020 proposed rule that we consider assignment rates as a source of cost data and consider it a measure of the sufficiency of payment to cover a supplier's costs for furnishing items and services under the Medicare program (85 FR 70366). Assignment rates for items subject to the fee schedule adjustments have not varied significantly around the country, and they have consistently remained over 99 percent in all areas. Thus, for the overwhelming majority of claims for items and services furnished in the non-CBAs that were subject to the fee schedule adjustments, suppliers have decided to accept the Medicare payment amount in full, and have not needed to charge the beneficiary for any additional costs that the Medicare allowed payment amount did not cover. Of note, for the 17 months from January 2017 through May 2018 when Medicare paid at the fully adjusted fee level in all areas, or about 40 percent below the unadjusted fee schedule amounts on average, the assignment rate did not dip below 99 percent for the items and services subject to the adjusted fee schedule amounts.

e. Average Volume of Items and Services Furnished by Suppliers in the Area Analysis

Section 16008 of the Cures Act requires that we take into account a comparison of the average volume of items and services furnished by suppliers in CBAs and non-CBAs. In the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34377), we found that in virtually all cases, the average volume of items and services furnished by suppliers is higher in CBAs than non-CBAs. In the November 2020 proposed rule we reviewed updated data from 2018, and found that in most cases, the average volume of items and services furnished by suppliers was higher in

CBAs than in non-CBAs (85 FR 70367). We reviewed the number of allowed claim lines on a national level for 15 different product categories subject to the fee schedule adjustments. In doing so, we found that non-CBAs had more allowed claim lines than CBAs for 4 of the 15 product categories that we reviewed (nebulizer, oxygen, seat lifts, and transcutaneous electrical nerve stimulation (TENS) devices). Rural non-CBAs had more allowed claim lines than CBAs for 2 of the 15 product categories that we reviewed (seat lifts and TENS). Finally, non-rural non-CBAs had more allowed claims lines than CBAs for those same two product categories (seat lifts and TENS).

Additionally, total services per supplier continued to increase in 2018 and 2019 in all non-CBAs. Thus, we found that the average volume per supplier in non-CBAs continues to increase while assignment rates are 99 percent or higher, and overall utilization remains steady or is increasing. We believe these findings support a payment methodology that takes into account and ensures beneficiary access to items and services in non-CBAs with relatively low volume.

f. Number of Suppliers Analysis

Section 16008 of the Cures Act requires us to take into account a comparison of the number of suppliers in the area.

The number of suppliers billing Medicare Fee-for-Service (FFS) for items subject to fee schedule adjustments in all non-CBAs declined from June 2018 through the end of 2019, which is the time period in which we paid the fully adjusted fees in non-rural, contiguous non-CBAs and the blended rates in rural and non-contiguous non-CBAs, in accordance with 42 CFR 414.210(g)(9)(iii) and (iv). More specifics about this decline can be found in Table 2. We note that the decline in the number of billing suppliers is part of a long-term trend that preceded the adjustment of the fee schedule amounts beginning in 2016, but we are still concerned about this trend, particularly for rural and non-contiguous areas, because beneficiaries could have trouble accessing items and services in these lower population areas if more suppliers decide to stop serving these areas.

In the November 2020 proposed rule we studied supplier numbers and found that when looking at a sample of HCPCS codes for high volume items subject to fee schedule adjustments (E1390 for oxygen concentrators, E0601 for CPAP machines, E0260 for semi-electric hospital beds, and B4035 for enteral nutrition supplies), that the average volume of items furnished by suppliers before they stopped billing Medicare is very small compared to the average volume of items furnished by suppliers who continued to bill (85 FR 70367). Data showed that large national chain suppliers were accepting a large percentage of the beneficiaries who were previously served by the smaller suppliers that exited the Medicare market. In addition, the average volume per supplier continues to increase (as the number of suppliers who bill Medicare has declined in recent years, the suppliers that still bill Medicare are picking up more volume), while overall services continue to grow, suggesting industry consolidation rather than any type of access issue for DME. Therefore, the decline in the number of supplier locations may be largely a result of the same degree of consolidation of suppliers furnishing items subject to the fee schedule adjustments rather than a decline in beneficiary access to items subject to the fee schedule adjustments. In addition, this trend in consolidation is matched by an increase in the average volume of items furnished per supplier, increasing economies of scale for these suppliers, although this does decrease the number of overall suppliers' beneficiaries can choose from to provide DMEPOS items. We do note that the number of enrolled DMEPOS suppliers did increase by 2 percent from 86,061 in 2019 to 87,800 in 2020, the highest total since 2016 when the total number of enrolled DMEPOS suppliers was 88,786. There are therefore still many DMEPOS supplier locations throughout the country furnishing DMEPOS items and services.

However, to determine what effect, if any, our payment amounts have had on the number of billing suppliers, in the November 2020 proposed rule, we also examined supplier numbers during defined timeframes in which we paid suppliers the unadjusted and adjusted fees, and the 50/50 blended rates (50 percent unadjusted and 50 percent adjusted) (85 FR 70367). The declines in the number of billing suppliers in both rural and non-rural non-CBAs were very similar, even when we increased payment levels to the blended rates in rural and non-contiguous non-CBAs, and continued paying the fully adjusted fees in non-rural/contiguous non-CBAs. We did not see an appreciable difference in supplier reductions between the two areas. We noted that non-contiguous non-CBAs exhibited a slightly different trend than other non-CBAs, as the number of billing suppliers in these areas increased from 2015 to 2016 when we paid the unadjusted fees, and January 2017 to May 2018 when we paid the fully adjusted fees, but subsequently declined between June 2018 to November 2019 when we paid the blended rates.

For this analysis, we reviewed the following timeframes and noted the payment policies in effect at that time:

- *Period 1:* January 2015–December 2015: Unadjusted fees in all non-CBAs.
- *Period 2:* January 2016–December 2016: Blended rates in all non-CBAs (as noted previously, Congress passed section 16007 of the Cures Act on December 13, 2016, which made the blended rates effective retroactively in all non-CBAs from June 30 through December 31, 2016).
- *Period 3:* January 2017–May 2018: Fully adjusted fees in all non-CBAs.
- *Period 4:* June 2018–November 2019: Blended rates in rural and non-contiguous non-CBAs, fully adjusted fees in non-rural non-CBAs in the contiguous U.S.

TABLE 2—NUMBER OF SUPPLIERS WHO BILLED FOR DME SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS

Period	CBA	% Change	Non-CBA non-rural	% Change	Non-CBA rural	% Change	Non-CBA non-contiguous	% Change
Jan 2015–Dec 2015	12,717		10,694		11,491		1,150	
Jan 2016–Dec 2016	11,698	−8.0	10,103	−5.5	10,772	−6.3	1,229	6.9
Jan 2017–May 2018 (fully adjusted)	9,127	−22.0	9,520	−5.8	10,173	−5.6	1,295	5.4
Jun 2018–Nov 2019	10,381	13.7	8,778	−7.8	9,401	−7.6	1,238	−4.4

* Claims data through 2019/11/29 (2019 Week 48), Provider Enrollment, Chain, and Ownership System (PECOS) data through 2019/09/17.

As we noted in our previous analysis (83 FR 34380), we believe that oxygen and oxygen equipment is one of the most critical items subject to the fee schedule adjustments in terms of beneficiary access. If access to oxygen and oxygen equipment is denied to a beneficiary who needs oxygen, serious health implications can result. Oxygen and oxygen equipment are also items that must be delivered to the beneficiary, and set up and used properly in the home for safety reasons. Access to oxygen and oxygen equipment in remote areas thus remains critical and has been stressed by stakeholders. To determine if there were pockets of the country where access to oxygen and oxygen equipment was in jeopardy, in the November 2020 proposed rule, we reviewed data depicting how many non-CBA counties are being served by only one oxygen supplier (85 FR 70368). From 2016 to 2018, there was a total of 2,691 non-CBA counties with beneficiaries receiving Medicare-covered oxygen supplies. For each year, there were approximately 38 to 39 counties being served by only one oxygen supplier, serving approximately 68 to 78 beneficiaries receiving approximately 736 to 896 services (annually) in those areas. Among the counties with only one oxygen supplier, the majority had only one oxygen user during that year. All counties with a single oxygen supplier from 2016 to 2018 had 100 percent assignment rates for oxygen services, and more than half of the single-supplier counties were in Puerto Rico.

We believe this shows that access to oxygen and oxygen equipment is not in jeopardy. If there are oxygen claims for only one beneficiary in the area, then only one billing supplier would show up in the data. This does not mean that the supplier submitting the claims for this one beneficiary is the only supplier available to furnish oxygen and oxygen equipment in the area. There may be other suppliers able to serve these areas as well and this would show up in the claims data if there were more beneficiaries using oxygen in these areas and these beneficiaries used more than one supplier. This also shows how non-CBAs can have far less volume and fewer billing suppliers than CBAs. Thus, we believe paying more money to suppliers serving rural and non-contiguous non-CBAs takes into account those factors specified in section 16008 of the Cures Act (volume and number of suppliers), and it errs on the side of caution to prevent beneficiary access issues.

2. DMEPOS Fee Schedule Adjustment Impact Monitoring Data

In addition to the various Cures Act factors, we monitored other metrics we believe are important in measuring the impacts of our payment policies. We stated in the November 2020 proposed rule (85 FR 70368) that in reviewing claims data processed through mid-November in 2018 and 2019, that assignment rates for all claims for DMEPOS items and services subject to fee schedule adjustments went up slightly from 2018 to 2019 in both non-rural non-CBAs (from 99.826 percent or 12,948,603 assigned services out of 12,971,110 to 99.833 percent or 11,594,547 assigned services out of 11,613,970) and rural non-CBAs (from 99.79 percent or 13,285,838 assigned services out of 13,313,575 to 99.81 percent or 11,863,434 assigned services out of 11,885,683). We stated to keep in mind that the 2019 claims data was not yet complete, so the number of allowed services will be greater than what we reported, but the final rate of assignment will likely not change much if at all.

When looking at claims processed through May 28, 2021, we found that assignment rates for all claims for DMEPOS items and services subject to fee schedule adjustments went slightly up in non-rural non-CBAs from 2019 to 2020 (99.82 percent to 99.85 percent) and 2020 to 2021 (99.85 percent to 99.88 percent). Assignment rates also increased in rural non-CBAs from 2019 to 2020 (99.80 to 99.84 percent) and 2020 to 2021 (99.84 to 99.85 percent). Finally, assignment rates also increased in non-contiguous non-CBAs from 2019 to 2020 (99.53 percent to 99.79 percent) and 2020 to 2021 (99.79 percent to 99.89 percent). We have also been monitoring other claims data from non-CBAs, and we have not observed any trends indicating an increase in adverse beneficiary health outcomes associated with the fee schedule adjustments. We monitor mortality rates, hospitalization rates, ER visit rates, SNF admission rates, physician visit rates, monthly days in hospital, and monthly days in SNF. Except for death information, which comes from the Medicare Enrollment Database, all other outcomes are derived from claims (inpatient, outpatient, Part B carrier, and SNF). Our monitoring materials cover historical and regional trends in these health outcome rates across a number of populations, allowing us to observe deviations that require further drilldown analyses. We monitor health outcomes in the enrolled Medicare population (Medicare Parts A and B), dual Medicare and Medicaid population, long-term institutionalized population, as well as various DME utilizers and access groups. This helps paint a complete picture of whether an increase in an outcome is across the board (not linked to DME access), or is unique to certain populations. Specifically, we focus on any increases that are unique to the DME access groups, which include beneficiaries who are likely to use certain DME based on their diagnoses, and we would conduct drilldown analyses and policy research to pinpoint potential reasons for such increases.

In addition, in the November 2020 proposed rule, we examined what effect, if any, paying the blended rates in rural and non-contiguous non-CBAs had on utilization of DME (85 FR 70368). We compared the utilization of oxygen equipment between June 2017 through December 2017, and June 2018 through December 2018. We compared these two time periods, because we paid the blended rates in rural and non-contiguous non-CBAs from June 1, 2018 through December 31, 2018, in accordance with the 2018 IFC (83 FR 21915). During the 2017 time period, we paid the fully adjusted fees in all non-CBAs. During the 2018 time period, we paid the blended rates in rural and non-contiguous non-CBAs and the fully adjusted fees in the non-rural contiguous non-CBAs from June 1, 2018 through December 31, 2018. We specifically studied oxygen utilization in rural areas without Micropolitan Statistical Areas, that is OCBSAs, as these counties have the least populated urban areas, and as we stated in the CY 2019 ESRD PPS DMEPOS final rule, one reason for paying higher rates was to ensure beneficiary access in rural and remote areas (83 FR 57029). We found that the number of allowed units in OCBSAs decreased comparably in all areas. Payment at the blended rates between June 1, 2018, and December 31, 2018, increased allowed charges in OCBSAs by 42 percent, but this had no apparent effect on increasing services in OCBSAs. Additionally, the significant reduction of liquid oxygen equipment allowed services trend continued in OCBSAs as well as in all areas. The decline in the number of oxygen concentrators that were furnished declined at the same rate in OCBSAs as in all areas. Access to oxygen equipment in OCBSAs was unchanged, despite a 49 percent increase in unit prices.

In sum, we do not believe our payment rates had a discernible impact on any trends that were already occurring before we paid the higher fees, and we did not see any appreciable differences between the areas in which

we paid the higher 50/50 blended rates in rural and non-contiguous non-CBAs and the areas in which we pay the fully adjusted fees in non-rural/contiguous non-CBAs. In addition, assignments rates are still high in all non-CBAs—over 99 percent—which means over 99 percent of suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME.

We sought comments on all of our findings.

TABLE 3—SUMMARY OF OUR ANALYSIS OF THE SECTION 16008 CURES ACT FACTORS

Section 16008 Cures Act factors	Summary of our analysis
Stakeholder Input	• Most of the input we have received has come from the DMEPOS industry, such as DMEPOS suppliers, expressing that the fully adjusted fee schedule amounts are too low, and that CMS should increase how much Medicare pays DMEPOS suppliers to furnish items and services to beneficiaries in non-CBAs. These stakeholders expressed concerns that the level of the adjusted payment amounts constrains suppliers from furnishing items and services to rural areas. • Stakeholder input that did not support such payment increases included input from the Medicare Payment Advisory Commission (MedPAC), which believed any adjustment for rural and non-contiguous areas should be limited to only the amount needed to ensure access, targeted at areas and products for which an adjustment is needed, and that CMS should consider taking steps to offset the cost of any adjustments. MedPAC supported setting fee schedule rates in urban, contiguous non-CBAs based 100 percent on information from the CBP.*
Highest Winning Bid	• In the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57026), we found no pattern indicating that maximum bids are higher for areas with lower volume than for areas with higher volume.
Travel Distance	• Average travel distance between the supplier and beneficiary is generally higher in CBAs than in non-CBAs, except for non-CBAs classified as FAR, super rural, or OCBSA.
Cost	• We examined four sources of cost data: (1) The Practice Expense Geographic Practice Cost Index (PE GPCI), (2) delivery driver wages from the Bureau of Labor Statistics (BLS), (3) real estate taxes from the U.S. Census Bureau's American Community Survey (ACS), and (4) gas and utility prices from the Consumer Price Index (CPI). • Overall, in comparing CBAs to non-CBAs, CBAs tended to have the highest costs out of the cost data we examined. For certain cost data, we also found that Alaska and Hawaii—both non-contiguous areas—tended to have higher costs than many contiguous areas of the U.S. Assignment rates, which we consider to be a measure of the sufficiency of payment to cover a supplier's costs for furnishing items and services under the Medicare program, have consistently remained high at over 99 percent (out of 100) in non-CBAs, meaning over 99 percent of suppliers furnishing items subject to fee schedule adjustments in the non-CBAs are accepting the Medicare payment in full.
Volume	• CBAs generally have higher volume than non-CBAs. • Total services per supplier continued to increase in 2018 and 2019 in non-CBAs.
Number of Suppliers	• The number of suppliers billing Medicare for furnishing items and services subject to fee schedule adjustments in the non-CBAs has been declining for several years, and this downward trend started years before CMS started adjusting fee schedule amounts in the non-CBAs in 2016. • When looking at a sample of HCPCS codes for high volume items subject to fee schedule adjustments, the average volume of items furnished by suppliers before they stopped billing Medicare is very small compared to the average volume of items furnished by suppliers who continued to bill. Data shows that large national chain suppliers are accepting a large percentage of the beneficiaries who were previously served by the smaller suppliers that exited the Medicare market. In addition, the average volume per supplier continues to increase (as the number of suppliers who bill Medicare decline, the suppliers that still bill Medicare are picking up more volume), while overall services continue to grow, suggesting industry consolidation rather than any type of access issue for DME. Therefore, the decline in the number of supplier locations is largely a result of the consolidation of suppliers furnishing items subject to the fee schedule adjustments rather than a decline in beneficiary access to items subject to the fee schedule adjustments. • When looking at different timeframes over the last several years in which we paid different fee schedule amounts (unadjusted fees, adjusted fees, and the 50/50 blended rates), we did not see an appreciable effect that these payment changes had on stemming the reduction in the number of suppliers billing Medicare. • All counties with a single oxygen supplier from 2016 to 2018 had 100 percent assignment rates for oxygen services, and more than half of the single-supplier counties were in Puerto Rico.

* *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.*

C. Proposed Provisions

After reviewing updated information that must be taken into consideration in accordance with section 1834(a)(1)(G) of the Act in determining adjustments to DMEPOS fee schedule amounts, we proposed to revise § 414.210(g) to establish three different methodologies for adjusting fee schedule amounts for DMEPOS items and services included in more than 10 competitive bidding programs furnished in non-CBAs on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later (85 FR 70370). We proposed three different fee schedule adjustment methodologies, based on the non-CBA in which the items are furnished: (1) One fee schedule adjustment methodology for items and services furnished in non-contiguous non-CBAs; (2) another adjustment methodology for items and services furnished in non-CBAs within the contiguous United States that are defined as rural areas at § 414.202; and (3) a third adjustment methodology for items and services furnished in all other non-CBAs (non-rural areas within the contiguous United States) (85 FR 70370). With respect to

items and services furnished in no more than ten competitive bidding programs, we proposed to continue using the methodology in § 414.210(g)(3) to adjust the fee schedule amounts for these items furnished on or after April 1, 2021 (85 FR 70370). The rest of the discussion that follows addresses the fee schedule adjustments for items and services that have been included in more than ten competitive bidding programs.

First, we proposed to continue paying the 50/50 blended rates in non-contiguous non-CBAs (85 FR 70370). However, we proposed that the 50/50 blend will no longer be a transition rule under § 414.210(g)(9), and will instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking. We proposed that the fee schedule amounts for items and services furnished on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, in non-contiguous non-CBAs be adjusted so that they are equal to a blend of 50 percent of the greater of the average of the SPAs for the item or service for CBAs located in non-contiguous areas or 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the unadjusted fee schedule amount for the area, which is the fee schedule amount in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment. We explained our rationale for a methodology that incorporates 110 percent of the national average price in our CY 2015 ESRD PPS DMEPOS final rule (79 FR 66225). We stated that we believe that a variation in payment amounts both above and below the national average price should be allowed, and we believe that allowing for the same degree of variation (10 percent) above and below the national average price is more equitable and less arbitrary than allowing a higher degree of variation (20 percent) above the national average price than below (10 percent), as in the case of the national ceiling and floor for the Prosthetic & Orthotic fee schedule, or allowing for only 15 percent variation below the national average price, as in the case of the national ceiling and floor for the DME fee schedule (79 FR 66225).

Second, we proposed to continue paying the 50/50 blended rates in rural contiguous areas; however, we proposed that the 50/50 blend will no longer be a transition rule under § 414.210(g)(9), and will instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking (85 FR 70370). We proposed that the fee schedule amounts for items and services furnished in rural contiguous areas on or after April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, be adjusted so that they are equal to a blend of 50 percent of 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment. We also proposed to revise § 414.210(g)(1)(v) to address the period before April 1, 2021, to say that for items and services furnished before April 1, 2021, the fee schedule amount for all areas within a State that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section. We decided to propose a policy of paying a 50/50 blend of adjusted and unadjusted rates in non-contiguous non-CBAs and in rural non-CBAs, as opposed to a different ratio (such as a 75/25 blend, which is an alternative we considered and discuss further in this section), because past stakeholder input from the DME industry has expressed support for this 50/50 blend. For instance, we proposed paying the 50/50 blend for rural and non-contiguous non-CBAs from January 1, 2019 through December 31, 2020 in our CY 2019 ESRD PPS DMEPOS proposed rule, and we finalized this policy in our CY 2019 ESRD PPS DMEPOS final rule. Most of the comments we received on the proposed rule were from commenters in the DME industry, such as homecare associations, DME manufacturers, and suppliers, and these commenters generally supported the 50/50 blended rates provisions.

Third, for items and services furnished on or after April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, in all other non-rural non-CBAs within the contiguous United States, we proposed that the fee schedule amounts be equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv) (85 FR 70370).

Accordingly, we proposed to add paragraph § 414.210(g)(9)(vi) to say that for items and services furnished in all areas with dates of service on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under § 414.210(g) (85 FR 70370).

Thus under our proposed provision, we will continue paying suppliers significantly higher rates for furnishing items and services in rural and non-contiguous areas as compared to items and services furnished in other areas because of stakeholder input indicating higher costs in these areas, greater travel distances and costs in certain non-CBAs compared to CBAs, the unique logistical challenges and costs of furnishing items to beneficiaries in the non-contiguous areas, significantly lower volume of items furnished in these areas versus CBAs, and concerns about financial incentives for suppliers in surrounding urban areas to continue including outlying rural areas in their service areas. Previous feedback from industry stakeholders expressed concern regarding beneficiary access to items and services furnished in rural and remote areas.

Furthermore, in our analysis, we found that suppliers must travel farther distances to deliver items to beneficiaries located in super rural areas and areas outside both MSAs and micropolitan statistical areas than the distances they must travel to deliver items to beneficiaries located in CBAs (while the CBP was in effect). We also found that certain non-contiguous areas tended to have higher costs, and had smaller numbers of oxygen suppliers and beneficiaries. Rural and non-contiguous areas also have much lower volume of DMEPOS items furnished by suppliers than in CBAs, and we are also concerned that national chain suppliers or suppliers in higher populated urban areas that are currently serving rural areas may abandon these areas if they are less profitable markets due to fee

schedule adjustments and may instead concentrate on the larger markets only. We believe that this feedback as well as these findings supports a payment methodology that errs on the side of caution and ensures adequate payment for items and services furnished to beneficiaries in all rural and non-contiguous non-CBAs. We also believed that the proposed fee schedule adjustment methodologies would create an incentive for suppliers to continue serving areas where fewer beneficiaries reside and will therefore further ensure beneficiary access to items and services in these areas. We proposed to continue paying the 50/50 blended rates in rural and non-contiguous non-CBAs, and 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv) in non-rural non-CBAs in the contiguous U.S., takes into account stakeholder feedback as well as information from our previous and updated analyses of the Cures Act factors (85 FR 70371).

The proposed fee schedule adjustment methodologies rely on SPAs generated by the CBP. We only awarded Round 2021 CBP contracts to bidders in the OTS back braces and OTS knee braces product categories.[12] We did not award Round 2021 CBP contracts to bidders that bid in any other product categories that were included in Round 2021 of the CBP, therefore, CMS does not have any new SPAs for these items and services. As a result, we stated in the November 2020 proposed rule that we were seriously considering whether to simply extend application of the current fee schedule adjustment transition rules for all of the items and services that were included in Round 2021 of the CBP but have essentially been removed from Round 2021 of the CBP (85 FR 70371). That is, for non-CBAs, the fee schedule adjustment transition rules at § 414.210(g)(9) and, for CBAs and former CBAs (CBAs where no CBP contracts are in effect), the fee schedule adjustment rules at § 414.210(g)(10), would be extended until a future round of the CBP. More specifically, for non-CBAs, we proposed to extend the transition rules at § 414.210(g)(9)(iii) and (v) for items and services included in product categories other than the OTS back and knee brace product categories, and, for these same items and services furnished in CBAs or former CBAs, we proposed to extend the rules at § 414.210(g)(10), until such product categories are competitively bid again in a future round of the CBP (85 FR 70371). In this situation, we stated that the proposed fee schedule adjustments discussed previously in the November 2020 proposed rule and in this final rule would only apply to OTS back braces and OTS knee braces furnished in non-CBAs on or after April 1, 2021 (85 FR 70371) . However, as we discussed previously in this final rule, now that April 1, 2021 has passed, but the PHE is still ongoing, and this rule has yet to be finalized, we are finalizing the proposed language with a technical edit to reference the effective date specified in the **DATES** section of this final rule to reflect the new effective date.

In short, beginning on the effective date specified in the **DATES** section of this final rule or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, there would be several different fee schedule adjustment methodologies in effect, depending on where an item or service is furnished, and whether CMS has awarded Round 2021 CBP contracts for that item or service. For OTS back braces and OTS knee braces included in Round 2021 of the CBP and furnished in CBAs, payment would be made in accordance with the methodologies described in 42 CFR 414.408. For OTS back braces and OTS knee braces included in Round 2021 of the CBP and furnished in rural and non-contiguous non-CBA areas, payment would be made in accordance with the methodologies we have proposed in the November 2020 proposed rule (85 FR 70371) and discuss in this final rule at § 414.210(g)(2). For OTS back braces and OTS knee braces included in Round 2021 of the CBP furnished in non-rural and contiguous non-CBA areas, payment would be made using the methodologies described in 42 CFR 414.210(g)(1)(iv).

For items and services included in the product categories that have essentially been removed from Round 2021 of the CBP, payment would be based on the methodologies described in 42 CFR 414.210(g)(10) when such items and services are furnished in CBAs or former CBAs. When such items and services are furnished in rural and non-contiguous non-CBAs, payment would be based on the methodologies we proposed at 42 CFR 414.210(g)(2) and the methodology at 42 CFR 414.210(g)(4). In non-rural and contiguous non-CBA areas, payment for these items and services would be based on the methodologies described in 42 CFR 414.210(g)(1)(iv) and the methodology at (g)(4). CMS welcomed comment on whether the transition rules at § 414.210(g)(9) and fee schedule adjustment rules at § 414.210(g)(10) should continue for these items and services that have essentially been removed from Round 2021 of the CBP. Specifically, we invited comment on whether we should extend the transition rules at § 414.210(g)(9)(iii) and (v) for items and services furnished in non-CBAs and included in product categories other than the OTS back and knee brace product categories, and, for these same items and services furnished in CBAs or former CBAs, whether we should extend the rules at § 414.210(g)(10), until such product categories are competitively bid again in a future round of the CBP.

Comment: Several commenters supported paying the 50/50 blended rates in rural and non-contiguous non-CBAs on a permanent basis. A few commenters believed this methodology will better ensure beneficiary access by helping DMEPOS suppliers stay in business and account for costs related to the COVID–19 pandemic. A commenter stated that there are costs related to the pandemic that are unlikely to be eliminated by the end of the COVID–19 public health emergency, and they thus support a permanent extension of the current rural non-CBA blended rates. A commenter stated they appreciated that the proposal would bring stability to DMEPOS suppliers by eliminating the transitional nature of these rates and making them part of the fee schedule adjustment methodology until revised in future rulemaking. A commenter supported higher payments in rural areas, and stated they supported the proposal that for DME items and services furnished before April 1, 2021, the fee schedule amount for all areas within a State that are defined as rural areas would be adjusted to 110 percent of the national average price.

Response: We thank the commenters for support of our proposal. In finalizing this fee schedule adjustment methodology, we aim to ensure that suppliers are incentivized to serve beneficiaries in rural and non-contiguous non-CBAs.

We agree that higher payments can better ensure access to items and services and maintain, if not increase, a supplier's willingness to furnish items and services. We do point out however that higher payments to suppliers results in higher cost sharing for beneficiaries, which could negatively affect access to DMEPOS items and services if beneficiaries decide to forego such items and services due to higher cost sharing.

Regarding comments supporting a permanent adoption of the 50/50 blended rates in rural and non-contiguous non-CBAs, as well as the

[12] The link to the announcement is *https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf.*

comment appreciating that this methodology will no longer be a transition rule under § 414.210(g)(9), we note that although we are finalizing our proposal to pay 50/50 blended rates in the rural and non-contiguous non-CBAs, as we further discuss in section ''E. Provisions of Final Rule'' of this final rule, we will likely be revisiting this issue and the fee schedule adjustment methodologies for all items in all areas again in the future. Furthermore, regarding commenter's concerns about the potential for lasting COVID–19 pandemic costs, and the permanence of the 50/50 blended rate fee schedule adjustment methodology, we are unsure of the extent to which COVID–19 has affected the costs of furnishing DMEPOS and whether such costs will indeed be permanent. For example, we have not seen any significant changes in assignment rates across the country, and we consider assignment rates to be indicative of the sufficiency of payment to cover a supplier's costs for furnishing DMEPOS items and services to Medicare beneficiaries. We will continue to monitor payments in rural and contiguous areas and all non-CBAs, as well as health outcomes, assignment rates, and other information in such areas.

Regarding the comment supporting our proposal that for DME items and services furnished before April 1, 2021, the fee schedule amount for all areas within a State that are defined as rural areas would be adjusted to 110 percent of the national average price, we note that the effective date for this final rule will now be the effective date specified in the **DATES** section of this final rule rather than April 1, 2021. Additionally, the COVID–19 PHE was renewed, effective on October 18, 2021.

As a result, we are finalizing the language as proposed with a technical edit to now address the period before the effective date specified in the **DATES** section of this final rule, instead of before April 1, 2021. Specifically, for items and services furnished before the effective date specified in the **DATES** section of this final rule, the fee schedule amount for all areas within a State that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section. In the November 2020 proposed rule, we proposed to reference April 1, 2021 in the revised § 414.210(g)(1)(v). However, as we previously discussed in this final rule, April 1, 2021 has passed and the PHE is still ongoing. Because this rule has not finalized yet, we are finalizing the proposed regulation text with a technical edit to reference the effective date specified in the **DATES** section of this final rule rather than the April 1, 2021 effective date.

Comment: A commenter believed that the closer the rates are to the 2015 unadjusted fee schedule, the more innovation there would be from providers.

Response: We thank the commenter for their comment. The commenter did not elaborate on why they believed the closer the rates are to the 2015 fee unadjusted fee schedule, the more innovation there would be from providers. Nevertheless, we are not aware of, nor do we believe there is a link between innovation and the 2015 fee schedule. In fact, the Government Accountability Office (GAO) and the HHS Office of Inspector General (OIG) have published numerous reports detailing how the unadjusted fee schedule amounts were higher, often significantly, than the amounts that suppliers paid to purchase products from manufacturers and wholesalers, the list prices on suppliers' websites, and the amounts paid by private payers and other government purchasers.[13] We do not think using the 2015 fee schedule rates leads to innovation.

Comment: Some commenters, in expressing their support of the proposed 50/50 blended rates in rural and non-contiguous non-CBAs, highlighted differences between rural and urban areas. A commenter stated that non-urban costs-to-serve is higher due to labor/drive times, use of higher cost third party distribution services, and lower equipment return rates. A commenter also discussed their hiring practices and associated labor costs, stating that employing individuals they deemed to be qualified in areas outside of the metropolitan areas is more challenging and costlier because of a limited pool of qualified individuals in these areas. Another commenter stated that Medicare beneficiaries in rural areas are geographically dispersed, hard to reach, and do not have the same access to systems of care available in more populated areas. The commenter stated that tough terrain, long distances between patients and providers/suppliers, and fewer health care resources mean that DME suppliers must incur added costs to deliver the appropriate medical equipment and supplies to patients on a timely basis. The commenter stated that this translates into added costs for transportation, delivery and clinical staff, fuel, and other expenses. The commenter stated that extension of the blended rates promotes access for beneficiaries in rural areas, making it less likely suppliers will be forced to close or stop providing DME to Medicare beneficiaries, and that they provide choices to beneficiaries to select from among a greater number of DME suppliers, as well as a greater variety of brand-name items and services that may meet their needs better than others.

Response: We have presented our analysis of factors that affect the cost of furnishing DMEPOS items and services in rural areas (areas outside MSAs) versus non-rural areas (MSAs) in past rulemaking (83 FR 57025) and in the preamble of the proposed rule and this final rule. While the data shows that the volume of items furnished in CBAs and MSAs is higher than the volume of items furnished in areas outside MSAs, the data we analyzed indicates that other factors such as: Labor rates/wages; gasoline prices; rent, utilities and other overhead costs; average travel time and distances; etc., suggest that these costs are higher in CBAs and MSAs than in areas outside MSAs. We have not been able to definitively conclude that the overall costs of furnishing DMEPOS items and services are higher or lower in rural areas than in other areas. However, for now, we believe it is necessary to continue paying the higher rates to suppliers for furnishing items in rural and non-contiguous areas to maintain access to DMEPOS items and services in these more remote areas.

Comment: Several commenters stated that the fee schedule rates for non-rural areas should be at a 75/25 blended rate. Commenters stated that the 75/25 blended rates that are currently in effect in non-rural contiguous non-CBAs, in accordance with section 3712(b) of the CARES Act, should continue even after the public health emergency ends. A commenter supported continuing the 75/25 blend, and to phase in the full fee schedule adjustments in these areas beginning January 1, 2024. A commenter clarified that the 75 percent portion should be based on the current rates in former CBAs, and the 25 percent portion of the blended payment formula should be based on the unadjusted fee schedule. A few commenters stated that the current rates were developed via a flawed auction bid methodology, and they were based on pre-pandemic demand and cost structure. A commenter stated that this payment should last not just through the end of the public health emergency, but until the product categories can be re-bid under a program structured to reflect

[13] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_medpacreporttocongress_rev_nov2019_note_sec.pdf.*

what they say are true market conditions. Another commenter stated the 75/25 blended rates will ensure suppliers can continue to provide critical DME to beneficiaries as suppliers encounter increased costs and a different market as a result of the pandemic. A few commenters stated that there are costs related to the pandemic that are unlikely to be eliminated by the end of the public health emergency, and they thus support a permanent extension of the current non-rural non-CBA blended rates.

A few commenters also stated concerns regarding access to home respiratory services, including oxygen. For instance, commenters discussed how the COVID–19 PHE has caused more patients to receive home respiratory therapy. Commenters were unsure how many of these patients would require home respiratory therapy on a long-term basis, and that it was therefore important that CMS establish payment rates that will sustain DME and home respiratory therapy suppliers now and over the longer term.

Response: Section 3712 of the CARES Act (Pub. L. 116–136) specifies the payment rates for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs through the duration of the emergency period described in section 1135(g)(1)(B) of the Act. Section 3712(a) of the CARES Act continued our policy of paying the 50/50 blended rates for items furnished in rural and non-contiguous non-CBAs through December 31, 2020, or through the duration of the emergency period, if longer. Section 3712(b) of the CARES Act increased the payment rates to a 75/25 blend for DME and enteral nutrients, supplies, and equipment furnished in areas other than rural and non-contiguous non-CBAs through the duration of the COVID–19 public health emergency period.

In the May 2020 COVID–19 IFC, we stated we believed the purpose of section 3712 of the CARES Act was to aid suppliers in furnishing items under very challenging situations during the COVID–19 PHE (85 FR 27571).

Furthermore, we have long maintained that the fully adjusted rates in non-rural non-CBAs are sufficient. For instance, we indicated in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34382) that although the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, the travel distances and costs for these areas are lower than the travel distances and costs for CBAs. We stated that because the travel distances and costs for these areas are lower than the travel distances and costs for CBAs, we believe the fully adjusted fee schedule amounts are sufficient.

Assignment rates were above 99 percent in non-rural contiguous non-CBAs when the fully adjusted rates were implemented. With regards to oxygen, in 2019 when we were paying the fully adjusted rates in non-rural non-CBAs, the assignment rate for oxygen was 99.95 percent. From 2020 to 2021, assignment rates for oxygen in non-rural non-CBAs were nearly identical—99.96 percent in 2020, and 99.95 percent in 2021. Additionally, when looking at non-CBAs on a national level, we have not seen evidence of a sustained increase in oxygen use as a result of the COVID–19 PHE. For all non-CBAs, the total number of claim lines for oxygen declined from 2019 to 2020 by 5.63 percent, and declined by 2.27 percent from 2020 to 2021. This is from using data through the same week in the respective year (week 42), to understand the impact of the fee schedule adjustment while accounting for claim delay.

We will continue to monitor payments in all non-CBAs, as well as health outcomes, assignment rates, and other information.

Comment: A commenter stated the rates for the non-rural non-CBAs should increase at least to the clearing price (or to the maximum winning bids) of the ''old'' SPA, or an additional 5–10 percent, to account for an increase in costs of raw materials, production, and supply chain. The commenter stated that they expected SPAs to increase under the new bidding methodologies we finalized in the CY 2019 ESRD PPS DMEPOS final rule, and that the non-rural non-CBA rates should reflect these expected increases.

Another commenter stated CMS should apply an adjustment to the pricing methodology to offset the lack of volume increase in the non-rural non-CBAs.

Response: We continue to believe that the fully adjusted rates in non-rural non-CBAs are sufficient and that paying any additional amount once the PHE ends would be unnecessary. We will continue to monitor payments in these and all non-CBAs, including health outcomes, assignment rates, and other information.

Comment: A commenter stated CMS should extend the 50/50 blended rates to non-rural, non-CBAs to ensure that beneficiaries have appropriate access and choice of quality DME items and services, including OTS orthoses subject to competitive bidding for the first time.

Response: As noted previously, once the PHE ends, we believe paying fee schedule amounts equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv) in non-rural contiguous non-CBAs will be sufficient. Assignment rates were above 99 percent in these areas when the fully adjusted rates were implemented. We will continue to monitor payments in these and all non-CBAs, including health outcomes, assignment rates, and other information.

Comment: A few commenters discussed how in a bidding program, there is a guarantee that there will be fewer competitors and larger volume of business, but that does not exist in non-bid areas and therefore there is no logical nexus between rates established in CBAs and the costs to serve in non-CBAs. The commenters also cited concern with the steady decreasing number of DME suppliers across the country, and stated it indicates a dwindling number of suppliers and real potential access issues.

Response: We believe there is a logical nexus between rates established in CBAs and the costs to furnish items in non-CBAs. We believe the 99 percent assignment rate in non-CBAs is a strong indication that there is a logical nexus between CBAs and the costs to furnish items in non-CBAs. As we noted in the November 2020 proposed rule, we consider assignment rates as a source of cost data and consider it a measure of the sufficiency of payment to cover a supplier's costs for furnishing items and services under the Medicare program (85 FR 70366). Assignment rates for items subject to the fee schedule adjustments have not varied significantly around the country, and they have consistently remained over 99 percent in all areas. Thus, for the overwhelming majority of claims for items and services furnished in the non-CBAs that were subject to the fee schedule adjustments, suppliers have decided to accept the Medicare payment amount in full, and have not needed to charge the beneficiary for any additional costs that the Medicare allowed payment amount did not cover. We also have not seen evidence of fee schedule adjustments causing access issues, but we will continue to monitor for any such issues. Finally, we note that the number of enrolled DMEPOS suppliers increased by 2 percent from 86,061 in 2019 to 87,800 in 2020, the highest total since 2016 when the total number of enrolled DMEPOS suppliers was 88,786. There are therefore still many DMEPOS supplier locations throughout the

country furnishing DMEPOS items and services.

Comment: The commenters shared the changes they have experienced as a result of the COVID–19 pandemic, as well as their recommendations for what the payment rates should be in the former CBAs. Several commenters stated they oppose extending the application of the current fee schedule adjustment transition rules for all of the items and services that were included in Round 2021 of the CBP but were effectively removed from Round 2021 of the CBP. A few commenters cited the COVID–19 pandemic as a reason for opposing extending the transition period and rates, saying that these rates were based on pre-PHE demand, and that fee schedule adjustments should reflect a new environment suppliers and manufacturers are facing as a result of the COVID–19 pandemic. Commenters stated additional costs from increased freight and other supply chain costs, shipping delays, hazard pay for direct care employees, personal protective equipment (PPE), and software and hardware to enable employees to work remotely. Commenters stated that these additional costs will likely continue throughout the pandemic, and may continue post-pandemic. A few commenters stated that SPAs were developed via a flawed auction bid methodology, and were outdated. A commenter recommended that the rates in former CBAs should reflect those established for Round 2 and Round 1 re-compete, updated by the CPI–U for each year since then. The commenter stated that setting the SPAs at these prior rates will provide suppliers with an increase that is necessary to reflect the 2020 change in the market.

Many commenters stated payment rates in the former CBAs should be based on a 90/10 blended payment formula, with the 90 percent based on the current payment rates in former CBAs (including the CPI–U updates), and the 10 percent based on the 2015 unadjusted fee schedules. Commenters stated that setting the rates based upon a 90–10 blended rate would provide for a modest increase to compensate for what they say is a flawed SPA setting methodology, for rates they say are 6 years old in a market they say has changed over those years, and for what they say are increased costs caused by the COVID–19 pandemic. A commenter stated that rates in former CBAs should at least be increased to the clearing price of those former bid program amounts.

Response: Per § 414.210(g)(10), during a temporary gap in the entire DMEPOS CBP and National Mail Order CBP or both, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

We do not agree that increasing the adjusted fee schedule amounts for items and services furnished in the former CBAs based on a 90/10 blended payment formula is necessary. The assignment rate for the vast majority of the items and services that were included in Round 2021 of the CBP has remained around 99 percent in the former CBAs in 2020 and 2021. If the costs to furnish DMEPOS items and services in the former CBAs increased as a result of COVID–19 or the DME market has fundamentally changed as a result of the COVID–19 pandemic to the point where the current payment rates are insufficient, we believe this would be reflected in the assignment rates and assignment rates would decrease across a variety of former CBAs and product categories in 2020 and 2021. However, that has not happened. For instance, when looking at the monthly assignment rate for oxygen in 2020 (the assignment rates of all former CBAs aggregated, with claims data through May 14, 2021), every month in 2020 had an assignment rate of 99 percent.

Further, in 2021, the assignment rate has remained the same except for the months of March and April, in which there was 100 percent assignment. Finally, in response to comments saying that setting the rates based upon a 90–10 blended rate would provide for a modest increase to compensate for a flawed SPA calculation methodology, and 6-year-old rates in a changed market, we would like to note that it has not been 6 years since the last CBP contract performance period ended.

Until the next round of the CBP commences, we believe the payment rates set forth in § 414.210(g)(10) for the former CBAs will be sufficient, but we will continue to monitor for any issues.

Comment: A few commenters supported the proposal for CBAs and former CBAs (CBAs where no CBP contracts are in effect), in which the fee schedule adjustment rules at § 414.210(g)(10) would be extended until a future round of the CBP.

Response: We thank the commenters for their support of our proposal.

Comment: A couple of commenters requested that given concerns and uncertainty caused by the COVID–19 pandemic, CMS should postpone the implementation of the fee schedule adjustment methodologies in non-CBAs for the orthotics, back and knee braces included in Round 2021 of the CBP. The commenters stated that they should be paid at the unadjusted fee schedule amount for furnishing such items outside of CBAs. The commenters stated there are significant differences between the provision of DME and O&P care in urban/suburban areas and the rural or non-contiguous areas that make up the majority of non-CBAs. For instance, a commenter discussed how Medicare beneficiaries in rural areas are geographically dispersed, hard to reach, and do not have the same access to systems of care available in more populated areas. The commenter stated that tough terrain, long distances between patients and providers/suppliers, and fewer health care resources mean that DME suppliers must incur added costs to deliver the appropriate medical equipment and supplies to patients on a timely basis. The commenter stated this translates into added costs for transportation, delivery and clinical staff, fuel, and other expenses.

Response: We have been closely monitoring the implementation of Round 2021 of the CBP, and have not detected any issues with the fee schedule adjustments for OTS back and knee braces. In the non-CBAs, the assignment rates for the back and knee braces included in Round 2021 of the CBP are over 99 percent. We also believe that continuing to pay for those orthotic codes at the unadjusted fee schedule amount would be fiscally imprudent as that would mean continuing to pay at rates the HHS Office of Inspector General has previously found to be grossly excessive.[14] MedPAC noted in its comments on the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57035) that, ''Expanding CBP into new product categories, such as orthotics, would produce substantial savings and help

[14] *https://oig.hhs.gov/oas/reports/region5/51700033.pdf.*

prevent fraud and abuse.'' [15] MedPAC, when discussing the history of DMEPOS payment methods, has also noted that excessively high payment rates increased expenditures and likely encouraged inappropriate utilization.[16] This is of particular relevance because of recent past instances of fraud involving orthotic braces.[17] [18]

We believe fee schedule adjustments for these items and services are appropriate, and we would like to note that such adjustments are mandated by section 1834(a)(1)(F) of the Act. We will continue to monitor for any issues.

Comment: A commenter stated there were flaws in the data CMS presented, such as not having a control group to see if data like ER admission rates are relative to DMEPOS changes or other trends like pressure on hospitals from CMS to decrease readmissions or face penalties.

Response: We believe our health outcomes monitoring data are robust and a valuable tool. We compare historical health outcomes data between CBAs, non-rural non-CBAs, and rural CBAs in the same BEA region. Thus, we do see if health outcomes changes are unique to certain BEA regions or areas within those regions, and if they track with other BEA regions or other areas within the same BEA region. We also compare historical health outcomes data for non-contiguous non-CBAs and non-contiguous CBAs.

As we indicated in the November 2020 proposed rule, we monitor mortality rates, hospitalization rates, ER visit rates, SNF admission rates, physician visit rates, monthly days in hospital, and monthly days in SNF (85 FR 70368). Except for death information, which comes from the Medicare Enrollment Database, all other outcomes are derived from claims (inpatient, outpatient, Part B carrier, and SNF). Our monitoring materials cover historical and regional trends in these health outcome rates across a number of populations, allowing us to observe deviations that require further drilldown analyses. We monitor health outcomes in the enrolled Medicare population (Medicare Parts A and B), dual Medicare and Medicaid population, long-term institutionalized population, as well as various DME utilizers and access groups. This helps paint a complete picture of whether an increase in an outcome is across the board (not linked to DME access), or is unique to certain populations. Specifically, we focus on any increases that are unique to the DME access groups, which include beneficiaries who are likely to use certain DME based on their diagnoses, and we would conduct drilldown analyses and policy research to pinpoint potential reasons for such increases.

Additionally, our health outcomes monitoring data is but one piece of multiple sources of data that we use to analyze the effects of the fee schedule adjustments. We also analyze assignment rates, total services, total services by supplier, travel distance, and other data to provide a more complete picture on the effects of the fee schedule adjustments.

Comment: A commenter discussed the assignment rate data that continues to be above 99 percent in non-CBAs, saying the increase in assignment rate over time does not surprise them, as the commenter, a DME supplier, says customers choose to pay cash for common affordable items, such as walkers, instead of pursuing a prescription or documentation as it is not worth the time and hassle. The commenter stated that if a beneficiary sees a doctor for a walker, in order for the beneficiary to get reimbursed for the walker, the beneficiary will likely have to schedule another visit for the more major health issues they are experiencing, as the commenter stated most doctors now only address one issue at a time, and that this will never be measured in the CMS data.

Response: Although there could be a situation in which a beneficiary elects to pay cash for some DME items, we do not believe this explains the consistently high assignment rates across different parts of the country for prolonged periods of time. High assignment rates preceded the fee schedule adjustments, and high assignment rates have continued even after the fee schedule adjustments have been in effect for the last several years. We believe the high assignment rates are an indication that the payment rates are sufficient and that assignment rates are a valuable tool in monitoring the effects of the fee schedule adjustments.

Comment: Commenters shared their concerns in regards to beneficiary complaints and patient choice of equipment. Specifically, a commenter stated its hypothesis that beneficiary complaints to CMS have decreased because beneficiaries have become resigned to accept low quality products because the commenter, a DME supplier, has told beneficiaries they cannot afford to buy the name brand products at the rates Medicare pays. The commenter also stated that spending an hour navigating through call centers to complain about the big national and regional chains where they are being consolidated is fruitless. Additionally, the commenter stated that complaining to CMS is fruitless if the beneficiary does not like the one option offered by a supplier accepting assignment, and that beneficiaries accept what they can get and if it does not work they come back and buy the nice piece of equipment out of pocket. The commenter also stated that suppliers will continue to consolidate, and that beneficiaries will continue to have fewer options not just in terms of suppliers, but in DMEPOS products. Another commenter expressed concern that suppliers have stopped carrying specific items for which Medicare payments are too low, and stated that they have seen many essential items such as heavy-duty walkers are not well reimbursed and thus it is harder to find a DME supplier that carries one and will sell to Medicare patients.

Response: We recognize the value of and encourage beneficiaries to communicate any complaints about their DME to Medicare. More information on filing a complaint about DME can be found here: *https://www.medicare.gov/claims-appeals/file-a-complaint-grievance/complaints-about-durable-medical-equipment-dme.*

With regard to patient choice and suppliers supplying specific equipment, we believe the situations the commenters describe underscore one of the many benefits of the DMEPOS CBP. We also believe that expanding the CBP into additional areas of the country would provide these benefits to more beneficiaries and could work towards addressing some of the concerns the commenters have expressed.

The Medicare Learning Network Fact Sheet MLN900927 titled, ''DMEPOS Competitive Bidding Program Referral Agents'' discusses some of these benefits that are relevant to those situations the commenters describe.[19]

In particular, and as discussed in MLN900927, the CBP includes a beneficiary safeguard to ensure that beneficiaries have access to specific

[15] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.*

[16] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_medpacreporttocongress_rev_nov2019_note_sec.pdf.*

[17] *https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.*

[18] *https://www.justice.gov/opa/pr/five-individuals-charged-roles-65-million-nationwide-conspiracy-defraud-federal-health-care.*

[19] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DME_Ref_Agt_Factsheet_ICN900927.pdf.*

brands when needed to avoid an adverse medical outcome. This safeguard, which is sometimes called the Physician Authorization Process, allows a physician (including a podiatric physician) or treating practitioner (that is, a physician assistant, clinical nurse specialist, or nurse practitioner) to prescribe a specific brand or mode of delivery to avoid an adverse medical outcome. The physician or treating practitioner must document in the beneficiary's medical record the reason why the specific brand is necessary to avoid an adverse medical outcome. This documentation, which would be in the physician's order and notes, must include all of the following:

- The product's brand name.
- The features that this product has versus other brand name products.
- An explanation of how these features are necessary to avoid an adverse medical outcome.

If a physician or treating practitioner prescribes a particular brand for a beneficiary to avoid an adverse medical outcome, the contract supplier must, as a term of its contract, ensure that the beneficiary receives the needed item. The contract supplier has three options:

- The contract supplier can furnish the specific brand as prescribed.
- The contract supplier can consult with the physician or treating practitioner to find another appropriate brand of item for the beneficiary and obtain a revised written prescription.
- The contract supplier can assist the beneficiary in locating a contract supplier that will furnish the particular brand of item prescribed by the physician or treating practitioner.

If the contract supplier cannot furnish the specific brand and cannot obtain a revised prescription or locate another contract supplier that will furnish the needed item, the contract supplier must furnish the item as prescribed. We discuss this particular issue further in the final rule we published in the **Federal Register** on April 10, 2007 titled ''Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues'' (72 FR 18064).

A contract supplier is prohibited from submitting a claim to Medicare if it provides an item other than that specified in the written prescription. Any change in the prescription requires a revised written prescription. In addition, contract suppliers are required to accept assignment for items they furnish to Medicare beneficiaries.

Comment: A commenter questioned why the total number of DMEPOS services had been increasing from 2016 to 2018 despite a decline in enrolled beneficiaries. The commenter posited several theories for this increase, including the notion that it is because items supplied have decreased in quality and require more frequent replacement, the surviving regional and national suppliers know that they can only be profitable when ''up-selling'' customers to accept all eligible accessories and supplies when dispensing, that technology advances have allowed for an increase in resupply rates, and that there is rampant fraud resulting in billions of dollars of claims. Finally, the commenter questioned whether the numbers would look different if all the fraud-related items and suppliers were not in this data.

Response: We have been monitoring claims and health outcomes data such as deaths, emergency room visits, physician office visits, hospital and nursing home admissions and lengths of stay, etc., very closely since the fee schedule adjustments were implemented in 2016 and have not seen any signs that health outcomes have been negatively affected by the fee schedule adjustments. Overall, health outcomes have remained the same or have improved since 2016, and this is an indication that there has not been a decrease in the quality of DMEPOS items and services furnished. Although we know that a certain percentage of Medicare claims for DMEPOS items and services are fraudulent, we do not currently have data to determine whether fee schedule adjustments have had any impact on the number of fraudulent claims furnished for DMEPOS items and services.

In the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 57032), we discussed utilization trends in the non-CBAs for the 2016 to 2018 time period. In particular, we noted that while utilization of DME varied throughout area and by particular item, the number of total services increased from 2016 to 2017 (2.05 percent), and from 2017 to 2018 (3.08 percent) when looking at the number of total services furnished through week 34 of the respective year. We noted that there had been a persistent increase in total volume of services furnished in non-CBAs from 2016 to 2018, and that this was driven by an increase in CPAP/RADs. All other products exhibited either a continuous decline from 2016 through 2018, or at least a decline from 2017 to 2018.

When looking at updated data from 2019 to 2020 and 2020 to 2021 (using data through the same week in the respective year—week 42—to understand the impact of the fee schedule adjustment while accounting for claim delay), the total number of claim lines for all items and services subject to fee schedule adjustments in the non-CBAs slightly decreased, and we believe COVID–19 likely played a role in this decrease. For instance, researchers have documented that in 2020 there was a decrease in health care utilization as a result of the COVID–19 pandemic.[20] [21]

From 2019 to 2020, the only product categories that experienced an increase in total number of claim lines were CPAP device and supplies, infusion pump and supplies, and insulin infusion pump and supplies. For example, for CPAP device and supplies, the total number of claim lines increased by 3.43 percent from 2019 to 2020 (when using data through week 42 of the respective year). From 2020 to 2021, only the transcutaneous electrical nerve stimulation (TENS) product category experienced an increase in total number of claim lines with a 0.78 percent increase.

Comment: Commenters provided insights into our travel distance analysis. Specifically, a commenter stated that the travel distance analysis CMS presented in the November 2020 proposed rule, which presented the average number of miles between suppliers and beneficiaries, does not accurately reflect their business network, nor service and clinical support infrastructure. For instance, the commenter stated that while their patients do receive services directly to their home, the majority of services are delivered to the hospital or outpatient setting at the time of discharge. The commenter stated they also maintain distribution centers to allow shipment of ongoing supplies as needed, and that often their central distribution warehouses are used to ship on behalf of the service billing locations. Another commenter stated that average travel distance to furnish items and services to beneficiaries in 2017 was far greater outside of CBAs than in CBAs.

Response: We appreciate learning about the nature of the commenter's business network and how it effects their travel distance for furnishing services to beneficiaries. Section 16008 of the Cures Act requires us to conduct a comparison of several factors with respect to non-CBAs and CBAs, and one of those factors is the average travel distance and cost associated with

[20] *https://www.healthsystemtracker.org/chart-collection/how-have-healthcare-utilization-and-spending-changed-so-far-during-the-coronavirus-pandemic/#item-covidcostsuse_marchupdate_4.*

[21] *https://aspe.hhs.gov/pdf-report/Medicare-FFS-Spending-Utilization.*

furnishing items and services in the area. The kind of travel that the commenter experiences may be true for their particular company. However, past stakeholder input from the DME industry has often focused on the travel distances DME suppliers travel to reach beneficiaries' homes, particularly in rural areas. As such, that is why we decided to focus on the travel distance between the beneficiary's residential ZIP code and the supplier's ZIP code. With regard to the commenter saying that the average travel distance to furnish items and services to beneficiaries in 2017 was far greater outside of CBAs than in CBAs, our data does not show that to be the case, unless looking at specific types of areas. As we found in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34367 through 34371) and in the November 2020 proposed rule (85 FR 70366), travel distances were only greater in certain non-CBAs, which included Frontier and Remote (FAR), OCBSAs, and Super Rural areas.

D. Alternatives Considered but Not Proposed

We considered, but did not propose, three alternatives to our provisions and we sought comments on these alternatives:

1. Adjust Fee Schedule Amounts for Super Rural Areas and Non-Contiguous Areas Based on 120 Percent of the Fee Schedule Amounts for Non-Rural Areas

Under the first alternative, we considered prior suggestions from stakeholders to use the ambulance fee schedule concept of a ''super rural area'' when determining fee schedule adjustments for non-CBAs (85 FR 70371). Specifically, we considered the provision to eliminate the definition of rural area at § 414.202 and 42 CFR 414.210(g)(1)(v), which brings the adjusted fee schedule amounts for rural areas up to 110 percent of the national average price determined under § 414.210(g)(1)(ii). In place of this definition and rule, we considered the provision for an adjustment to the fee schedule amounts for DMEPOS items and services furnished in super rural non-CBAs within the contiguous U.S. equal to 120 percent of the adjusted fee schedule amounts determined for other, non-rural non-CBAs within the same State. For example, the adjusted fee schedule amount for super rural, non-CBAs within Minnesota would be based on 120 percent of the adjusted fee schedule amount (in this case, the regional price) for Minnesota established in accordance with § 414.210(g)(1)(i) through (iv). Consistent with the ambulance fee schedule rural adjustment factor at § 414.610(c)(5)(ii), we considered defining ''super rural'' as a rural area determined to be in the lowest 25 percent of rural population arrayed by population density, where a rural area is defined as an area located outside an urban area (MSA), or a rural census tract within an MSA as determined under the most recent version of the Goldsmith modification as determined by the Federal Office of Rural Health Policy at the Health Resources and Services Administration. Per this definition and under this alternative rule, certain areas within MSAs would be considered super rural areas whereas now they are treated as non-rural areas because they are located in counties that are included in MSAs. For all other non-CBAs, including areas within the contiguous U.S. that are outside MSAs but do not meet the definition of super rural area, we considered adjusting the fee schedule amounts using the current fee schedule adjustment methodologies under § 414.210(g)(1) and § 414.210(g)(3) through (8).

In addition to addressing past stakeholder input, this alternative approach would provide a payment increase that is somewhat higher than, but similar to the 17 percent payment differential identified by stakeholders in 2015 based on a survey of respiratory equipment suppliers.[22] In addition, we have received input from suppliers that serve low population density areas within MSAs that are not CBAs. These stakeholders claim that they are serving low population density areas that are not near to or served by suppliers located in the urban core areas of the MSA and believe they must receive higher payments than suppliers serving the higher population density areas of the MSA. Under the alternative fee schedule adjustment methodology, if these low population density areas were to meet the definition of super rural area, they would receive a 20 percent higher payment than areas that are not super rural areas. This alternative payment rule would address these concerns with how the current payment rules and definition of rural area affect these areas, and would target payments for those rural areas that are low population density areas, regardless of whether they are located in an MSA or not. This approach would also address concerns raised from stakeholders on the March 23, 2017 call regarding the cost of traveling long distances to serve far away, remote areas.

Under this alternative, § 414.210(g)(2), which addresses fee schedule adjustments for DMEPOS items and services furnished in non-contiguous areas, would be replaced with a new rule that adjusts the fee schedule amounts for non-contiguous areas based on the higher of 120 percent of the average of the SPAs for the item or service in CBAs outside the contiguous U.S. (currently only Honolulu, Hawaii), or the national average price determined under § 414.210(g)(1)(ii).

Comment: A couple commenters stated that while they did not support the alternative of adjusting the fee schedule amounts for super rural and non-contiguous areas based on 120 percent of the fee schedule amounts for non-rural areas, they recommend eliminating the fee schedule amounts for rural areas up to 110 percent of the national average price determined under § 414.210(g)(1)(ii)) and maintaining the 50/50 blend, but replacing the current rural definition (and corresponding ZIP codes) by including the ''super rural'' ZIP codes within the current array of rural ZIP codes. The commenters stated that because certain areas within MSAs are treated as non-rural areas, as they are located in counties that are included in MSAs, the commenters were concerned that the current array of suppliers in higher populated urban areas that are currently serving these rural areas within an MSA may abandon these areas if they are less profitable.

Response: Although we are not finalizing this particular alternative that we considered, we acknowledge the commenters' recommendations regarding this particular alternative and we will keep these points in mind for future consideration.

Comment: A commenter stated it would not be appropriate to adjust the fee schedule amounts relying on the geographic designations used in the Ambulance Fee Schedule, or suggested rates based on industry data from 2015. The commenter stated many things have changed since 2015 that have affected the costs of furnishing items and services, including the COVID–19 pandemic and the increased costs of personal protective equipment (PPE), supply shortages, and personnel costs. The commenter also stated that the Census Bureau has shifted to a sampling methodology that impacts the RUCAs, which has changed the way the ZIP code designations are calculated under the Ambulance Fee Schedule, and that they were concerned that these changes have led super-rural areas and rural areas being designated as urban. The

[22] *https://www.cqrc.org/img/CQRCCostSurveyWhitePaperMay2015Final.pdf.*

commenter stated that before this methodology is applied to any other part of Medicare, CMS must work to address the underlying problems these changes have created.

Response: We are not finalizing this particular alternative and will keep these points in mind for future consideration.

After consideration of the public comments we received, we are not finalizing this alternative considered.

2. Establish Additional Phase-in Period for Fully Adjusted Fee Schedule Amounts for Rural Areas and Non-Contiguous Areas

We considered proposing an alternative fee schedule adjustment methodology that would establish an additional transition period to allow us to determine the impact of the new SPAs and monitor the impact of adjusted fee schedule amounts (85 FR70372). Under this alternative, we considered adjusting the fee schedule amounts for items and services furnished in rural areas and non-contiguous non-CBAs based on a 75/25 blend of adjusted and unadjusted rates for the 3-year period from April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, through December 31, 2023. Such a phase-in would bring the fee schedule payment amounts down closer to the fully adjusted fee levels and allow for a 3-year period to monitor the impact of the lower rates on access to items and services in these areas before potentially phasing in the fully adjusted rates in 2024.

Comment: A commenter stated they favor the permanent extension of the current rural and non-rural non-CBA blended rates instead of the alternative phase-in of the fully adjusted fee schedule amounts discussed in the November 2020 proposed rule, as it is important for patients and suppliers to have stable rates, in their view.

Response: We did not propose to extend the 75/25 blended rates in the non-rural contiguous non-CBAs once the PHE ends. We did, however, propose a fee schedule adjustment methodology under § 414.210(g)(1) for the non-rural contiguous non-CBAs that is not time-limited, transitional, or dependent upon the next round of the CBP. We agree with the commenter that it is important to provide patients and suppliers with stable rates to the extent feasible. Of note, the fully adjusted rates had been in continuous effect in the non-rural contiguous non-CBAs from January 2017 through March 5, 2020. During that time period, the rate of assignment for items and services subject to fee schedule adjustments furnished in those areas was over 99 percent. We believe that the fully adjusted rates will be sufficient for when the PHE ends.

After consideration of the public comments we received, we are not finalizing this alternative considered.

3. Extend Current Fee Schedule Adjustments for Items and Services Furnished in Non-CBAs, CBAs, and Former CBAs That Were Included in Product Categories Removed From Round 2021 of the CBP

CMS only awarded Round 2021 CBP contracts to bidders in the OTS back braces and OTS knee braces product categories. CMS did not award Round 2021 CBP contracts to bidders that bid in any other product categories that were included in Round 2021 of the CBP, therefore, CMS does not have any new SPAs for these items and services. As a result, under this alternative, we considered whether to simply extend application of the current fee schedule adjustment rules for all of the items and services that were included in Round 2021 of the CBP but were essentially removed from Round 2021 of the CBP (85 FR 70372). Specifically, for items and services included in product categories that have essentially been removed from Round 2021 of the CBP, CMS considered extending the transition rules at § 414.210(g)(9)(iii) and (v) for items and services furnished in non-CBAs and the fee schedule adjustment rules at § 414.210(g)(10) for items and services furnished in CBAs or former CBAs until such product categories are competitively bid again in a future round of the CBP. Under this alternative, we would adjust the fee schedule amounts for items and services furnished in areas other than rural areas and non-contiguous non-CBAs in accordance with § 414.210(g)(9)(v) based on 100 percent of the adjusted rates beginning on April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, through the date immediately preceding the effective date of the next round of CBP contracts. As previously discussed in this final rule, now that April 1, 2021 has passed, but the public health emergency is still ongoing, and this rule has yet to be finalized, we are making a technical edit to reflect the new effective date for this final rule. The fee schedule amounts for items and services removed from the CBP and furnished in rural and non-contiguous non-CBAs would continue to be adjusted based on a 50/50 blend in accordance with § 414.210(g)(9)(iii) through the date immediately preceding the effective date of the next round of CBP contracts. Under, this alternative, the fee schedule adjustment transition rules under § 414.210(g)(9) would continue in effect through the date immediately preceding the effective date of the next round of CBP contracts. This alternative differs from our proposal and this final rule, as we proposed and are finalizing a fee schedule adjustment methodology for non-CBAs under § 414.210(g)(1) and (g)(2), that is not time-limited, transitional, or dependent upon the next round of the CBP.

For items and services included in product categories that have effectively been removed from Round 2021 of the CBP, the fee schedule amounts for items and services furnished in CBAs or former CBAs would continue to be adjusted in accordance with § 414.210(g)(10) through the date immediately preceding the effective date of the next round of CBP contracts. In contrast, for items and services that are included in Round 2021 of the CBP, the fee schedule amounts for such items and services would be adjusted in accordance with the adjustment methodologies outlined in this final rule; we would pay the 50/50 blended rates in rural and non-contiguous non-CBAs, and 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv) in non-rural non-CBAs in the contiguous U.S.

Comment: Commenters opposed this alternative for the reasons discussed in previous comments in section III.C. of this final rule. Most commenters opposed continuation of the current rates in the former CBAs, supported a permanent extension of the 50/50 blended rates in rural and non-contiguous non-CBAs, and opposed paying 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv) in non-rural non-CBAs in the contiguous U.S. Commenters opposed continuation of the current rates in the former CBAs saying they are based on SPAs established by a flawed bid methodology developed over 6 years ago. Instead, and as previously discussed, many commenters supported a permanent extension of the 50/50 blended rates in rural and non-contiguous non-CBAs, a 75/25 blended rate methodology in the non-rural non-CBAs in the contiguous U.S., and a 90/10 blended rate methodology in the former CBAs in which the 90 percent must be based on the current payment

rates in the former CBAs (including the CPI–U updates) and the 10 percent must be based on the 2015 unadjusted fee schedule. Finally, as previously discussed, a few commenters supported the proposal for CBAs and former CBAs (CBAs where no CBP contracts are in effect), in which the fee schedule adjustment rules at § 414.210(g)(10) would be extended until a future round of the CBP. However, these commenters did not support the non-CBA policies in this alternative considered, and instead supported a permanent extension of the 50/50 blended rates in rural and non-contiguous non-CBAs, and a 75/25 blended rate methodology in the non-rural non-CBAs in the contiguous U.S.

Response: After consideration of the public comments we received, we are not finalizing this alternative considered. As we discuss in section III.E. of this final rule titled ''Provisions of Final Rule'', we will be finalizing our proposals discussed later in this section. We expect to revisit fee schedule adjustments in the future.

E. Provisions of Final Rule

We are finalizing our proposals, with the modification of the effective date, in this final rule. In the November 2020 proposed rule, we proposed the fee schedule adjustment methodologies for items and services furnished in non-CBAs on or after April 1, 2021, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later (85 FR 70370). However, as we previously discussed in this final rule, now that April 1, 2021 has passed, and given that the COVID–19 PHE is still ongoing, we are making a technical edit to change the April 1, 2021 date to the effective date specified in the **DATES** section of this final rule to reflect the new effective date for these provisions. Other than the modification of the April 1, 2021 effective date, we are finalizing our proposals without modification.

First, we will continue paying the 50/50 blended rates in non-contiguous non-CBAs, but the 50/50 blend will no longer be a transition rule under § 414.210(g)(9), and will instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking. For items and services furnished in non-contiguous non-CBAs, the fee schedule amounts for such items and services furnished on or after the effective date specified in the **DATES** section of this final rule, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, will be adjusted so that they are equal to a blend of 50 percent of the greater of the average of the SPAs for the item or service for CBAs located in non-contiguous areas or 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the unadjusted fee schedule amount for the area, which is the fee schedule amount in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

Second, we will continue paying the 50/50 blended rates in rural contiguous areas, but the 50/50 blend will no longer be a transition rule under § 414.210(g)(9), and will instead be the fee schedule adjustment methodology for items and services furnished in these areas under § 414.210(g)(2) unless revised in future rulemaking. For items and services furnished in rural contiguous areas on or after the effective date specified in the **DATES** section of this final rule or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, the fee schedule amounts will be adjusted so that they are equal to a blend of 50 percent of 110 percent of the national average price for the item or service determined under § 414.210(g)(1)(ii) and 50 percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

We note that the 50/50 blended rates for DMEPOS items and services furnished in rural and non-contiguous areas that we are finalizing in this rule are, on average, approximately 66 percent higher than the fully adjusted fee schedule amounts. Previous stakeholder input from MedPAC has indicated that the 50/50 blended rates are ''costly'' and create ''. . . a financial burden for the Medicare program and beneficiaries''. MedPAC has also previously opined on the appropriateness of the unadjusted fee schedule, which comprises 50 percent of the 50/50 blended rates. MedPAC stated, ''products not included in the CBP continue to largely be paid on the basis of the historical fee schedule, and the Commission has found many of these rates are likely excessive.'' [23] In light of this previous stakeholder input from MedPAC, we are concerned that this fee schedule adjustment methodology may result in payment amounts that are excessive compared to the fully adjusted fee schedule amounts. However, as we discussed in the November 2020 proposed rule, this fee schedule adjustment methodology errs on the side of caution, as we aim to ensure beneficiary access to items and services in rural and remote areas of the country. For instance, we proposed paying the 50/50 blend for rural and non-contiguous non-CBAs from January 1, 2019, through December 31, 2020, in our CY 2019 ESRD PPS DMEPOS proposed rule, and we finalized this policy in our CY 2019 ESRD PPS DMEPOS final rule. Most of the comments we received on this proposal were from commenters in the DME industry, such as homecare associations, DME manufacturers, and suppliers, and these commenters generally supported the 50/50 blended rates proposal.

The 50/50 blended rates were initially established for phase in purposes, so we may consider alternative methodologies for adjusting fee schedule amounts for rural and non-contiguous areas in the future. We will be undertaking analyses to assess the extent to which these payments are ''excessive'', as per MedPAC's comment. In addition, we may decide it is necessary to propose changes to the fee schedule adjustment methodologies in the future depending on potential changes to the CBP. Therefore, we will likely be revisiting this issue and the fee schedule adjustment methodologies for all items in all areas again in the future.

Third, we will revise § 414.210(g)(1)(v) to establish that for items and services furnished before the effective date specified in the **DATES** section of this final rule, the fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section. In the November 2020 proposed rule, we proposed to reference April 1, 2021 in the revised § 414.210(g)(1)(v). However, as we previously discussed in this final rule,

[23] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.*

April 1, 2021, has passed and the COVID–19 PHE is still ongoing. Because this rule has yet to be finalized, the regulation text will reference the effective date specified in the **DATES** section of this final rule effective date rather than April 1, 2021.

Fourth, we are finalizing our proposal so that for items and services furnished on or after the effective date specified in the **DATES** section of this document, or the date immediately following the termination of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) (that is, the COVID–19 PHE), whichever is later, in all other non-rural, non-CBAs within the contiguous United States, the fee schedule amounts will be equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1)(iv).

Fifth and finally, we are finalizing our proposal to add paragraph § 414.210(g)(9)(vi) to establish that for items and services furnished in all areas with dates of service on or after the effective date specified in the **DATES** section of this document, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under § 414.210(g).

IV. DMEPOS Fee Schedule Adjustments for Items and Services Furnished in Rural Areas From June 2018 Through December 2018 and Exclusion of Infusion Drugs From the DMEPOS CBP

A. Overview

On May 11, 2018 we published an IFC (83 FR 21912) in the **Federal Register** titled ''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''. In this section of this final rule, we will present the provisions of the May 2018 IFC followed by summation of the comments received and our responses.

Section 5004(b) of the Cures Act amended section 1847(a)(2)(A) of Act to exclude drugs and biologicals described in section 1842(o)(1)(D) of the Act from the DMEPOS CBP. In the May 2018 IFC, we made 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.

As discussed in section II. of this rule, in the May 2018 IFC, we also expressed an immediate need to resume the transitional, blended fee schedule amounts in rural and non-contiguous areas, noting strong stakeholder concerns about the continued viability of many DMEPOS suppliers, our finding of a decrease in the number of suppliers furnishing items and services subject to the fee schedule adjustments, as well as the Cures Act mandate to consider additional information material to setting fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished on or after January 1, 2019 (83 FR 21918). We amended § 414.210(g)(9) by adding § 414.210(g)(9)(iii) 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. We also amended § 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, fully adjusted fee schedule amounts would apply (83 FR 21922). We also added § 414.210(g)(9)(iv) to specify that fully adjusted fee schedule amounts would apply for certain items furnished in non-CBAs other than rural and non-contiguous areas from June 1, 2018 through December 31, 2018 (83 FR 21920). We explained that we would use the extended transition period to further analyze our findings and consider 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 were necessary (83 FR 21918 through 21919). We respond to the comments we received on these issues later in this final rule.

B. Background

1. Background for Payment Revisions for DMEPOS

For further background regarding the DMEPOS CBP, payment methodology for CBAs, and the fee schedule adjustment methodology for non-CBAs, we refer readers to section III.A. of this final rule.

On February 26, 2014, we published an Advance Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** titled, ''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 State government offices. Commenters generally stated that costs 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. A 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** titled ''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 is described in section III.A. of this final rule.

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 (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 a 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 recompeted. 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).

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

We 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 to ensure access to necessary items and services in these areas. The May 2018 IFC amended § 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. The May 2018 IFC also amended § 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 final rule.

a. 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 must: (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.[24] 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 industry stakeholders expressed concerns that the level of the adjusted payment amounts constrained suppliers from furnishing items and services to rural areas. These 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 commenters claimed that the adjusted fees were not sufficient to cover the costs of furnishing items and services in rural and non-contiguous areas and that it was having an impact on access to items and services in these areas. For additional details about the national provider call and a summary of oral and written comments received, we refer readers to the CY 2019 ESRD PPS/DMEPOS proposed rule (83 FR 57026).

In the May 2018 IFC, we stated that 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

[24] *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-03-23-DMEPOS.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.*

services furnished by suppliers in an area (83 FR 21917). We then noted that data for items furnished in 2016 and 2017 showed that the average volume of items furnished by suppliers in CBAs exceeded the average volume of items furnished by suppliers in rural and non-contiguous areas. We stated that 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 (83 FR 21917).

In addition, at the time of this May 2018 IFC, the adjusted fee schedule amounts for stationary oxygen equipment in non-contiguous, non-CBAs were 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 were lower than the SPAs in CBAs within the same State. This was due to the combination of the fee schedule adjustments and the budget neutrality offset that CMS applied 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 is located at section 1834(a)(9)(D) of the Act, and at the time of the May 2018 IFC, section 1834(a)(9)(D) of the Act only allowed CMS to establish new classes of oxygen and oxygen equipment if such classes were budget neutral, which meant that the establishment of new oxygen payment classes did not result in oxygen and oxygen equipment expenditures for any year that were more or less than the expenditures that would have been made had the new classes not been established. We also stated that in the May 2018 IFC that accordance with § 414.226(c)(6), CMS reduced the fee schedule amounts for stationary oxygen equipment in non-CBAs to make the payment classes for oxygen and oxygen equipment budget neutral as required by section 1834(a)(9)(D) of the Act (83 FR 21917). 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 were lower than the SPAs in Honolulu, Hawaii, and CBAs within the same State, respectively. We stated that this was significant because the methodology at 42 CFR 414.210(g) attempted to ensure that the adjusted fee schedule amounts for items and services furnished in rural areas within a State were no lower than the adjusted fee schedule amounts for non-rural areas within the same State. We then noted that 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, and that CBAs tend to have higher population densities and typically correspond with urban census tracts (83 FR 21917).

We explained that the budget neutrality offset resulted in payment amounts for stationary oxygen equipment in CBAs being higher than the adjusted fee schedule amounts in some cases. We stated that 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, we stated payment at the blended rates would avoid situations where payment for furnishing oxygen in a rural or non-contiguous, non-CBA was lower than payment for furnishing oxygen in a CBA (83 FR 21917). The May 2018 IFC also contained provisions related to wheelchair payment. For further discussion of the wheelchair payment provisions that were included in the May 2018 IFC, see the final rule titled: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program; Payment for Complex Rehabilitative Wheelchairs and Related Accessories (Including Seating Systems) and Seat and Back Cushions Furnished in Connection With Such Wheelchairs, published on August 4, 2021 (86 FR 42362).

Since the publication of the May 2018 IFC, the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) was signed into law on December 27, 2020. Effective April 1, 2021, section 121 of this Act eliminated the budget neutrality requirement set forth in section 1834(a)(9)(D)(ii) of the Act for separate classes and national limited monthly payment rates established for any item of oxygen and oxygen equipment using the authority in section 1834(a)(9)(D)(i) of the Act. Effective for claims with dates of service on or after April 1, 2021, the fee schedule amounts for HCPCS codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444, E0447, E1390, E1391, E1392, E1405, E1406, and K0738 are adjusted to remove a percentage reduction necessary to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Act.

b. Fee Schedule Adjustment Impact Monitoring Data

We also discussed in the May 2018 IFC how we monitor claims data from non-CBAs, some of which at the time pre-dated the implementation of the fully adjusted fee schedule amounts (83 FR 21917). The data did 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. We have continued to monitor claims data from non-CBAs and have not observed any trends indicating an increase in adverse beneficiary health outcomes associated with the fee schedule adjustments.

In addition, we monitored and continue to monitor 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. Before and after the publication of the May 2018 IFC, assignment rates for items subject to fee schedule adjustments have continued to remain around 99 percent. We also solicited comments on ways to improve our fee schedule adjustment impact monitoring data in the May 2018 IFC.

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

We stated that the monitoring data described in section II.C.2. of the May 2018 IFC was retrospective claims data for payment of items already furnished, and that it was limited to a retrospective view to address potential future problems (83 FR 21918).

We also provided Medicare claims data showing that the number of supplier locations furnishing DME items and services subject to the fee schedule adjustments decreased by 22 percent from 2013 to 2016 (83 FR 21918).

We stated there were 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. For instance, we stated 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, we stated that the number of suppliers in general has been steadily decreasing over time, and as the number of suppliers serving non-CBAs continues to decline, the volume of items and services furnished by the remaining suppliers increases (83 FR 21918). At the time of the publication of the May 2018 IFC, we did not know if the suppliers that remained would have the financial ability to continue expanding their businesses to continue to satisfy market demand. We also did not know if large suppliers serving both urban and rural areas would continue to serve the rural areas representing a much smaller percentage of their business than urban areas (83 FR 21918).

Based on the stakeholder comments and decrease in the number of supplier locations, we stated there was an immediate need to resume the transitional, blended fee schedule amounts in rural and non-contiguous areas. We stated that resuming these transitional blended rates would 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 (83 FR 21918).

We stated that 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 (83 FR 21918). Industry stakeholders stated that the fully adjusted fee schedule amounts were 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 continued to decline. We stated that 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 collected at the time included input from many stakeholders in the DMEPOS industry indicating that the fully adjusted fee schedule amounts were too low and that this was having an adverse impact on beneficiary access to items and services, particularly in rural and non-contiguous areas. Given these concerns about the continued viability of many DMEPOS suppliers, coupled with the Cures Act mandate to consider additional information material to setting fee schedule adjustments, we stated it would be unwise to continue with the fully adjusted fee schedule rates in the rural and non-contiguous areas for 7 months. We stated that any adverse impacts on beneficiary health outcomes, or on small businesses exiting the market, could be irreversible. We stated that it was 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. We stated that while our systematic monitoring in these areas has not shown problematic trends to this point, that monitoring by its nature looks backward. We stated that given the rapid changes in health care delivery that may disproportionately impact rural and more isolated geographic areas, there was concern that the continued decline of the fees and the number of suppliers in such areas may impact beneficiary access to items and services. We stated that 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. Therefore, we revised § 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 analyzed this issue (83 FR 21918).

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

Another provision in the May 2018 IFC that we are finalizing in this final rule relates to section 5004(b) of the Cures Act, which amended 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 made conforming technical changes to the regulations text consistent with statutory requirements to exclude drugs and biologicals from the CBP (83 FR 21920). We amended 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 reads as follows: ''Supplies necessary for the effective use of DME other than inhalation and infusion drugs.''

We also removed a reference to drugs being included in the CBP by deleting the phrase ''or subpart I'' in § 414.412(b)(2). The sentence reads 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 made 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 reads 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.''

D. Provisions of the May 11, 2018 Interim Final Rule With Comment Period

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

We amended § 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 also amended § 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 also added § 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 added § 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.

We discussed in section II.C.1. of the May 2018 IFC that industry stakeholders stated that the fully adjusted fee schedule amounts were not sufficient to cover supplier costs for furnishing items and services in rural and non-contiguous areas and were impacting beneficiary health outcomes (83 FR 21918). 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. We stated that 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 analyzed this issue to safeguard beneficiaries' access to necessary items and services in rural and non-contiguous areas. We stated that additional information and factors would 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 associated with furnishing items in heavier populated CBAs versus less populated or remote rural and non-contiguous areas (83 FR 21920). Even though January 1, 2019 was just 7 months away from the June 1, 2018, effective date of this May 2018 IFC, we believed that it would be unwise to continue with the fully adjusted fee schedule rates in the rural and non-contiguous areas for 7 months. Therefore, we concluded that we should resume the transition period's blended fee schedule rates for items furnished in rural areas and non-contiguous areas not subject to the CBP from June 1, 2018, through December 31, 2018. We stated that the volume of items furnished per supplier in rural and non-contiguous areas was 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 (83 FR 21920). We also expressed concern 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 (83 FR 21920).

We received a total of 208 timely pieces of correspondence in response to the May 2018 IFC. Many of the comments we received on the May 2018 IFC were similar to or the same as comments we received on the CY 2019 ESRD PPS DMEPOS proposed rule and which we summarized and responded to in the CY 2019 ESRD PPS DMEPOS final rule (83 FR 56922). Most of the commenters were DME suppliers.

Comment: Most commenters supported extending the 50/50 blended rates to the rural and non-contiguous non-CBAs. Some reasons that commenters gave for why they supported this policy were that it would help suppliers stay in business and service rural patients. Commenters also discussed how rural areas face unique circumstances. For example, a commenter stated many of their patients are in islands in remote areas, and another commenter discussed the challenges they face when servicing Native American reservations, such as power failures, weather changes, longer travel distances, poor cell phone reception, and higher delivery charges. Another commenter stated beneficiaries in rural areas are geographically dispersed, harder to reach, and do not have the same access to systems of care as those in more populated areas. Some commenters who were DME suppliers stated that they have reduced their delivery service area due to not getting paid enough, and that the cost of doing business has increased, which warranted higher payments. Some commenters also stated that costs are higher in rural areas, and travel distances are larger than in urban areas. A commenter stated this policy furthers a goal of achieving rural health equity with healthier, wealthier suburban and urban areas.

Response: We acknowledge the comments for this particular provision in the May 2018 IFC.

Comment: Many commenters wanted CMS to extend the blended rates to all non-CBAs, and to do so for longer than the 7-month period that was established in the May 2018 IFC. Several commenters stated we should extend the blended rates to all non-CBAs in 2019. Some stated we should permanently extend the blended rates to all non-CBAs. As support for this some commenters stated that non-CBAs do not have the same level of volume as CBAs, non-CBAs have a lower population density, less suppliers, the cost of doing business is higher in non-CBAs than it is in CBAs, and that suppliers serving rural areas also serve non-rural areas. A commenter stated that providing the same services in some non-CBAs requires more staff than in CBAs, and that Bureau of Labor Statistics (BLS) data show fuel and health care expenditures are higher in rural areas. Some commenters were concerned that beneficiaries would not get the items or services they need and their health outcomes would worsen as a result.

Response: We continue to believe that the fully adjusted rates in non-rural and contiguous non-CBAs are sufficient. Assignment rates continued to remain above 99 percent after the publication of the May 2018 IFC, and we have not found evidence that these fee schedule adjustments are causing beneficiary access or health outcomes issues. As we indicated in the CY 2019 ESRD PPS DMEPOS final rule (83 FR 56922), we agree that the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, and that total population and population density are both lower in non-rural non-CBAs than in CBAs. However, volume of services furnished is only one factor impacting the cost of furnishing DMEPOS items and services. A number of other factors affecting the costs of furnishing DMEPOS items and services such as wages, gasoline, rent, utilities, travel distance and service area size point to higher costs in CBAs than non-rural non-CBAs. Additionally, as we found in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34367 through 34371) and in the November 2020 proposed rule (85 FR 70366), travel distances were only greater in certain non-CBAs, which included Frontier and Remote (FAR), OCBSAs, and Super Rural areas.

Comment: Many commenters also wanted us to retroactively apply the blended rates to all the claims in 2017 and 2018 that we paid at the fully adjusted rate. Commenters stated that if we were concerned about the adequacy of the fully adjusted fees, then we should retroactively pay suppliers the blended rates for the time we paid them the fully adjusted rates. Commenters explained that 7 months of blended rates were not enough to stabilize an industry with a declining number of suppliers, and that paying the blended rates retroactively would also help ensure beneficiary access to DME.

Response: In the May 2018 IFC we amended § 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, as required by section 16007(a) of the Cures Act. In the May 2018 IFC, we also continued the 50/50 blend for rural, non-contiguous areas from June 1 through December 31, 2018. We did not believe it was appropriate or necessary to retroactively increase the rates paid for items and

services subject to the fee schedule adjustments that were furnished in 2017. Retroactively increasing payment amounts for items and services that had already been furnished to beneficiaries would not result in an increase in access to such items and services.

Comment: Some commenters stated CMS should adopt add-on payments for non-CBAs because of higher costs in non-CBAs. For instance, a commenter stated that CMS should establish two percentage add-ons for the non-CBA areas: One for the non-rural non-CBAs and one for the rural non-CBAs. The commenter stated that the costs of providing respiratory services can be higher than the costs for other products and they recommended setting the non-rural non-CBAs at the regional standard payment amount (SPA) + 16 percent, and the rural non-CBAs at the regional SPA + 22 percent. The commenter stated that they based these amounts on their own cost survey of oxygen and sleep therapy providers and manufacturing companies that showed costs were 5 percent higher than the SPAs in CBAs, that costs are 13 percent higher in non-CBAs than in CBAs, and 17.5 percent higher in super-rural areas than in CBAs. Some commenters used the Ambulance Fee Schedule as an example of an add-on policy CMS could use, which includes super-rural add-on payment. A commenter stated that CMS should set the 50/50 blend rates in all non-CBAs, and then pay an even higher amount of 10 percent in rural and non-contiguous areas. The commenter also stated that the most significant variables that affect DME supplier costs are labor rates, transportation, population density, miles/time between points of service, and regulatory costs. The commenter stated specific costs that CMS should take into account when adjusting fees in non-CBAs include geographic wage index factors, gas, taxes, employee wages and benefits, wear and tear of vehicles, average per capita income, training, delivery, set up, historical Medicare home placement volume, proximity to nearby CBAs, employing a respiratory therapist (required by State law in several States), electricity charges freight charges, 24/7 service availability, documentation requirements, average per patient cost, licensing, accreditation surety bonds, audits, population density, miles and time between points of service, local and state regulatory costs, and vehicle insurance and liability insurance. Another commenter stated how CMS uses a special rule for rural areas for items included in more than 10 CBAs. The commenter stated CMS could supplement this special rule by making it more generous, and also applying the national ceiling prices in areas with a limited number of suppliers or low average volume of Medicare business. The commenter stated CMS could also establish an add-on payment for low volume or low supplier areas, based on its general approach used for rural areas in the ambulance fee schedule, which would involve increasing the base payment by a percentage amount. A commenter stated the 50/50 blended rates were not enough and that CMS should return to paying the 2015 unadjusted fee schedule rates in all non-CBAs.

Response: We did not implement any of the add-on payments described by the commenters in the May 2018 IFC, and did not discuss such policies in the Alternatives Considered section of the May 2018 IFC (83 FR 21924). In the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57034), in response to similar comments requesting such add-on payments, we thanked the commenters for their specific recommendations regarding adopting add-on payments for items and services furnished in non-CBAs. We also stated that we did not propose any payments like those described by commenters, but that we would keep these recommendations in mind for future rulemaking.

In the November 2020 proposed rule, one of our Alternatives Considered (85 FR 70371) was proposing to eliminate the definition of rural area at §§ 414.202 and 414.210(g)(1)(v), which brings the adjusted fee schedule amounts for rural areas up to 110 percent of the national average price determined under § 414.210(g)(1)(ii). In place of this definition and rule, we considered proposing an adjustment to the fee schedule amounts for DMEPOS items and services furnished in super rural non-CBAs within the contiguous U.S. equal to 120 percent of the adjusted fee schedule amounts determined for other, non-rural non-CBAs within the same State. For example, the adjusted fee schedule amount for super rural, non-CBAs within Minnesota would be based on 120 percent of the adjusted fee schedule amount (in this case, the regional price) for Minnesota established in accordance with § 414.210(g)(1)(i) through (iv).

Consistent with the ambulance fee schedule rural adjustment factor at § 414.610(c)(5)(ii), we considered defining ''super rural'' as a rural area determined to be in the lowest 25 percent of rural population arrayed by population density, where a rural area is defined as an area located outside an urban area (MSA), or a rural census tract within an MSA as determined under the most recent version of the Goldsmith modification as determined by the Federal Office of Rural Health Policy at the Health Resources and Services Administration. Per this definition and under this alternative rule, certain areas within MSAs would be considered super rural areas whereas now they are treated as non-rural areas because they are located in counties that are included in MSAs. For all other non-CBAs, including areas within the contiguous U.S. that are outside MSAs but do not meet the definition of super rural area, we considered adjusting the fee schedule amounts using the current fee schedule adjustment methodologies under § 414.210(g)(1) and (g)(3) through (8).

We did not receive comments supporting finalizing this alternative, and we did not finalize this alternative considered in this final rule.

Finally, as we stated in the CY 2019 ESRD PPS DMEPOS final rule (83 FR 57034), we recognize that there are certain supplier cost and volume differences in rural and non-contiguous non-CBAs, which is why this final rule distinguishes rural and non-contiguous non-CBAs from other non-CBAs and results in higher payments to suppliers furnishing items in the rural and non-contiguous non-CBAs. We also believe that paying an amount in addition to the blended 50/50 payment rates would be excessive and unnecessary, and not in line with what most commenters requested, as most commenters specifically requested the blended 50/50 payment rates in rural and non-contiguous non-CBAs. This indicates that such payment rates are sufficient, which is why we are also not incorporating the ambulance fee schedule's concept of a super rural add-on into our 50/50 blend. With regard to taking into account certain costs when adjusting fees in non-CBAs, we have already analyzed and taken into account several cost data variables as part of section 16008 of the Cures Act in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 57027), and in the November 2020 proposed rule (85 FR 70367).

Comment: Some commenters disagreed with our definition of rural at § 414.202. Some commenters that were DME suppliers were dissatisfied that some areas that they service did not qualify as a rural area. A few commenters stated CMS should define all non-CBAs as rural. Another commenter stated the CMS definition of a rural area is extremely narrow, and that CMS should adopt, what the commenter referred to as OMB's rural definition, which the commenter stated

were all counties that are not part of an MSA. A commenter wondered why the rural definition at § 414.202 did not match the criteria for a critical access hospital. A commenter stated all of West Virginia should be considered rural, and another commenter stated there were remote areas in West Virginia that were classified as non-rural per the rural definition at § 414.202.

Response: As defined in § 414.202, rural area means, 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 area (MSA). A rural area also includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area in accordance with the authority provided by section 1847(a)(3)(A) of the Act at the time the rules at § 414.210(g) are applied. We did not propose or implement any changes to our rural definition in the May 2018 IFC, but we will keep these points in mind for future rulemaking. For further background on the origin of our rural definition, see our CY 2015 ESRD PPS DMEPOS proposed rule (79 FR 40284) and the CY 2015 ESRD PPS DMEPOS final rule (79 FR 66228).

Comment: MedPAC did not support our proposal extending the 50/50 blended rates to rural non-CBAs. MedPAC stated that if CMS determines that payment rates in non-CBAs should be increased to maintain access to medically necessary DMEPOS products, then increases should be limited and targeted, and CMS should consider taking steps to offset the cost of higher payment rates. MedPAC stated that returning to a 50/50 blend of historical fee schedule rates and competitive bidding program (CBP) derived rates will result in large payment increases, often of 50 percent or more. Further, these large increases are in addition to other payment rate adjustments CMS has already made to protect access, such as an increase of roughly 10 percent in rural non-CBAs.

MedPAC stated that while they understand CMS continues to study supplier costs in non-CBAs in accordance with its mandate under the Cures Act, the interim final rule does not present supplier cost data that could be used to justify the magnitude of the payment increase. MedPAC encouraged CMS to use the best available data to determine whether costs that suppliers must necessarily incur are higher in non-CBAs relative to CBAs and, if so, whether an adjustment smaller than the one discussed in the interim final rule would be sufficient to ensure access.

MedPAC stated any payment increase in non-CBAs should be directed only to products that exhibit signs of potential access problems, and that the cost of DMEPOS products themselves likely do not vary substantially across geographic areas, but other costs might (for example, delivery or personnel costs). Therefore, depending on the nature of the product, MedPAC concluded that the total cost associated with furnishing a product may or may not vary substantially across geographic areas, and the magnitude of that variation might also be different across products.

Additionally, MedPAC stated that any payment increase in non-CBAs should be directed only to areas that exhibit signs of potential access problems. Non-CBAs include a wide variety of areas, ranging from moderate-size urban areas to remote rural areas. An identified potential access problem in a rural or non-contiguous area should not be used as a basis to increase payment rates across all non-CBAs. MedPAC stated issues faced by suppliers in rural and non-contiguous areas are likely different from those faced in urban non-CBAs, many of which are metropolitan statistical areas with populations of 250,000 or more. Furthermore, if CMS has concerns about payment rates in urban non-CBAs, CMS has better ways to establish appropriate payment rates than applying a large, across-the-board payment increase. For example, CMS could set payment rates in moderate-size urban non-CBAs by expanding the CBP to include those areas and use the information from those competitions to help set payment rates in smaller non-CBAs. Finally, MedPAC stated CMS should consider offsetting the increased costs by further expanding the products included in the CBP.

Response: We appreciate MedPAC's comments on the May 2018 IFC. We agree that the 50/50 blended rates were a significant payment increase, and that they affected large parts of the country. However, at the time of publication of the May 2018 IFC, we were concerned about the potential for beneficiary access issues to occur based off of feedback from industry stakeholders and our data showing a reduction in the number of suppliers billing Medicare Fee-for-Service for items and services subject to fee schedule adjustments. To err on the side of caution, we decided we should immediately resume the transition period and pay 50/50 blended rates in rural and non-contiguous non-CBAs for all items and services subject to fee schedule adjustments.

In looking back at the years since the publication of the May 2018 IFC, we still have not seen evidence of the beneficiary access issues industry stakeholders claimed were happening as a result of the fee schedule adjustments. We also note that in the ensuing months in which we paid the fully adjusted rates in the non-rural and contiguous non-CBAs and the 50/50 blended rates in the rural or non-contiguous non-CBAs, the assignment rates for both areas remained around 99 percent. We will certainly keep MedPAC's points in mind for future rulemaking, particularly as we continue to evaluate the appropriateness of such significant payment increases for wide swaths of the country, and as we contemplate future changes to the CBP. Finally, we also agree with expanding the products included in the CBP, and we note that we have included OTS back and knee braces in Round 2021 of the CBP.

Comment: Several commenters submitted comments on ways to improve the DMEPOS fee schedule adjustment impact monitoring data, in response to us soliciting comments on ways to improve our fee schedule adjustment impact monitoring data in the May 2018 IFC (83 FR 21917). Some commenters left comments about the Medicare complaint process. A commenter stated that it is hard for beneficiaries to navigate through the Medicare complaint process and that they have to get transferred to different offices to complain about access. The commenter was concerned complaints were going unreported or given up on due to the complexity of the reporting process, and the commenter encouraged CMS to develop one central, public facing hotline where beneficiaries can submit a complaint hotline without being transferred to several offices. Another commenter stated the CMS patient complaint and access monitoring is not capturing patient complaints, and that many patients are either paying out of pocket or are going without the care. The commenter recommended reaching out to hospital case managers and social workers about this issue. Another commenter stated that CMS should get another process for complaints that is easier to navigate. The commenter stated CMS should enhance beneficiary awareness of the complaint process, and to publicly report on the complaints we register, and to not only report those that are resolved by a supplier. The commenter also stated that CMS should establish a patient satisfaction survey/patient-reported outcomes measure for respiratory services that would capture

issues like isolation, reduced services, reduced delivery areas, and other impacts the commenter stated cannot be measured using claims data. The commenter also stated CMS should survey using statistically appropriate method prescribers of respiratory services to evaluate the difficulty of discharging patients who require such therapy, which would provide CMS with information about the delays in obtaining DME and respiratory services.

Another commenter stated that CMS should create an ombudsman position for non-CBAs to monitor and address access, quality, supplier availability and other issues in non-CBAs. A commenter stated that CMS does not capture reports from Medicare beneficiaries and their caregivers going to other resources to get their home medical equipment and supplies (for example, garage/online sales) to get the medical equipment needed, and that this will never show up in CMS' reports unless they reach out to those resources or survey beneficiaries and healthcare providers. The commenter stated CMS should work with DME industry advocates on a survey to healthcare professionals who are responsible for ordering DME and supplies for their patients to determine any access to DME issues.

A commenter provided several comments regarding impact monitoring data for respiratory services, particularly oxygen. They stated to compare the number of Medicare beneficiaries diagnosed with COPD, with the number of beneficiaries receiving home oxygen therapy. The commenter stated that there should be a standard benchmark to assess whether the percentage of patients who require the therapy because of their diagnosis actually receive it. The commenter stated CMS could compare the Medicare population receiving respiratory services with the expected incidence and prevalence of the most common disease indications for the therapy (for example, COPD) in the Medicare population, to determine if the percentage of Medicare patients receiving home respiratory therapy is aligned with the percentage of the population receiving the therapy. The commenter stated that this would help CMS see if there are delays in receiving the therapy, and if the therapy is being utilized by the patients who are likely to have a medical need for it. The commenter stated that CMS should determine whether hospital data (including observation stays), admissions, or readmissions are specific enough to track admissions/readmissions related to complications associated with noncompliance with respiratory services. The commenter stated the analysis should note that if metrics of hospitalizations for other chronic conditions are improving but the metric for COPD patients is flat or declining, there is a problem with access to home therapies. Finally, the commenter stated CMS should find out if skilled nursing facilities (SNF)/long term care (LTC) beneficiaries using home respiratory services is increasing.

A commenter stated that the impact monitoring data does not reflect the companies closing their doors but who are still trying to collect money owed to them to help decrease the debt they owe to vendors. The commenter stated that the data falsely reflects a higher number of providers than are actually available to beneficiaries. Another commenter stated CMS should understand why utilization has decreased in non-CBAs. The commenter stated they do not agree with the conclusion that it is because of CMS efforts to address fraud, abuse and overutilization. The commenter stated it is because beneficiaries are going outside Medicare for DME and access problems. A commenter stated CMS should find out how access to Part B services affect an increase in the use of Part A services.

Response: In the 2019 ESRD PPS DMEPOS proposed rule, we also sought comments on ways to improve our fee schedule adjustment impact monitoring data (83 FR 34380). We summarized and responded to these comments in our CY 2019 ESRD PPS DMEPOS final rule (83 FR 57036). Similarly, and as we indicated in the CY 2019 ESRD PPS DMEPOS final rule, these comments are outside the scope of the proposals in the May 2018 IFC. We will take these comments into consideration going forward.

Comment: Many commenters reiterated their opposition to the budget neutrality requirements discussed in the May 2018 IFC (83 FR 21917), and summarized in section IV.B.3.a. of this final rule. Commenters were disappointed that this requirement resulted in non-CBA area fee schedules for oxygen concentrators being below the SPA in certain CBAs. Some stated the reimbursement for oxygen is not enough and that it makes it harder to supply oxygen services to patients.

A commenter stated that CMS incorrectly applied the oxygen budget neutrality to non-CBAs. The commenter stated that the regulation establishing the offset for E1390 concentrators applies to the unadjusted fee schedules under the fee schedule methodology mandated by Congress under section 1834 (a) of the Act. In contrast, the commenter stated that the 2017 fee schedules for concentrators in rural areas are based on information from competitive bidding programs under the methodology in 42 CFR 414.210 (g). The commenter stated that, §§ 414.226 and 414.210(g), describe different reimbursement methodologies that do not overlap. The commenter noted that while § 414.226 applies to fee schedules based on suppliers' reasonable charges from 1986 to 1987, § 414.210 (g) applies to fee schedules based on regional average special payments amounts (SPAs) from competitive bidding areas (CBAs). Similarly, another commenter stated that CMS has the authority to eliminate the budget neutrality requirement. The commenter stated that in implementing the requirement to adjust the DME Fee Schedule, CMS has replaced the national limited monthly payment amount at § 414.226(c) with the regional price or 110 percent of the national average price at § 414.210(g). By adopting the regional price for non-rural non-CBAs and 110 percent of the national average price for rural non-CBAs, the commenter stated that CMS has eliminated the national limited monthly payment amount, which was prior to this change the methodology for establishing rates under the fee schedule. Since the budget neutrality language applied only to the national limited monthly payment amount, the commenter stated it is not applicable to the new regional price or national average price. Finally, a commenter stated that CMS should change oxygen reimbursement to the 50/50 blended rates at a minimum.

Response: Since the publication of the May 2018 IFC, the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) was signed into law on December 27, 2020. Effective April 1, 2021, section 121 of this Act eliminated the budget neutrality requirement set forth in section 1834(a)(9)(D)(ii) of the Act for separate classes and national limited monthly payment rates established for any item of oxygen and oxygen equipment using the authority in section 1834(a)(9)(D)(i) of the Act. Effective for claims with dates of service on or after April 1, 2021, the fee schedule amounts for HCPCS codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444, E0447, E1390, E1391, E1392, E1405, E1406, and K0738 are adjusted to remove a percentage reduction necessary to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Act.

After consideration of the public comments we received, we are finalizing the May 2018 IFC provision titled ''Transition Period for Phase-In of Fee Schedule Adjustments'' without

modification. Of note, we published in the **Federal Register** on April 26, 2021 a continuation of effectiveness and extension of timeline for publication for the May 2018 IFC, titled ''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; Extension of Timeline for Final Rule Publication'' (86 FR 21949). In accordance with sections 1871(a)(3)(B) and 1871(a)(3)(C) of the Act, we provided a notification of continuation for the May 2018 IFC, announcing the different timeline on which we intended to publish the final rule, and explained why we were unable to publish the final rule on the regular, required 3-year timeline. As a result of the publication of this notification of continuation, the timeline for publication of the final rule was extended until May 11, 2022.

With regard to the May 2018 IFC provision titled ''Transition Period for Phase-In of Fee Schedule Adjustments'', this provision:

- Changed 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.
- Amended § 414.210(g)(9)(ii) to reflect that fully adjusted fee schedule amounts applied from January 1, 2017 through May 31, 2018, and then on or after January 1, 2019.
- Added § 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.
- Added § 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 noncontiguous areas from June 1, 2018 through December 31, 2018.

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

We made conforming technical changes to the regulations text consistent with statutory requirements to exclude drugs and biologicals from the CBP. Specifically, we amended § 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 also removed a reference to drugs being included in the CBP by deleting the phrase ''or subpart I'' in § 414.412(b)(2). Similarly, we made 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''.

Comment: Commenters on the technical changes we made in the May 2018 IFC to conform the regulations to section 5004(b) of the Cures Act for the exclusion of DME infusion drugs under CBPs supported this change, saying such changes were consistent with the statute.

Response: After further consideration of the public comments we received, we are finalizing our conforming technical changes to the regulations text consistent with statutory requirements to exclude drugs and biologicals from the CBP. Specifically, we amended § 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 also removed a reference to drugs being included in the CBP by deleting the phrase ''or subpart I'' in § 414.412(b)(2). Similarly, we made 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''.

V. Benefit Category and Payment Determinations for Durable Medical Equipment, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

A. Background

1. Benefit Category Determinations

Medicare generally covers an item or service that—(1) falls within a statutory benefit category; (2) is not statutorily excluded from coverage; and (3) is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member as described in section 1862(a)(1)(A) of the Act. We make benefit category determinations (BCDs) based on the scope of Part B benefits identified in section 1832 of the Act, as well as certain statutory and regulatory definitions for specific items and services. Section 1832(a)(1) of the Act defines the benefits under Part B to include ''medical and other health services,'' including items and services described in section 1861(s) of the Act such as surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations under paragraph (5), prosthetic devices under paragraph (8), leg, arm, back, and neck braces, artificial legs, arms, and eyes under paragraph (9), therapeutic shoes under paragraph (12), and durable medical equipment (DME) under paragraph (6) and as defined in section 1861(n) of the Act. The words ''orthotic(s)'' or ''orthosis(es)'' are used in various parts of the statute and regulations instead of the word brace(s) but have the same meaning as brace(s). For example, section 1847(a)(2)(C) of the Act refers to ''orthotics described in section 1861(s)(9)'' of the Act. However, section 1861(s)(9) of the Act describes ''leg, arm, neck, and back braces'' and does not use the word ''orthotics.'' Likewise, section 1834(h)(4)(C) of the Act specifies that ''the term 'orthotics and prosthetics has the meaning given such term in section 1861(s)(9)'' of the Act; however, section 1861(s)(9) of the Act describes ''leg, arm, neck, and back braces'' and does not use the word ''orthotics.'' Also, the word ''prosthetic(s)'' is used in various parts of the statute and regulations to describe artificial legs, arms, and eyes referenced in section 1861(s)(9) of the Act, but it is important to note that these items are not the same items as the prosthetic devices referenced in section 1861(s)(8) of the Act.

While the statutory definition of DME in section 1861(n) of this Act sets forth some items with particularity, such as iron lungs, oxygen tents, hospital beds, wheelchairs, and blood glucose monitors, whether other items and services are covered under the Medicare Part B DME benefit is based on our interpretation of the statute, which does not, for example, elaborate on the meaning of the word ''durable'' within the context of ''durable medical equipment.'' Therefore, we further defined DME in the regulation at 42 CFR 414.202 as equipment that: (1) Can withstand repeated use; (2) effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; (3) is primarily and customarily used to serve a medical purpose; (4) generally is not useful to a person in the absence of an illness or injury; and (5) is appropriate for use in the home. In conducting an analysis of whether an item falls within the DME benefit category, we review the functions and features of the item, as well as other supporting material, where applicable. For example, research and clinical studies may help to demonstrate that the item meets the prongs of the

definition of DME at § 414.202. For items to be considered DME, all requirements of the regulatory definition must be met. Additional details on the Medicare definition of DME are located in section 110.1 of the Medicare Benefit Policy Manual (CMS 100–02). The Medicare definitions for surgical dressings, splints, casts, and other devices used for reductions of fractures and dislocations, prosthetic devices, orthotics and prosthetics, and therapeutic shoes and inserts are located in sections 100, 120, 130, and 140, respectively, of the Medicare Benefit Policy Manual (CMS 100–02).

In situations where CMS has not established a BCD for an item or service, the BCD is made by the MACs on a case-by-case basis as they adjudicate claims. The MACs may have also addressed the benefit category status of an item or service locally in a written policy article. This final rule would apply to BCDs for all items and services described in section 1861(s) of the Act such as surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations under paragraph (5), prosthetic devices under paragraph (8), leg, arm, back, and neck braces, artificial legs, arms, and eyes under paragraph (9), therapeutic shoes under paragraph (12), and DME under paragraph (6) and as defined in section 1861(n) of the Act.

2. Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554)

Section 531(b) of BIPA required the Secretary to establish procedures for coding and payment determinations for new DME under Medicare Part B of the Act that permit public consultation in a manner consistent with the procedures established for implementing coding modifications to ICD–9–CM. Accordingly, we hosted public meetings that provide a forum for interested parties to make oral presentations and to submit written comments in response to preliminary HCPCS coding and Medicare payment determinations for new DME items and services. A payment determination for DME items and services would include a determination regarding which of the paragraphs (2) through (7) of subsection (a) of section 1834 of the Act the items and services are classified under as well as how the fee schedule amounts for the items and services are established so that they are in compliance with the exclusive payment rules under sections 1834(a) and 1847(a) and (b) of the Act. The preliminary HCPCS coding and Medicare payment determinations for new DME items and services are made available to the public via our website prior to the public meetings. In addition, although this type of forum and opportunity for obtaining public consultation on preliminary HCPCS coding and Medicare payment determinations for items and services other than new DME items is not mandated by the statute, we expanded this process for obtaining public consultation on preliminary coding and payment determinations to all HCPCS code requests for items and services in 2005, and since January 2005, we have been holding public meetings to obtain public consultation on preliminary coding and payment determinations for non-drug, non-biological items and services. As discussed in the November 2020 proposed rule (85 FR 70376), we proposed to continue holding these public meetings for non-drug, non-biological items and services and, in limited circumstances, for drug or biological products (85 FR 70410)) that are associated with external requests for HCPCS codes. As indicated in the proposed rule (85 FR 70397), external requests for HCPCS codes are made by submitting a HCPCS application (OMB control number 0938–1042 titled HCPCS Modification to Code Set Form CMS–10224) available on the *CMS.gov* website at the following address: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions*.

HCPCS Level II codes are used by Medicare, Medicaid, and other public health insurance programs and private insurers for the purpose of identifying items and services on health insurance claims. A code identifies and describes a category of items and services and the HCPCS Level II coding system and process is not used to make coverage or payment determinations on behalf of any insurer. Once a code describing a category of items and services is established, separate processes and procedures are used by insurers to determine whether payments for the item or service can be made, what method of payment, for example, purchase or rental, will be used to make payment for the item or service, and what amount(s) will be paid for the item or service. Whether or not an item falls under one of the Medicare benefit categories such as DME is a decision made by CMS or the MACs based on statutory and regulatory definitions, separate from the HCPCS Level II coding system and process for identifying items and services. Once a Medicare benefit category is identified, the coverage and payment indicators attached to any new HCPCS code(s) describing the item or service for claims processing purposes would reflect the benefit category and payment determinations made pursuant to the process established by this final rule.

To make a Medicare payment determination for an item or service, that is, to determine the statutory and regulatory payment rules that apply to the item or service and how to establish allowed payment amounts for the item or service, CMS must first determine whether the item or service falls under a benefit category, for example DME, and if so, which benefit category in particular. Therefore, since 2001, the procedures established by CMS to obtain public consultation on national payment determinations for new DME items as mandated by section 531(b) of BIPA have also in effect been procedures for obtaining public consultation on national DME BCDs, or determinations about whether an item or service meets the Medicare definition of DME. Then in 2005, when these procedures were expanded to include requests for HCPCS codes for all items and services, they became in effect procedures for obtaining public consultation on BCDs and payment determinations for all items and services.

B. Current Issues

To increase transparency and structure around the process for obtaining public consultation on benefit category and payment determinations for these items and services, we stated in the November 2020 proposed rule (85 FR 70397) that it would be beneficial to set forth in our regulations the process and procedures that have been used since 2001 for obtaining public consultation on BCDs and payment determinations for new DME and since 2005 for requests for HCPCS codes for items and services other than DME. As further discussed in section IV.A.2. of the 2020 November proposed rule (85 FR 70374 through 70375), we recently revised our coding cycle for requests for HCPCS Level II codes to implement shorter and more frequent coding application cycles.[25] Beginning January 2020, for non-drug, non-biological items and services, we shortened the existing annual coding cycle to conduct more frequent coding cycles on a bi-annual basis and include public meetings to obtain consultation on preliminary coding determinations twice a year

[25] CMS, Announcement of Shorter Coding Cycle Procedures, Applications, and Deadlines for 2020, HCPCS—General Information. Available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo*.

under these new bi-annual coding cycles. We believe that continuing to establish payment determinations, which, include BCDs, for new DME items and services and the other items and services described previously at these same bi-annual public meetings would be an efficient and effective way to address coding, benefit category, and payment issues for these new items and services and would prevent delays in coverage of new items and services.

In addition, in the past, manufacturers of new products would often ask CMS for guidance on whether or not the product(s) fall under a DMEPOS benefit category. Our informal advice regarding these products were sent directly to the manufacturers, outside of the HCPCS public meeting process. In the future, if a manufacturer requests a BCD for their product(s) outside of the process established in this final rule, we will instead issue a BCD and payment determination for the manufacturer through the BCD and payment determination procedures established by this rule. Such requests would be added as soon as possible to the agenda for an upcoming public meeting, which will be posted on *CMS.gov* two weeks prior to the meeting. Likewise, if CMS decides to address the benefit category for a new item or service that is not identified through the HCPCS editorial process, the benefit category determination and payment determination, if applicable, will be subject to the procedures established by this rule. Any manufacturer or other entity requesting a benefit category determination outside of the HCPCS editorial process) would still need to provide information on the product such as intended use, FDA clearance documents, any clinical studies, etc., that CMS will need to determine whether the product falls under a Medicare benefit category.

C. Proposed Provisions

We proposed in the November 2020 proposed rule (85 FR 70397 through 70398) to set forth in regulations BCD and payment determination procedures for new DME items and services described in sections 1861(n) and (s)(6) of the Act, as well as the items and services described in sections 1861(s)(5), (8), (9), and (12) of the Act, that permit public consultation at public meetings. The payment rules for these items and services are located in 42 CFR part 414, subparts C and D, so we proposed to include these procedures under both subparts C and D. We proposed that the public consultation on BCDs and payment determinations would be heard at the same public meetings where consultation is provided on preliminary coding determinations for new items and services the requestor of the code believes are: DME as described in sections 1861(n) and (s)(6) of the Act; surgical dressings, splints, casts, and other devices as described in section 1861(s)(5) of the Act; prosthetic devices as described in section 1861(s)(8) of the Act; leg, arm, back, and neck braces (orthotics), and artificial legs, arms, and eyes (prosthetics) as described in section 1861(s)(9) of the Act; or therapeutic shoes and inserts as described in section 1861(s)(12) of the Act. The proposal generally reflected the procedures that have been used by CMS since 2005, however, we proposed to specifically solicit or invite consultation on preliminary BCDs for each item or service in addition to the consultation on preliminary payment and coding determinations for new items and services.

Accordingly, we proposed procedures under new § 414.114 for determining whether new items and services meet the Medicare definition of items and services subject to the payment rules at 42 CFR part 414 subpart C (85 FR 70397). This would include determinations regarding whether the items and services are parenteral and enteral nutrition (PEN), which are nutrients, equipment, and supplies that are categorized under the prosthetic device benefit, as defined at section 1861(s)(8) of the Act and covered in accordance with section 180.2 of Chapter 1, Part 3 of the Medicare National Coverage Determinations Manual (Pub 100–03). This would also include determinations regarding whether items and services are intraocular lenses (IOLs) inserted in a physician's office, which are also categorized under the prosthetic device benefit at section 1861(s)(8) of the Act. We stated we would also use the proposed procedures to determine whether items and services are splints, casts, and other devices used for reduction of fractures and dislocations at section 1861(s)(5) of the Act. For purposes of the proposed procedures and § 414.114, we proposed to establish the following definition:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of a prosthetic device at section 1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

We proposed procedures under new § 414.240 for determining whether new items and services meet the Medicare definition of items and services subject to the payment rules at 42 CFR part 414 subpart D (85 FR 70398). This would include determinations regarding whether the items and services are in the DME benefit category as defined at section 1861(n) of the Act and under 42 CFR 414.202. This would also include determinations regarding whether the items and services are in the benefit category for prosthetic devices that fall under section 1861(s)(8) of the Act other than PEN nutrients, equipment and supplies or IOLs inserted in a physician's office. This would also include determinations regarding whether the items and services are in the benefit category for leg, arm, neck, and back braces (orthotics), and artificial legs, arms, and eyes (prosthetics) under section 1861(s)(9) of the Act. This would also include determinations regarding whether the items and services are in the benefit category for surgical dressings under section 1861(s)(5) of the Act or custom molded shoes or extra-depth shoes with inserts for an individual with diabetes under section 1861(s)(12) of the Act. For purposes of these proposed procedures and new § 414.240, we proposed to establish the following definition:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Act, a prosthetic device at section 1861(s)(8) of the Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

We proposed that if a preliminary determination is made that a new item or service falls under one of the benefit categories for items and services paid in accordance with subpart C or D of 42 CFR part 414, then CMS will make a preliminary payment determination regarding how the fee schedule amounts for the item or services would be established in accordance with these subparts, and, for items and services identified as DME, under which of the payment classes under sections 1834(a)(2) through (7) of the Act the item or service falls (85 FR 70398). We proposed that the procedures for making BCDs and payment determinations for new items and services subject to the payment rules under subpart C or D of

42 CFR part 414 would be made by CMS during each bi-annual coding cycle and the proposed procedures under new §§ 414.114 and 414.240 would include the following steps.

First, at the start of the coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from Medicare coverage under any of the provisions at section 1862 of the Act, and, if not excluded by statute, CMS determines if the item or service falls under a Medicare benefit category defined in the statute and regulations for any of the items or services subject to the payment rules under subparts C or D of 42 CFR part 414. Information such as the description of the item or service in the HCPCS application, HCPCS codes used to bill for the item or service in the past, product brochures and literature, information on the manufacturer's website, information related to the FDA clearance or approval of the item or service for marketing or related to items that are exempted from the 510(k) requirements or otherwise approved or cleared by the FDA is considered as part of this analysis. This step could generally take anywhere from 1 week to 2 months. For more complex items or services, the process may take several months, in which case public consultation on the benefit category and payment determinations would slip to a subsequent coding cycle.

Second, if a preliminary determination is made by CMS that the item or service is an item or service falling under a benefit category for items and services paid for in accordance with subpart C or D of 42 CFR part 414, a preliminary payment determination is made by CMS regarding how the fee schedule amounts will be established for the item or service and what payment class the item falls under if the item meets the definition of DME. This step could also generally take anywhere from 1 week to 2 months. For more complex items or services, the process may take several months, in which case public consultation on the benefit category and payment determinations would slip to a subsequent coding cycle.

Third, approximately 4 months into the coding cycle, the preliminary benefit category and payment determinations are posted on *CMS.gov* 2 weeks prior to the public meeting described under proposed § 414.8(d) in which CMS receives consultation from the public on the preliminary benefit category and payment determinations made for the item or service. After consideration of public consultation on any preliminary benefit category and payment determinations made for the item or service, the benefit category and payment determinations are established through program instructions issued to the MACs.

We noted that even though a determination may be made that an item or service meets the Medicare definition of a benefit category, and fee schedule amounts may be established for the item or service, this does not mean that the item or service would be covered for a particular beneficiary. After a BCD and payment determination has been made for an item or service, a determination must still be made by CMS or the relevant local MAC that the item or service is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, as required by section 1862(a)(1)(A) of the Act.

We sought public comment on our proposed process and procedures for making BCDs and payment determinations for new items and services paid for in accordance with subpart C or D of 42 CFR part 414. We noted that our proposed approach does not affect or change our existing process for developing National Coverage Determinations (NCDs), which we can continue to use to develop NCDs both in response to external requests and internally-generated reviews. We further noted that we are not limited to only addressing benefit categories in response to external HCPCS code applications and could decide to use the proposed process to address benefit categories in response to internally generated HCPCS coding changes as well. As aforementioned, requests for BCDs that are not associated with a HCPCS code application will also be addressed through the preliminary benefit category and payment determination process established in this final rule.

Comment: A few commenters supported the codification of formal BCD procedures including stakeholder input, noting this proposal is a step in the right direction.

Response: For the reasons we articulated previously as well as later in this section, we intend to finalize these procedures as proposed with a technical modification. At proposed §§ 414.114(b)(3) and (4), 414.240(b)(3) and (4), we included the language ''a public meeting described under § 414.8(d)'' to identify the existing bi-annual public meetings used to review new DME items and services and the other items and services. We intend to keep using the same public meetings for BCD purposes, but as discussed in section X. of this final rule, we are not finalizing the proposed HCPCS Level II code application process, and we are not finalizing the proposed regulation text for § 414.8(d). Therefore, we are finalizing in the regulation text at §§ 414.114(b)(3) and (4), as well as 414.240(b)(3) and (4), a reference to a ''public meeting'' without a cross-reference to § 414.8(d). We emphasize that this change is technical only, and both the final regulation text and BCD procedures are functionally the same as what we proposed in the November 2020 proposed rule.

Comment: A few commenters from associations and consultants representing manufacturers and suppliers of DMEPOS noted that there was no mention of the minimum qualifications for the individuals who will be making the preliminary determinations, claiming that this differs from the Coverage and Analysis Group (CAG) or by Medicare Administrative Contractors processes that affect both coverage and coding, where the process is either supervised or conducted by individuals with the appropriate professional credentialing and experience, such as licensed health care professionals or individuals with graduate-level training in related fields such as epidemiology. Commenters further stated that as many innovations rely on more complex technology and clinical factors, and rely on clinical trial evidence and interpretation of that evidence, it was incumbent on CMS to ensure that the reviewers making the preliminary determinations are familiar with current developments and have the technical skills necessary to conduct a thorough evaluation of the item and the related clinical information. Commenters recommended either having the applicant indicate the minimum and preferred credentials of a proposed reviewer or lengthening the current 40-page limit to allow relevant technical data and published papers that describe the innovation, its mechanism of action, and how it differs from other items and services that are described in existing HCPCS code.

Response: CMS has years of experience making benefit category determinations and our initial and final determinations are formulated in conjunction with experts such as medical officers, certified orthotists and prosthetists, nurses and other allied health professionals, and biomedical engineers. We are not adopting the commenters' suggestion that we adopt specific qualifications for the specific group of CMS reviewers that makes initial benefit category determinations. Moreover, we note our initial determinations are preliminary, giving the public an opportunity to provide additional feedback at the public

meeting. Accordingly, we find it is unnecessary for the applicant to request preferred or minimal credentials for the group that makes initial benefit category determinations.

We also find it is unnecessary to adjust the HCPCS application because a BCD is a separate process that is not limited to the information in the HCPCS application. For the BCD recommendation, we conduct research, as needed, and also may request information from the manufacturer or industry. We recognize that a HCPCS application often triggers a BCD, but the determination of a BCD can be a separate and distinct process from the HCPCS review.

Comment: Commenters suggested that CMS allow applicants to request either a BCD, a HCPCS code, or both. The rationale being some applicants may need a BCD alone at one stage of commercialization and do not want or need to invest in the costs of a complete HCPCS application. The commenters claimed that many applicants would not invest in the resources needed to apply for a new code if they knew they would receive a determination that the item or service did not fall under a Medicare benefit category.

Response: We want to clarify that the BCD process is separate and distinct from the HCPCS application, and an interested party can make a request for a BCD independent from any associated HCPCS code request. Any party can request a BCD for an item or service without requesting a change to the HCPCS. Once the BCD request is received, we would follow the same process which includes discussing the BCD at a public meeting. We also note that interested parties can request a national BCD through the NCD process or in some cases we could make a BCD through rulemaking; however, we believe these procedures we are finalizing under the regulations will allow us to make BCDs for these new items and services more quickly.

Comment: A few commenters recommended that the BCD coverage and the coding process should remain separate.

Response: We did not propose to integrate the two processes, but we reiterate that a HCPCS code application often triggers a BCD. We proposed to discuss the BCD requests during the bi-annual public meetings for new items and services, as this is an efficient and effective way to address coding, benefit category, and payment issues for these new items and services and will prevent delays in access to new items and services.

With regard to the use of the term ''BCD coverage,'' we want to clarify that BCDs and coverage determinations are two distinct processes with separate statutory authorities. A BCD is a determination regarding whether or not an item or service falls under a Medicare benefit category (for example, DME as defined in section 1861(n) of the Act). A coverage determination, on the other hand, is a decision by a Medicare contractor regarding whether to cover a particular item or service in accordance with section 1862(a)(1)(A) of the Act (see 42 CFR 400.202). We note that stakeholders can still request a BCD through the NCD process, as an alternative to these procedures.

Comment: A few commenters expressed concern that the timeframe of publishing the preliminary BCD decisions 2 weeks prior to a public meeting is too brief. The commenters were concerned that this proposal shortens the time necessary for an applicant to bring forth an expert or health care professional.

Response: We understand commenters' concern on the timing of the preliminary decisions; however, we must balance the time needed to assess and make a preliminary decision and issuing it within the specified timeframes. We believe that giving 2 weeks' notice of the meeting and announcing the dates of the public meetings in advance provides stability to stakeholders on the expected meeting times while also ensuring we have sufficient time necessary to make preliminary determinations for as many new items and services as possible. The HCPCS cycle was shortened from a 12-month cycle to two 6-month cycles to allow for more opportunities for the public to request HCPCS codes, but one tradeoff is that this can compress all stages of the coding process, including the time for developing preliminary coding, benefit category, and payment determinations, as well as the time allowed for the public to react to these preliminary determinations and prepare for the public meetings.

Comment: Some commenters expressed interest in expanding the DME definition in 42 CFR 414.202 to cover items such as software and vision aids or to clarify the definition of prosthetic device in 42 CFR 414.202.

Response: We did not propose to expand the scope of the DME or prosthetic device benefits in these BCD provisions, and therefore these comments fall outside the scope of this section of the rule.

Comment: A commenter requested that CMS allow the HCPCS process to serve as an appeal process for the BCD and payment decisions.

Response: We do not believe a further appeals process is necessary. There is already an appeals process in the claims appeals process under which a party could challenge the amount of payment if the party with standing was dissatisfied with the amount of payment. In light of the available appeal process, there would seem to be no need to establish a further appeals process.

Comment: A commenter recommended that CMS provide details regarding the basis and data used to make any preliminary BCD and payment decision, stating that this information should be included in the letters to the applicants as well as in the information for the relevant public meetings.

Response: We do not agree with the commenter that details on preliminary BCDs need to be included in a letter to the requestor of the HCPCS code. The HCPCS is a coding system for the public in general and is not a coding system for specific manufacturers or specific products. We will provide enough information so the public, which includes the manufacturer, individual, or entity that submitted the HCPCS request, can meaningfully comment on the preliminary BCD and payment decisions and also understand our underlying rationale for such decisions.

Comment: A commenter representing manufacturers and beneficiaries stated that they do not prefer that BCDs be made through public notice and comment rulemaking, which they believe would dramatically reduce the timeliness of approval of benefit category determinations for new devices and technologies, and consequently, access to care.

Response: We agree with the commenter that solely using notice and comment rulemaking would significantly extend the time it takes to make a BCD and could negatively impact beneficiaries' access to new item and services. The BCD procedures we are finalizing allow for multiple determinations within 1 year and build on the statutory process outlined in BIPA. We also note that stakeholders can still request a BCD through the NCD process, as an alternative to these procedures.

Comment: A commenter expressed their opinion that CMS has not been following the BCD process and that CMS did not make these determinations for a number of DME items assigned new HCPCS codes since 2019. The commenter stated their opinion that the lack of BCDs for new items assigned HCPCS codes since 2019 continues to

impede beneficiary access to these new, clinically proven technologies.

Response: We acknowledge BCDs reviews have been slowed down the past few years because this process was not formalized. We believe there is a benefit to finalizing these procedures and anticipate being able to make decisions more quickly and on a consistent timeframe outlined under the final regulation. However, we note that in situations where CMS has not established a BCD for an item or service, the BCD can be made by the MACs on a case-by-case basis as they adjudicate claims.

After consideration of the public comments we received and for the reasons we articulated, we are finalizing at §§ 414.114 and 414.240 the definitions related to and procedures for making BCDs and payment determinations for new items and services subject to the payment rules under subparts C or D of 42 CFR part 414 as proposed with a technical modification to remove a cross-reference to a HCPCS-related regulation we are not finalizing.

VI. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

This section addresses classification and payment for CGMs under the Medicare Part B benefit for DME. We proposed to replace a CMS Ruling issued in January 12, 2017 titled Classification of Therapeutic Continuous Glucose Monitors as ''Durable Medical Equipment'' under Medicare Part B [Ruling] (CMS–1682–R) with this new rule.

A. General Background

DME is a benefit category under Medicare Part B. Section 1861(n) of the Act defines ''durable medical equipment'' as including ''iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)) of the Act, whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.''

In addition to this provision, in most cases, an item must also meet the requirements of section 1862(a)(1)(A) of the Act, which precludes payment for an item or service that is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and section 1862(a)(6) of the Act, which precludes payment for personal comfort items.

The Medicare program was created as part of the Social Security Amendments of 1965 (Pub. L. 89–97), and the Part B benefit payments for DME were initially limited to ''rental of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home (including an institution used as his home)'' in accordance with the definition of DME at section 1861(s)(6) of the Act. The Social Security Amendments of 1967 (Pub. L. 90–248) amended the statute to allow for payment on a purchase basis for DME in lieu of rental for items furnished on or after January 1, 1968. Section 144(d) of the Social Security Amendments of 1967 changed the language under section 1861(s) of the Act to ''durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home (including an institution used as his home), whether furnished on a rental basis or purchased.'' Payments for purchase of expensive items of DME were limited to monthly installments equivalent to what would have otherwise been made on a rental basis, limited to the period of medical need and not to exceed the purchase price of the equipment.

In 1975, Medicare program instructions in section 2100 of chapter 2 of part 3 of the Medicare Carrier's Manual (HCFA Pub. 14–3) indicated that expenses incurred by a beneficiary for the rental or purchase of DME are reimbursable if the following three requirements are met: The equipment meets the definition of DME in this section; and the equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his malformed body member; and the equipment is used in the patient's home. The instructions also indicated that payment may also be made under the DME benefit category for repairs and maintenance of equipment owned by the beneficiary as well as expendable and non-reusable supplies and accessories essential to the effective use of the equipment. DME was defined under these program instructions from 1975 as equipment meeting four requirements (quoted later in the section verbatim and with text underscored as in the original instructions):

Durable medical equipment is equipment which (a) can withstand repeated use, *and* (b) is primarily and customarily used to serve a medical purpose, *and* (c) generally is not useful to a person in the absence of an illness or injury; and (d) is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be durable medical equipment.

Additional detailed instructions were provided in 1975 describing the underlying policies for determining whether an item meets the definition of DME and specifically addressed what the terms ''durable'' and ''medical equipment'' mean. The instructions indicated that an item is considered durable if it can withstand repeated use, that is, it is the type of item that could normally be rented, and that medical supplies of an expendable nature are not considered ''durable'' within the meaning of the definition. To be considered DME, the item must be able to be rented out to multiple patients and thus withstand repeated use. The instructions indicated that medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. The instructions indicated that in some cases information from medical specialists and the manufacturer or supplier of products new to the market may be necessary to determine whether equipment is medical in nature. Additional instructions provide examples of equipment which presumptively constitutes medical equipment, such as canes, crutches, and walkers, and equipment that is

primarily and customarily used for a nonmedical purpose and cannot be considered DME even when the item has some remote medically related use, such as air conditioners. Equipment that basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment, first-aid or precautionary-type equipment, self-help equipment, and training equipment are considered nonmedical in nature. These program instructions from 1975 are still in effect and are now located in section 110 of chapter 15 of the Medicare Benefits Policy Manual (CMS Pub. 100–02).

The Social Security Amendments of 1977 (Pub. L. 95–142) amended the statute to mandate a ''rent/purchase'' program or payment methodology for DME; CMS would pay for each item furnished to each beneficiary on either a rental or purchase basis depending on which method was considered more economical. The decision regarding whether payment for DME was made on a rental or purchase basis was made by the Medicare Part B carrier (Medicare contractor) processing the claim. The rent/purchase program was implemented from February 1985 through December 1988.

Section 2321 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) moved the definition of DME from section 1861(s)(6) of the Act to section 1861(n) of the Act and included a more detailed definition of DME.

Section 4062(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Pub. L. 100–203) amended the statute to terminate the rent/purchase program and add section 1834(a) to the Act with special payment rules for DME furnished on or after January 1, 1989. DME items were to be classified into different classes under paragraphs (2) through (7) of section 1834(a) of the Act, with specific payment rules for each class of DME. Section 1834(a) of the Act still governs payment for items and services furnished in areas that are not included in the competitive bidding program mandated by section 1847(a) of the Act. Section 1834(a)(2) of Act indicates that payment is made on a rental basis or in a lump sum amount for the purchase of an item the purchase price of which does not exceed $150 (inexpensive equipment) or which the Secretary determines is acquired at least 75 percent of the time by purchase (routinely purchased equipment) or which is an item specified under sections 1834(a)(2)(A)(iii) and (iv) of the Act. The term ''routinely purchased equipment'' is defined in regulations at 42 CFR 414.220(a)(2) as equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

Medicare began covering blood glucose monitors under the DME benefit in the early 1980s and the test strips and other supplies essential for the effective use of the glucose monitor were also covered. Blood glucose monitors were expensive equipment within the meaning of section 1834(a)(2) of the Act but were routinely purchased (more than 75 percent of the time on a national basis) during the period July 1986 through June 1987. Therefore, payment was made on a fee schedule basis for blood glucose monitors based on the lower of the supplier's actual charge for the item or a statewide fee schedule amount calculated for the item based on the average rental or purchase payment for the item in the State for the 12-month period ending on June 30, 1987. The rental and purchase fee schedule amounts are increased on an annual basis based on the provisions set forth in section 1834(a)(14) of the Act.

The special payment rules for DME mandated by section 1834(a) of the Act were implemented via program instructions for all DME items other than oxygen and oxygen equipment on January 1, 1989. CMS established and implemented fee schedule amounts for inexpensive or routinely purchased items, for payment on a rental basis, payment on a lump sum purchase basis when the item is new, and payment on a lump sum purchase basis when the item is used. We also promulgated rules implementing the special payment rules for DME mandated by section 1834(a) of the Act. For more information, see the October 9, 1991 and December 7, 1992 **Federal Registers** (56 FR 50821 and 57 FR 57675, respectively), and a July 10, 1995, final rule (60 FR 35492).

We established a definition for DME items and services during this time at 42 CFR 414.202, which simply mirrored the general definition of DME established in 1975 via program instructions.

Section 1861(n) of the Act was revised by section 4105(b)(1) of the Balanced Budget Act of 1997 (Pub. L. 105–33) to expand coverage of blood glucose monitors and test strips to patients with type II diabetes. As noted, these items had already been covered as DME (glucose monitoring equipment) and disposable supplies (test strips) since the early 1980s, but coverage was limited to patients with type I diabetes.

We added to the definition of DME at 42 CFR 414.202 effective for items furnished after January 1, 2012, to require that the item have a minimum lifetime of 3 years to be considered DME. This 3-year minimum lifetime requirement was established in a final rule published in the November 10, 2011 **Federal Register** titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (76 FR 70228 and 70314). This final rule included a discussion of how the 3-year minimum lifetime requirement (MLR) is applied to multicomponent devices or systems consisting of durable and nondurable components (76 FR 70291). In this rule, we noted that a device may be a system consisting of durable and nondurable components that together serve a medical purpose, and that we consider a multicomponent device consisting of durable and nondurable components nondurable if the component that performs the medically necessary function of the device is nondurable, even if other components of the device are durable. In regards to the 3-year MLR, the component(s) of a multicomponent device that performs the medically necessary function of the device must meet the 3-year MLR (76 FR 70291).

In summary, DME is covered under Medicare Part B. DME is defined under section 1861(n) of the Act and Medicare claims for DME are paid in accordance with the special payment rules under section 1834(a) of the Act or under the competitive bidding program mandated by sections 1847(a) and (b) of the Act. Rules related to the scope and conditions of the benefit are addressed at 42 CFR 410.38. Under § 414.202, durable medical equipment means equipment which—

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3years;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be DME.

B. Continuous Glucose Monitors

On January 12, 2017, we issued a CMS Ruling (CMS–1682–R) articulating the CMS policy concerning the classification of therapeutic continuous

glucose monitoring systems as DME under Part B of the Medicare program. CMS–1682–R is available on the *CMS.gov* website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/CMS-Rulings.*

CMS–1682–R classified continuous glucose monitoring systems as ''therapeutic continuous glucose monitors (CGMs)'' that meet the definition of DME if the equipment—

- Is approved [or cleared] by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions (for example, changes in diet and insulin dosage);
- Generally is not useful to the individual in the absence of an illness or injury;
- Is appropriate for use in the home; and
- Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.

Under CMS–1682–R, in all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered DME. We reasoned that enabling a beneficiary to make diabetes treatment decisions was the medical purpose of a glucose monitor, that non-therapeutic CGMs did not serve that medical purpose, and that non-therapeutic CGMs therefore were not DME. CMS–1682–R also addressed the calculation of the fee schedule amounts for therapeutic CGMs in accordance with the rules at section 1834(a) of the Act and under regulations at 42 CFR part 414, subpart D.

CGMs are systems that use disposable glucose sensors attached to the patient to monitor a patient's interstitial fluid glucose level on a continuous basis by either automatically transmitting the glucose readings from the sensor via a transmitter to a device that displays the readings (''automatic'' CGMs), or by displaying the glucose readings from the sensor on a device that the patient manually holds over the sensor (''manual'' CGMs). Some CGMs are class III devices and require premarket approval by the FDA, while some newer CGM models are class II devices that do not require premarket approval and may go through FDA's 510(k) premarket process, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device. The glucose sensor continuously measures glucose values in the interstitial fluid, the fluid around the cells (in contrast to blood glucose monitors which measure glucose values using fingertip blood samples). The sensor is a small flexible metal probe or wire that is inserted under the skin and has a coating that prevents the body's immune system from detecting and attacking the foreign probe. Once the coating wears off, which in current models takes place in 7 to 14 days, the sensor must be replaced for safety reasons. The glucose sensor generates small electrical signal in response to the amount of sugar that is present (interstitial glucose). This electrical signal is converted into a glucose reading that is received/displayed on a dedicated continuous glucose monitor (the CGM). Insulin pumps covered as DME or a compatible mobile device (smart phone, smart watch, tablet, etc.) and app that are not covered as DME may also perform the function of a CGM, which receives and displays the glucose measurements in the form of a graph so that the patient can visualize how their glucose measurements are trending. CMS–1682–R only addressed whether CGMs meet the Medicare definition of DME and did not address whether insulin pumps that can also perform the function of a CGM are DME since insulin pumps are already classified as DME under an NCD (section 280.14 of Chapter 1, Part 4 of the Medicare National Coverage Determinations Manual, Pub. 100–03).

CMS–1682–R classifies CGM display devices as DME if they have been approved [or cleared] by the FDA for use in making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, that is, without verifying the CGM readings with readings from a blood glucose monitor. These CGMs are referred to as ''non-adjunctive'' or ''therapeutic'' CGMs in CMS–1682–R. In contrast, CGMs that patients use to check their glucose levels and trends that must be verified by use of a blood glucose monitor to make diabetes treatment decisions are not currently classified as DME. These CGMs are referred to as ''adjunctive'' or ''non-therapeutic'' CGMs in CMS–1682–R. It is important to note that there were no ''adjunctive'' or ''non-therapeutic'' CGM receivers being manufactured and sold on the market as of the time this rule was drafted. This fact was brought to light by comments submitted on the proposed rule and discussed in more detail later in this final rule.

C. Current Issues

As indicated previously, there are currently no adjunctive CGM receivers being manufactured and sold on the market. However, beneficiaries are currently using disposable continuous glucose sensors and transmitters that have not been approved or cleared by the FDA to replace a blood glucose monitor for use in making diabetes treatment decisions with insulin infusion pumps that also function as ''adjunctive'' or ''non-therapeutic'' CGM receivers. Beneficiaries are using the readings from these disposable sensors that are received and displayed by the insulin pump to help manage their diabetes. Claims submitted for CGM sensors and transmitters used with insulin pumps are being denied inappropriately based on CMS–1682–R even though this Ruling only addressed the classification of CGM receivers as DME and did not address coverage of CGM sensors and transmitters used with insulin pumps. This final rule addresses whether adjunctive or ''non-therapeutic'' CGMs meet the five requirements or prongs of the definition of DME at 42 CFR 414.202 and how the fee schedule amounts should be calculated for CGM supplies and accessories.

1. Requirements of DME Definition

(a) Ability To Withstand Repeated Use

This criterion under 42 CFR 414.202 addresses the issue of whether an item of medical equipment can withstand repeated use, which means it is an item that can be rented and used by successive patients. Equipment must be able to withstand repeated use to fall within the scope of the Medicare Part B benefit for DME. The continuous glucose monitor's receiver component is durable equipment that can be rented and used by successive patients to monitor the trending of glucose levels that are either transmitted to the device using disposable sensors or are read or received by the device when the patient holds the device near the sensor. Therefore, we believe this equipment meets the requirement to withstand repeated use; that is, equipment that could normally be rented and used by successive patients.

(b) Expected Life of at Least 3 Years

This criterion under 42 CFR 414.202 further addresses the issue of ''durability'' and provides a clear minimum timeframe for how long an item must last to meet the definition of DME. We believe the continuous glucose monitor or receiver meets the 3-year minimum lifetime requirement. In the case of one manufacturer, reliability analysis data from an engineering firm that evaluated their CGM product predicted a lifetime of greater than 3 years for the receiver. Because the CGM sensors and transmitters only have a

predicted life of days (for the sensors) or several months (for the transmitters), the receiver is the only durable component of a CGM system.

(c) Primarily and Customarily Used To Serve a Medical Purpose

We proposed that CGMs that have not been approved or cleared by the FDA for use in making diabetes treatment decisions without the use of a blood glucose monitor but can be used to alert the patient about potentially dangerous glucose levels while they sleep, are primarily and customarily used to serve a medical purpose. Likewise, we believe that disposable continuous glucose sensors and transmitters that work in conjunction with an insulin pump that also operates as a continuous glucose monitor's receiver component to alert the patient about potentially dangerous glucose levels while they sleep are primarily and customarily used to serve a medical purpose. We now believe that because adjunctive CGMs or adjunctive continuous glucose sensors and transmitters used with insulin pumps can provide information about potential changes in glucose levels while a beneficiary is sleeping and is not using a blood glucose monitor, these CGMs or CGM functions on insulin pumps are primarily and customarily used to serve a medical purpose.

(d) Generally Not Useful to a Person in the Absence of an Illness or Injury

CMS has determined that both adjunctive and non-adjunctive/therapeutic CGM systems are generally not useful to a person in the absence of an illness or injury because people who do not have diabetes generally would not find a monitor that tracks their glucose levels to be useful. Thus far, Medicare's coverage policy for CGMs has supported the use of therapeutic CGMs in conjunction with a smartphone (with the durable receiver as backup), including the important data sharing function they provide for patients and their families.[26] CMS previously concluded that therapeutic CGMs, when used in conjunction with a smartphone, still satisfied the definition of DME because the durable receiver, used as a backup, was generally not useful to a person in the absence of an illness or injury, even if the smartphone might be. We are not changing this policy. We proposed that both therapeutic and non-therapeutic CGMs, when used in conjunction with a smartphone, satisfy the definition of DME because the durable receiver, used as a backup, is not generally useful to a person in the absence of an illness or injury. Medicare does not cover or provide payment for smartphones under the DME benefit. In order for Medicare to cover disposable glucose sensors, transmitters and other non-durable components of a CGM system, these disposable items must be used with durable CGM equipment that meets the Medicare definition of DME, which smartphones do not. If a Medicare beneficiary is using durable CGM equipment or an insulin pump with a CGM feature that meets the Medicare definition of DME as a backup, but primarily uses a smartphone or other non-DME device to display their glucose readings in conjunction with the covered DME item as described previously, Medicare will cover the disposable items since the beneficiary is using their covered DME item as a backup to display their glucose readings. However, if the beneficiary is exclusively using a non-DME item like a smartphone to display glucose readings from disposable sensors, transmitters or other disposable CGM supplies, these disposable supplies cannot be covered since there is no covered item of DME in this scenario, even as a backup.

(e) Appropriate for Use in the Home

The FDA has cleared or approved CGM systems as safe and effective for use by the patient in their homes similar to how blood glucose monitoring systems have been used in the home for many years. Both adjunctive and non-adjunctive CGMs are appropriate for use in the home for the same purpose that a blood glucose monitor is used in the home.

Comment: With regard to the proposal to expand classification of durable medical equipment (DME) to all types of CGMs (''adjunctive'' as well as ''non-adjunctive''), most commenters agreed with the proposal but multiple commenters pointed out that the only adjunctive CGM system on the market today does not include a dedicated durable CGM receiver. Some commenters recommended classifying the software application (App) that allows smart phones to function as CGM receivers as DME.

Response: We have confirmed with the FDA that the one adjunctive CGM product on the market today, the Guardian™ Connect System, consists of disposable glucose sensors and transmitters that work in conjunction with the patient's smart phone and App or with certain MiniMed insulin infusion pumps instead of a dedicated durable receiver. Software applications do not meet the definition of DME, nor do phones or computers. To cover the software application under the Medicare Part B benefit for DME, the equipment that the software is added to, or some part of the CGM system used with the software, must meet the Medicare definition of DME at 42 CFR 414.202, including the requirement that the equipment or system component not be useful in the absence of illness or injury. Smart phones are useful in the absence of illness or injury and therefore do not meet the definition of DME. Therefore, a CGM system that consists of a software application added to a smart phone and disposable supplies is not covered under the Medicare Part B benefit for DME. However, smart devices (watch, smartphone, tablet, laptop computer, etc.) can be used in conjunction with a continuous glucose monitor.

In contrast, durable insulin infusion pumps have been classified and covered as DME since the mid-1990s. Therefore, in accordance with this final rule, an insulin pump that also performs the functions of an adjunctive CGM would also be classified and covered as DME.

After consideration of the public comments we received, we are finalizing the proposed rule to expand classification of DME to both adjunctive and non-adjunctive CGMs as long as all requirements of the definition of DME at 42 CFR 414.202 are met. There are adjunctive continuous glucose monitoring sensors and transmitters that do not meet the durability requirement and are used exclusively in conjunction with devices such as smart phones, which are not DME for the previously stated reasons; neither the sensors and transmitters nor the smart phones meet the Medicare definition of DME. In situations where these adjunctive continuous glucose monitoring sensors and transmitters are used in conjunction with an insulin infusion pump that also functions as a CGM receiver, the sensors and transmitters can be covered under the DME benefit, subject to other requirements and criteria. We note that if the beneficiary does not meet the medical necessity criteria for an insulin pump, then the insulin pump would not be covered and therefore any supplies used with the insulin pump would also not be covered.

2. Fee Schedule Amounts for CGM Receivers/Monitors and Related Accessories

Medicare payment for DME was made on a reasonable charge basis prior to 1989. The regulations related to implementation of the reasonable charge payment methodology are found at 42 CFR part 405, subpart E. The current Medicare payment rules for glucose

[26] *https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.*

monitors and other DME are located at section 1834(a) of the Act and mandate payment on the basis of fee schedule amounts beginning in 1989. Blood glucose monitors are classified as routinely purchased items subject to the payment rules for inexpensive and routinely purchased DME at section 1834(a)(2) of the Act, which mandate payment for routinely purchased items on a purchase or rental basis using fee schedule amounts based on average reasonable charges for the purchase or rental of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987. These base fee schedule amounts are increased on an annual basis based on the update factors located in section 1834(a)(14) of the Act, which includes specific update factors for 2004 through 2008 for class III devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act. Routinely purchased equipment is defined in the regulations at 42 CFR 414.220(a)(2) as equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Section 1834(a)(1)(C) of the Act states that subject to subparagraph (F)(ii), this subsection must constitute the exclusive provision of this title [Title XVIII of the Act] for payment for covered items under this part [Medicare Part B] or under Part A to a home health agency. The fee schedule amounts for blood glucose monitors were revised in 1995 using special payment limits established in accordance with the ''inherent reasonableness'' authority at section 1842(s)(8) of the Act. The final notice (BPD–778–FN) establishing special payment limits for blood glucose monitors was published in the January 17, 1995 **Federal Register** (60 FR 3405), with the payment limits updated on an annual basis using the DME fee schedule update factors in section 1834(a)(14) of the Act.

Because certain CGMs have been approved or cleared by the FDA to replace blood glucose monitors for use in making diabetes treatment decisions, we believe that CGMs represent a newer technology version of glucose monitors paid for by Medicare in 1986 and 1987. In addition, the CGM systems function similar to the blood glucose monitors in using disposable supplies or accessories, such as test strips or sensors, to measure glucose levels in a patient's body, either from the patient's blood or interstitial fluid, and using durable equipment to convert these glucose measurements in a way that they can be displayed on a screen on the equipment. Therefore, we believe that the CGM receivers/monitors must be classified as routinely purchased DME since they are a technological refinement of glucose monitors routinely purchased from July 1986 through June 1987. The alternative would be to classify CGM receivers/monitors as other items of DME under section 1834(a)(7) of the Act and pay for the equipment on a capped rental basis. We also believe the average reasonable charge data for blood glucose monitors from 1986 and 1987 can be used to establish the fee schedule amounts for CGM receivers/monitors in accordance with our regulations 42 CFR 414.238(b) since CGM receivers/monitors are comparable to blood glucose monitors.

We do not believe that the special payment limits established in 1995 for blood glucose monitors must apply to CGM receivers/monitors because these special payment limits were based on specific pricing information on the cost of blood glucose monitors. We therefore proposed to continue using the fee schedule amounts established in CMS–1682–R based on the updated 1986/87 average reasonable charges for blood glucose monitors as the fee schedule amounts for CGM receivers/monitors. As noted, section 1834(a)(14) of the Act provides different annual update factors for class III DME versus other DME items and so the fee schedule amounts for class III CGM receivers are slightly higher (from $231.77 to $272.63 in 2020) than the fee schedule amounts for class II CGM receivers (from $208.76 to $245.59 in 2020).

With regard to the fee schedule amounts for supplies and accessories for CGMs, we proposed to separate payment for CGM supplies and accessories into three separate categories of supplies and accessories with different fee schedule amounts for each category. The current 2020 monthly fee schedule amounts of $222.77 and $259.20 for supplies and accessories for CGM systems apply to all types of class II or class III therapeutic CGMs, respectively, but were established based on supplier price lists for only one type of CGM system approved by FDA for use in making diabetes treatment decisions without the need to use a blood glucose monitor to verify the results (non-adjunctive CGMs). The supplier prices used to establish these fee schedule amounts were for non-adjunctive CGM systems that use a combination of sensors and transmitters to automatically send glucose measurements to the CGM receiver without manual intervention by the patient. We refer to this type of CGM system as a non-adjunctive system, or a system that both replaces a blood glucose monitor for use in making diabetes treatment decisions, and can alert the patient about dangerous glucose levels while they sleep based on the automatic transmission of the glucose readings to the receiver on a 24-hour basis. The fee schedule amounts of $222.77 and $259.20 for supplies and accessories for class II and class III CGMs, respectively, increased by the fee schedule update factor for 2021, would continue to apply to the supplies and accessories for automatic, non-adjunctive CGMs effective the effective date specified in the **DATES** section of this final rule.

If a beneficiary uses disposable ''adjunctive'' or ''non-therapeutic'' continuous glucose sensors and transmitters with an insulin infusion pump, the beneficiary and Medicare program would still incur expenses associated with use of blood glucose monitors and supplies. To avoid a situation where the beneficiary and program would pay twice for glucose monitoring supplies needed to accurately assess glucose levels, we proposed to establish the fee schedule amounts for supplies and accessories for adjunctive CGMs based on supplier prices for the sensors and transmitters minus the fee schedule amounts for the average quantity and types of blood glucose monitoring supplies used by insulin-treated beneficiaries who would be more likely to qualify for coverage of a CGM system based on a need to more closely monitor changes in their glucose levels. The adjunctive CGM system is not replacing the function of the blood glucose monitor and related supplies and therefore only provides an adjunctive or added benefit of alerting the beneficiary when their glucose levels might be dangerously high or low. Since the adjunctive CGM system cannot function alone as a glucose monitor for use in making diabetes treatment decisions, we proposed to reduce the payment for the adjunctive CGM system by the amount that is paid separately for the blood glucose monitor and supplies that are needed in addition to the adjunctive CGM system and are not needed in addition to the non-adjunctive CGM systems. Currently, Medicare is allowing coverage and payment for 135 test strips and lancets per month for insulin-treated beneficiaries using blood glucose monitors. Using the 2020 mail order fee schedule amounts for 50 test strips, divided by 50 and multiplied by 135,

plus the 2020 mail order fee schedule amounts for 100 lancets, divided by 100 and multiplied by 135, plus the 2020 mail order fee schedule amounts for a monthly supply of batteries, calibration solution, and lancet device, plus the 2020 fee schedule amount for the blood glucose monitor divided by 60 months (5-year lifetime) results in a 2020 monthly allowance of $34.35, which reflects what Medicare currently pays per month for an insulin-treated diabetic beneficiary. Based on supplier invoices and other prices, a 2020 monthly price for supplies and accessories used with class II or class III adjunctive CGMs would be calculated to be $209.97 and $233.12 respectively. Subtracting the monthly cost of the blood glucose monitor and supplies of $34.35 from the monthly cost of the supplies and accessories for class II adjunctive CGMs results in a net price of $175.62 ($209.97 − $34.35 = $175.62) for the monthly supplies and accessories used with a class II adjunctive CGM after backing out the cost of the separately paid blood glucose supplies. Subtracting the monthly cost of the blood glucose monitor and supplies of $34.35 from the monthly cost of the supplies and accessories for class III adjunctive CGMs results in a net price of $198.77 ($233.12 − $34.35 = $198.77) for the monthly supplies and accessories used with a class III adjunctive CGM after backing out the cost of the separately paid blood glucose supplies. Thus, we proposed 2020 fee schedule amounts of $175.62 and $198.77 (to be increased by the 2021 fee schedule update factor yet to be determined) for use in paying claims in 2021 for the monthly supplies and accessories for use with class II and class III adjunctive CGMs respectively. Reducing the payment amount for supplies and accessories used with adjunctive CGMs by the average monthly payment for the blood glucose monitor and supplies that Medicare and the beneficiary will still have to pay for avoids a situation where the beneficiary and the program pay twice for glucose testing supplies and equipment.

Finally, a third type of CGM system currently on the market is non-adjunctive but does not automatically transmit glucose readings to the CGM receiver and therefore does not alert the patient about dangerous glucose levels while they sleep. We refer to this as a manual, non-adjunctive CGM system. We proposed to establish 2020 fee schedule amounts of $46.86 (for class II devices) and $52.01 (for class III devices) for the monthly supplies and accessories for this third category, which only uses disposable batteries and sensors, based on supplier prices for the supplies and accessories for this category of CGMs.

Comment: Many commenters did not agree with the proposal to establish separate codes and pricing for supplies for three types of CGM systems on the market today. They strongly believe that linking coding and payment to the specific types of CGMs on the market today was not wise given the rapid pace in changes in technology for CGMs and diabetic equipment in general. Many commenters specifically objected to establishing separate codes and fee schedule amounts for automatic versus manual non-adjunctive CGMs. They recommended that the continuity of pricing regulations should be observed and that the initial prices established based on automatic non-adjunctive CGMs alone should apply to manual non-adjunctive CGMs as well. The manufacturer of the manual non-adjunctive CGM pointed out that their new product line for CGMs offers continuous data transmission from sensor to receiver, enabling customizable, real-time alarms and alerts that can automatically alert users when their glucose is high or low, including while they sleep, without any patient intervention. Therefore, it appears that the manual non-adjunctive CGM systems and classification are already becoming obsolete.

Response: We agree with the commenters that glucose monitoring technology is changing rapidly, and the Medicare fee schedule amounts for this equipment should not be limited solely to the technology that is currently on the market. We believe that the existing fee schedule amounts for non-adjunctive CGMs and supplies and accessories necessary for the effective use of non-adjunctive CGMs should continue to be used in paying claims for these items. However, the utility offered by adjunctive CGMs is not the same as the utility offered by non-adjunctive CGMs and so we do not believe that the existing fee schedule amounts established for the non-adjunctive CGMs and supplies and accessories necessary for the effective use of non-adjunctive CGMs should be used in paying claims for adjunctive CGMs and supplies and accessories necessary for the effective use of adjunctive CGMs, which clearly are different types of CGMs because they cannot be used in place of a blood glucose monitor. As explained further later in this section, we believe that separate fee schedule amounts are needed for adjunctive CGMs and supplies and related accessories versus non-adjunctive CGMs and related supplies and accessories.

Comment: Many commenters stated that more details were needed on how the proposed fee schedule amounts were established for the separate codes for supplies used with the three types of CGM systems on the market today.

Response: We are not finalizing the proposed fee schedule amounts for the monthly supplies and accessories associated with three different types of CGMs. Although we will continue using existing fee schedule amounts established for non-adjunctive CGMs, these are not fee schedule amounts for adjunctive CGMs and therefore do not apply to adjunctive CGMs.

Comment: Many commenters believe the proposed fee schedule amounts for supplies for CGMs were not sufficient to cover the cost of these items. A commenter stated that the proposed fee schedule amounts are below internet retail prices while other commenters simply stated that the proposed fee schedule amounts are below the cost of the products.

Response: The fee schedule amounts for supplies necessary for the effective use of CGMs is required to be established in accordance with the rules of the statute at section 1834(a) of the Act. In establishing Medicare fee schedule amounts for DME items, section 1834(a) of the Act requires that CMS base payment amounts on average reasonable charges in 1986 and 1987.

After consideration of the public comments we received, we are not finalizing the proposed fee schedule amounts for supplies and accessories used in conjunction with three types of CGMs. We believe the technology associated with the manual, non-adjunctive category is already becoming obsolete as more CGM products that automatically transmit sensor readings to the receiver and provide night time alarms come on the market. As the commenters pointed out, the technology is evolving quickly and establishing categories based on the different variations of CGMs on the market at any one time does not seem prudent or necessary. However, we do note that there is a substantial difference in the utility and capabilities of adjunctive CGMs versus non-adjunctive CGMs in that while both are able to alert the patient about dangerous or potentially dangerous glucose levels while they sleep, the non-adjunctive CGMs are also able to replace the use of a blood glucose monitor for accurate glucose measuring/testing purposes, while the adjunctive CGMs are not.

A blood glucose monitor and related supplies are necessary for patients using

adjunctive CGMs for accurate glucose measuring/testing purposes, while patients using a non-adjunctive CGM do not also need a blood glucose monitor. Existing fee schedule amounts for therapeutic or non-adjunctive CGMs and related supplies and accessories were specifically established for those types of CGMs and do not apply to adjunctive CGMs and related supplies and accessories. Therefore, fee schedule amounts for adjunctive CGMs and related supplies and accessories will be established in accordance with existing regulations for gap-filling under 42 CFR 414.238(b).

Summary of final provisions:

- We are finalizing our proposal to expand the classification of DME to a larger swath of CGMs, regardless of whether they are non-adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep and also replace blood glucose monitors) or adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep but do not replace blood glucose monitors), as long as such CGMs satisfy the regulatory definition of DME. For example, to be classified under the Medicare Part B benefit for DME, a potential CGM would need to have a durable component performing the medically necessary function of the device that can withstand repeated use for at least 3 years, and is not useful in the absence of illness or injury, in accordance with 42 CFR 414.202.
- We are not finalizing the proposed fee schedule amounts for CGMs and related supplies and accessories.
- Therefore, the fee schedule amounts for adjunctive CGM and related supplies and accessories will be established in accordance with existing regulations for gap-filling under 42 CFR 414.238(b).

VII. DME Interim Pricing in the CARES Act

In this final rule, we are finalizing the DME provisions of an IFC (May 2020 COVID–19 IFC) which made conforming changes to the DME payment regulations to reflect the CARES Act. The CARES Act (Pub. L. 116–136) was enacted on March 27, 2020. Section 3712 of the CARES Act specifies the payment rates for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs through the duration of the emergency period described in section 1135(g)(1)(B) of the Act. Section 3712(a) of the CARES Act continues our policy of paying the 50/50 blended rates for items furnished in rural and non-contiguous non-CBAs through December 31, 2020, or through the duration of the emergency period, if longer. Section 3712(b) of the CARES Act increased the payment rates for DME and enteral nutrients, supplies, and equipment furnished in areas other than rural and non-contiguous non-CBAs through the duration of the emergency period. Beginning March 6, 2020, the payment rates for DME and enteral nutrients, supplies, and equipment furnished in these areas are based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount, which results in higher payment rates as compared to the full fee schedule adjustments that were previously required under § 414.210(g)(9)(iv). We made changes to the regulation text at § 414.210(g)(9), consistent with section 3712 of the CARES Act, in an IFC that we published in the May 8, 2020 **Federal Register** titled ''Medicare and Medicaid Programs; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency.''

We received six timely pieces of correspondence in response to the May 2020 COVID–19 IFC provision titled ''DME Interim Pricing in the CARES Act''.

Comment: Many of the commenters appreciated that CMS modified the regulations consistent with section 3712 of the CARES Act.

Response: We thank the commenters for their support.

Comment: Many of the commenters cited reasons why the increased payments rates for DME are needed during the PHE. A commenter stated that ensuring access to personal protective equipment (PPE) and other DME for beneficiaries is essential to preventing the spread of COVID–19. Another commenter stated that this provision is in the overall interest to everyone—suppliers, health care professionals and beneficiaries—as suppliers will be able to maintain their inventory and be paid for items when there may be lags in care and beneficiaries may not be able to meet required visits due to the current PHE. Another commenter stated that there have been broad-based increases in the acquisition costs of certain home medical equipment (for example, ventilators, oxygen concentrators) as well as an increase in various overhead expenses (for example, requisite personal protective equipment and a more labor-intensive delivery/instruction methodology). The commenter stated that this has created financial hardships for many suppliers servicing the PHE patients.

Response: We believe that section 3712 of the CARES Act addresses these concerns about the need for payment increases during the PHE.

Comment: A commenter suggested that the adjustment for the 75/25 blend in the non-rural and contiguous non-CBAs should be maintained—at a minimum—to the end of 2020. The commenter also stated that if Round 2021 of the CBP is delayed, then the 75/25 blended rates should be extended from 2020 and subsequent years and maintained until the program is implemented. The commenter also stated that if Round 2021 is delayed, the 75/25 blended rates should be extended to all non-rural providers, including the former CBAs, until the next CBP can be implemented. The commenter then stated that if there is a delay in Round 2021, the 50/50 blended rates for rural areas should be extended until the next Round of the CBP is implemented.

Response: This provision implements section 3712 of the CARES Act. Section 3712(a) of the CARES Act continues our policy of paying the 50/50 blended rates for items furnished in rural and non-contiguous non-CBAs through December 31, 2020, or through the duration of the emergency period, if longer. Section 3712(b) of the CARES Act increased the payment rates for DME and enteral nutrients, supplies, and equipment furnished in areas other than rural and non-contiguous non-CBAs through the duration of the emergency period. As such, and because the PHE has continued into 2021, the 50/50 blended rates in rural and non-contiguous non-CBAs and the 75/25 blended rates in the non-rural contiguous non-CBAs have remained in effect. This provision does not address fee schedule adjustments after the PHE. We proposed a fee schedule adjustment rule for after the PHE in the November 2020 proposed rule.

After consideration of the public comments received, we are finalizing the following changes to § 414.210(g)(9):

- We are finalizing conforming changes to § 414.210(g)(9) as proposed, consistent with section 3712(a) and (b) of the CARES Act, but we are omitting the language in section 3712(b) of the CARES Act that references an effective date that is 30 days after the date of enactment of the law.
- We are finalizing our proposed revision to § 414.210(g)(9)(iii), which describes the 50/50 fee schedule adjustment blend for items and services furnished in rural and non-contiguous areas, to address dates of service from June 1, 2018, through December 31, 2020, or through the duration of the emergency period described in section

1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later.

- We are finalizing our proposed addition to § 414.210(g)(9)(v) which states that, for items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under ''this section'' (by which we mean § 414.210(g)(1) through (8)), and 25 percent of the unadjusted fee schedule amount. For items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) (referred to as ''this section'' in the regulation text).
- Finally, we are finalizing our revision of § 414.210(g)(9)(iv) to specify for items and services furnished in areas other than rural and noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) (''this section'' in the regulation text).

VIII. Collection of Information Requirements

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

IX. Regulatory Impact Analysis

A. Statement of Need

We are finalizing provisions that were included in the November 2020 proposed rule, as well as provisions that were in two IFCs—the May 2018 IFC and the May 2020 COVID–19 IFC.

The May 2018 IFC, finalized in this rule, with the exception of the wheelchair provisions, amended the regulations to revise the date that the initial fee schedule adjustment transition period ended and resumed 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 (83 FR 21912). The May 2018 IFC also made technical amendments to existing regulations for DMEPOS items and services to note the exclusion of infusion drugs used with DME from the DMEPOS CBP and reflected 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. Additionally, on April 26, 2021, we announced the continuation of effectiveness of the 2018 IFC and the extension of the timeline for publication of the final rule (86 FR 21949).

Specifically, this IFC resumed the blended adjusted Medicare fee schedule amounts for certain items and services that were furnished in rural and non-contiguous areas not subject to the CBP beginning June 1, 2018 in response to input from suppliers that the fully adjusted fee schedule amounts were not sufficient to cover the cost of furnishing items and services in remote areas of the country. Stakeholders and others posited that the increased fee schedule adjustments would ensure access to items and services in these areas to protect the health, safety, and well being of beneficiaries who needed these items and services. It was estimated that these adjustments 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. The goal of this IFC was to ensure beneficiary access to DME items and services in rural and non-contiguous areas not subject to the CBP during the transition period. CMS continued to study the impact of these change in payment rates on access to items and services in these areas. We believed that resuming the fee schedule adjustment transition period in rural and non-contiguous areas will promote stability in the DMEPOS market, and will enable CMS to work with stakeholders to preserve beneficiary access to DMEPOS.

The DMEPOS provisions included in the May 2020 COVID–19 IFC amended § 414.210 to temporarily increase the DME fee schedule amounts in certain areas during the PHE, as required by section 3712 of the CARES Act (85 FR 27569). The May 2020 IFC made several changes to payment and coverage policies, in an effort to allow health care providers maximum flexibility to minimize the spread of COVID–19 among Medicare and Medicaid beneficiaries, health care personnel, and the community at large, and increased their capacity to address the needs of their patients. The estimated Medicare gross benefit costs against the FY 2021 President's Budget baseline for the May 2020 IFC provision was $140 million (85 FR 27614). We also estimated that the May 2020 IFC provision also costs $30 million in Medicare beneficiary cost sharing at that time.

In addition, we are finalizing certain provisions that were included in the November 2020 proposed rule (85 FR 70358). This final rule establishes a fee schedule adjustment methodology for certain DMEPOS items and services furnished in non-competitive bidding areas (non-CBAs) on or after the effective date specified in the **DATES** section of this final rule, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. This policy continues higher fee schedule amounts for certain items and services furnished in rural and non-contiguous areas of the country. This fee schedule adjustment methodology is responsive to stakeholders such as DMEPOS suppliers, who are of the view that fully adjusted fee schedule amounts are not sufficient to cover the costs of furnishing DMEPOS items and services in remote areas of the country.

Section 1834(a)(1)(G) of the Act specifically mandates that we take into account the average volume of items and services furnished by suppliers in CBAs compared to the average volume of items and services furnished by suppliers in non-CBAs when adjusting fee schedule amounts for DMEPOS items and services. As noted elsewhere in this rule, the average volume of items and services furnished by suppliers in many non-CBAs that are rural and non-contiguous areas is lower than the average volume of items and services furnished by suppliers in many CBAs. We believe that different payments are necessary to ensure access to items and services for beneficiaries in these rural and non-contiguous areas to protect their health, safety, and well-being.

This final rule also establishes procedures for making benefit category and payment determinations for new items and services that are durable medical equipment (DME), prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B.

This policy would help to prevent delays in making benefit category and payment determinations for new and innovative DMEPOS technologies that could improve the health and safety of Medicare beneficiaries. This final rule also classifies continuous glucose monitors (CGMs) as DME under Medicare Part B. This policy increases the number and types of CGMs classified under the Medicare Part B benefit for DME, so that beneficiaries and their physicians have more treatment options available.

B. Overall Impact

We have examined the impact of the three provisions covered in this rule 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 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), and the Congressional Review Act (5 U.S.C. 801–808).

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 significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). This rule is economically significant. The aggregated transfer costs are estimated to be approximately $6.030 billion during the period CY 2022 through CY 2026. This aggregate transfer cost is the sum of transfers from the Federal Government, the beneficiaries, and the State governments to the DME suppliers. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). 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 these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

Our baseline assumption assumes that in the absence of this final rule, the fee schedule amounts for certain DMEPOS items furnished in non-CBAs on the effective date specified in the **DATES** section of this final rule or after the end of the PHE, whichever is later, would be fully adjusted based on information from the CBP. In addition, our baseline assumption assumes that in the absence of this final rule, benefit category determinations would continue to only be made through the NCD process, notice and comment rulemaking, or by the MACs on an individual, claim-by-claim basis. Also, the baseline assumption assumes that in the absence of this final rule, adjunctive CGMs would continue to be considered items that are not primarily and customarily used to serve a medical purpose and would not be classified as DME. Finally, it assumes that in the absence of this final rule, the DMEPOS provisions included in the 2018 and 2020 IFCs would not be finalized, and CMS would need to finalize these provisions at some other time. CMS has calculated a baseline based on predicted Medicare costs if CMS were to not finalize the provisions of this final rule noted previously.

For purposes of this detailed economic analysis, CMS established a baseline, as described previously, to measure the impacts of certain provisions of this final rule. CMS makes certain assumptions as part of this analysis. For example, this analysis assumes that nothing would arise or occur (for example, new legislation) to prevent CMS from fully adjusting the fee schedule amounts for certain DME items and services furnished in non-competitive bidding areas on or after the effective date of this final rule. Note that for the economic analysis in the November 2020 proposed rule, CMS used the FY 2021 President's budget as a baseline, which resulted in a proposed rule that was deemed primarily designated as not economically significant. However, as a result of the new baseline described previously, we have determined that this final rule is economically significant. We have determined the following impacts on benefits, costs, and transfers for this economically significant rule as follows:

1. Benefits

a. May 2018 IFC

This rule finalizes certain provisions of the May 2018 IFC, thereby benefitting DMEPOS suppliers. We assume that certain suppliers might have chosen not to furnish items and services in rural and non-contiguous areas in the absence of these higher payments.

b. May 2020 COVID–19 IFC

This rule finalizes certain provisions of May 2020 COVID–19 IFC, thereby benefitting DMEPOS suppliers that furnish items in certain non-CBAs. Such suppliers receive higher payments for furnishing DMEPOS items and services.

c. November 2020 Proposed Rule

This rule finalizes certain provisions of the November 2020 proposed rule. As a result of this final rule, access to DMEPOS items and services in rural and non-contiguous areas will be improved. In addition, this final rule establishes a BCD and payment determination process for DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations and classifies adjunctive CGMs as DME. These provisions will benefit Medicare beneficiaries and the DMEPOS industry by providing a clear, predictable process for benefit category and payment determinations, and will make more CGMs eligible for coverage and payment under the Medicare Part B benefit for DME.

2. Costs

The only cost that will be incurred is a one-time cost to private entities for reviewing and reading this final rule.

3. Transfers

a. May 2018 IFC

As a result of the provisions of this IFC, DME suppliers received increased payments for furnishing items in remote rural and non-contiguous areas in 2018. Medicare beneficiaries, on the other hand, incurred higher copayments, which resulted in higher transfer costs from the Federal Government and Medicare beneficiaries to DMEPOS suppliers. The provisions of the May 2018 IFC that CMS is finalizing in this final rule affected payment rates for DMEPOS items and services furnished from June through December of 2018. Therefore, finalizing these provisions of this IFC in this rule has no economic impact on payment or cost sharing for these items.

The May 2018 IFC resumed the transitional adjusted Medicare fee schedule amounts for certain items and services that were furnished in rural and non-contiguous non-competitive bidding areas beginning June 1, 2018 through December 31, 2018. The May 2018 IFC also made technical amendments to the regulation to reflect the extension of the fee schedule adjustment transition period from June 30, 2016 to December 31, 2016 that was mandated by the CURES Act. In addition, the May 2018 IFC also made technical amendments to existing regulations for DMEPOS items and services to reflect the exclusion of infusion drugs used with DME from the DMEPOS CBP. The May 2018 IFC also contained provisions related to wheelchair payment, which we further discuss in the FY 2022 IRF final rule (86 FR 42362).

In the May 2018 IFC, CMS estimated that the transitional adjusted Medicare fee schedule amounts for certain items and services that were furnished in rural and non-contiguous areas beginning June 1, 2018 through December 31, 2018, cost over $290 million in Medicare Part B benefit payments and $70 million in Medicare beneficiary cost sharing (83 FR 21923). These fee schedule adjustment costs—both to the Medicare program and to beneficiaries—were incurred during 2018 and will have no further financial impact at this time. Similarly, for dually eligible beneficiaries, the Medicaid Federal and States' costs for this May 2018 IFC were $10 million and $10 million, respectively. The portions of the May 2018 IFC that CMS is finalizing in this final rule are estimated to have no impact after the effective date of the final rule because all of the costs and financial impacts of the IFC happened in the past, and this IFC will not have an impact going forward.

Comment: A few commenters did not agree with CMS using the cost of the rule to determine how extensive the payment increases should have been. The commenters stated CMS used the budget implications as a primary determinant in choosing to extend payment increases only to the rural and non-contiguous non-CBAs. The commenters recommended that CMS instead base its policy decision primarily on ensuring appropriate beneficiary access, and that any budgetary impacts should be secondary to CMS establishing a policy that ensures that beneficiaries have appropriate access to medically necessary DMEPOS items. Another commenter stated that the cost of the rule is far less than costs to other health care entities and Medicare beneficiaries due to the lack of access to DME. Finally, a commenter stated the rule will increase costs for certain Medicare beneficiaries, potentially impacting those on the margin, but they believe increased access to quality DME and supplier/brand name choice is a reasonable trade-off. The commenter claimed that the true impact of the forecasted cost-sharing is unclear due to secondary insurance. The commenter also stated that for beneficiaries who are dually eligible for both Medicare and Medicaid, Medicaid will typically pay the cost sharing, offsetting this total amount. The commenter stated that many beneficiaries who do not qualify for Medicaid but cannot afford secondary insurance do not end up paying for DME cost sharing out of pocket, and that it is common for DME suppliers to write off co-payments when beneficiaries cannot afford to pay after the supplier has made reasonable attempts to collect the balance. The commenter encouraged CMS to monitor how this cost increase impacts beneficiaries.

Response: We believe that we considered beneficiary access to DMEPOS items in our analysis and that the policy was implemented, to a large degree, based on improved access.

In the May 2018 IFC, we summarized the feedback we received from the March 23, 2017 stakeholder call and related written comments (83 FR 21916). The majority of these comments were from the DMEPOS industry and focused on rural and non-contiguous areas of the country. For instance, commenters stressed that rural and non-contiguous areas of the country face unique costs, 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 in rural and non-contiguous areas, and 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. These comments factored into our decision to only apply the 50/50 blended rates to rural and non-contiguous non-CBAs. We also further explain in our CY 2019 ESRD PPS DMEPOS final rule our reasons for only applying the 50/50 blended rates to rural and non-contiguous areas (83 FR 57030).

b. May 2020 COVID–19 IFC

As a result of the provisions of this finalized May 2020 COVID–19 IFC, even though DME suppliers received increased payments for furnishing items in remote rural and non-contiguous areas, Medicare beneficiaries, on the other hand, incurred higher cost-sharing, which resulted in higher transfer costs from the Federal Government and Medicare beneficiaries to the DMEPOS suppliers. The provisions of the May 2020 COVID–19 IFC that CMS is finalizing in this final rule affect payment rates for DMEPOS items and services furnished from March 6, 2020 through the end of the PHE, which is assumed to end after the effective date of this rule in April 2022. Finalizing these provisions of this IFC in this rule has a negligible economic impact on payment or cost sharing for these items.

CMS's Office of the Actuary determined that this provision against the FY 2021 President's Budget baseline increased payments in the estimated amount of $140 million from the Federal Government to DMEPOS suppliers (85 FR 27614). Additionally, the Medicare beneficiary transfer was $30 million to DME suppliers. This provision also impacts the federal portion of the Medicaid increased payments: The federal cost is $5 million for dually eligible beneficiaries, while the State portion of the Medicaid increased payments is $5 million.

This section finalizes a temporary increase to certain DME payment rates, as required by section 3712 of the CARES Act. Section 3712 of the CARES Act increases Medicare expenditures, as well as beneficiary cost-sharing by increasing Medicare payment rates for certain DMEPOS items furnished in non-rural and contiguous non-competitively bid areas. The increase is a result of paying a blend of 75 percent of the fully adjusted payment rates and 25 percent of the unadjusted payment

rates for items and services furnished in non-rural and contiguous non-CBAs throughout the United States and is estimated to increase affected rates, averaging 33 percent.

Comment: A commenter referenced the impact of this provision, which states that ''this change may also affect the federal financial participation limit for DMEPOS items and services furnished to Medicaid beneficiaries, but we are unable to quantify the effect.'' The commenter stated that despite the potential effects this provision may have on the federal financial participation limit, they strongly believe that these DMEPOS items and services remain critical for beneficiaries. Therefore, they expressed their support for this provision.

Response: We agree Medicaid rates are affected due to the interaction between the federal financial participation limit and Medicare rate changes, although the amount of the change is currently not quantifiable.

c. November 2020 Proposed Rule

The fee schedule adjustment methodology that CMS is finalizing in this final rule involves three transfers of monies: (1) Federal Government to DMEPOS suppliers; (2) beneficiaries to DME suppliers; and (3) State governments to DME suppliers. The amounts of these transfers are explained later in this section. CMS's Office of the Actuary has determined that the fee schedule adjustment methodology will increase Medicare gross benefit payments in the estimated amount of $4.55 billion from CY 2022 to CY 2026 as compared to the baseline discussed previously. During the years CY 2022 to CY 2026, the estimated gross payments will be as follows: $200 million, $770 million, $1.110 billion, $1.190 billion and $1.280 billion, respectively.

TABLE 3—IMPACT OF CHANGING THE ADJUSTED FEE METHODOLOGY

CY	Impact on benefit gross payments (in dollars to the nearest 10 million)	Impact on beneficiary cost sharing (in dollars to the nearest 10 million)
2022	200	50
2023	770	190
2024	1,110	280
2025	1.190	300
2026	1,280	320

Payments increase each year as a result of annual fee schedule updates and increases in utilization of items and services. As stated before, the increased payments result from paying a 50/50 blended rate for certain DME items furnished in rural and non-contiguous non-competitive bidding areas. This will increase the beneficiary copayments by $1.14 billion from CY 2022 to CY 2026. In addition, the federal portion of the Medicaid increased payments during this period is $195 million for the dually eligible beneficiaries, and the State portion of the Medicaid increased payments is $145 million during CY 2022 to CY 2026 ($10 million, $25 million, $35 million, $40 million, and $40 million, respectively, during CY 2022 through CY 2026). Note, the federal financial participation limit for DME in Medicaid, as discussed in section 1903(i)(27) of the Act, adds an indeterminable cost to the federal share of the Medicaid payments to States.

Comment: A commenter stated that a blind spot is the impact of the trickle down of rates to Medicaid, Medicare Advantage, and private insurances who base their rates on Medicare rates.

Response: We thank the commenter for commenting on the impact of this particular provision. Impact analyses consider the impact of policies on the MA rates and on private insurances (as they provide supplemental insurance that pays copayments on behalf of Medicare beneficiaries). So, supplemental insurers pay more or less depending on whether fees increase or decrease. Regarding Medicaid, we note that we provided details regarding the impact this particular provision has on Medicaid in the November 2020 proposed rule (85 FR 70406) and this final rule.

d. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

We are finalizing the procedures for BCDs and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations with no additional administrative costs to CMS and no fiscal impact when measured against the baseline. We do not expect that the BCD and payment determination procedures that CMS is finalizing in this rule will affect the ability of manufacturers to make new items and services. We note that this final rule continues our use of an already established process (public meetings) to make BCD and payment determinations for new items and services that are durable medical equipment (DME), prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations.

e. Classification and Payment for Continuous Glucose Monitors Under Medicare Part B

This final rule classifies certain CGMs as DME. This will result in an increase in the number of CGM products beneficiaries and physicians can choose that would be classified as DME. We do not anticipate that this change will impact overall utilization of CGMs covered under the DME benefit and Medicare payment because beneficiaries have had access to some types of CGMs since 2017. Because we do not anticipate changes in CGM utilization or payments for glucose monitoring equipment as a result of this final rule, this final rule will not result in any transfers.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Thus, using the 2020 wage information from the Bureau of Labor Statistics (BLS) *https://www.bls.gov/oes/current/oes119111.htm* for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this

rule is $114.24 per hour, including overhead and fringe benefits. For manufacturers of DMEPOS products, DMEPOS suppliers, and other DMEPOS industry representatives, we assume the same cost for reviewing this rule. Assuming an average reading speed for those very familiar with the topic matter, we estimate that it would take approximately 5 hours for the medical and health service managers or industry representatives to review this final rule. For each entity that reviews this final rule, the estimated cost is $571.20 (5 hours x $114.24 per hour). Therefore, we estimate that the total cost of closely reviewing this final rule is a one-time cost of $1,005,312 ($571.20 × 1,760 reviewers). Note the 1,760 reviewers represent about 2 percent of the current number of DME suppliers. Two percent was chosen based on the assumption that most entities would use trade industry summaries to inform themselves on the contents of the rule.

D. Alternatives Considered

This section addresses the alternatives considered only for the fee schedule adjustment methodology provisions from the November 2020 proposed rule. This section does not consider alternatives to the BCD provisions, CGM provisions, May 2020 COVID–19 IFC DMEPOS provisions (no alternatives were contained in the IFC) or the May 2018 IFC (the effects of which were limited to 2018). In the case of the CGM provisions, we are not finalizing the proposed fee schedule amounts for CGMs and related accessories and supplies. We do not believe that the decision not to finalize the proposed fee schedule amounts results in any costs or savings for the program or beneficiaries since one of the proposed categories of CGM supplies and accessories is being phased out and the fee schedule amounts for another category of adjunctive CGMs and supplies and accessories will be established in accordance with 42 CFR 414.238, which reflects our longstanding policies and procedures for gap-filling fee schedule amounts in accordance with the rules of the statute. Therefore, the impacts of all three alternatives for the November 2020 proposed rule discussed later in this section, are considered against the previously discussed baseline (that is, the baseline calculations assume that CMS would fully adjust the fee schedule amounts for DME items and services furnished all non-CBAs, including rural and non-contiguous non-CBAs).

Therefore, in regards to the November 2020 proposed rule, the first alternative was to pay fully adjusted fee schedule rates in all areas except super rural areas or non-contiguous areas and pay 120 percent of national average of the single payment amounts in super rural areas and non-contiguous areas. The Office of the Actuary estimated that this alternative would increase Medicare gross payments from CY 2022 to CY 2026 by $380 million. This would increase beneficiary copayments by $80 million from CY 2022 to CY 2026. In addition, the federal portion of the Medicaid would increase payments during this period to $20 million for the dually eligible beneficiaries, and the State portion of the Medicaid would also increase payments to $20 million.

The second alternative was to adjust fee schedule amounts for items and services furnished in non-CBAs between 2022 and 2023 based on a 75/25 blend of adjusted and unadjusted rates and phase in the full fee schedule adjustments beginning January 1, 2024. The Office of the Actuary estimates that this alternative would increase Medicare gross payments by $1.13 billion and increase beneficiary copayments by $280 million from CY 2022 to CY 2026. In addition, the federal portion of the Medicaid would increase payments during this period to $50 million for the dually eligible beneficiaries, and the State portion of the Medicaid would increase payments to $35 million.

Finally, the third alternative was to extend the transition period for phasing in fully adjusted fee schedule rates at 42 CFR 414.210(g)(9), which would result in the same payment amounts as the proposed rule for just a 2-year period. The Office of the Actuary estimated that this alternative would increase Medicare gross payments from CY 2022 to CY 2026 by $1.41 billion for items and services furnished in non-CBAs between 2022 and 2023. As a result, this would increase beneficiary copayments by $350 million from CY 2022 to CY 2026. In addition, the federal portion of Medicaid payments would increase during this period from CY 2022 to CY 2026 by $60 million for dually eligible beneficiaries, and the State portion of Medicaid payments would increase by $45 million.

The three alternatives, which were estimated to cost less than the policy that CMS is finalizing in this rule, were not considered primarily due to the assumption that maintaining the current fee schedule adjustment methodology would provide for better access to DMEPOS items and services in rural and non-contiguous areas than two of the alternatives, and would provide such access for a longer period of time than the three alternatives.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), we have prepared an accounting statement in Table 4, showing the classification of the impacts associated with the fee schedule adjustment methodologies included in the November 2020 proposed rule in this final rule. The November 2020 proposed rule, which is being finalized in this rule, is estimated to increase payments ($912 million annualized at 7 percent) from the Federal Government to DMEPOS suppliers by $4.550 billion from CY 2022 to CY 2026, as compared to a baseline that assumes that as of the effective date, CMS would pay fully adjusted fee schedule amounts in all non-competitive bidding areas for DMEPOS items subject to competitive bidding. In addition, the accounting statement considers the transfer amounts from beneficiaries to DME suppliers of $1.14 billion ($219 million annualized at 7 percent) from CY 2022 to CY 2026. Finally, the accounting statement accounts for the cost of the States' portion of the Medicaid payments for dually eligible beneficiaries, costing approximately $150 million from CY 2022 to CY 2026 ($28 million annualized at 7 percent. The annual costs increase over time because of annual updates to adjusted fee schedule amounts and Medicare enrollment increases.

TABLE 4—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs:				

TABLE 4—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS—Continued

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($million/year)	0.20	2021	7	2022–2026
	0.20	2021	3	2022–2026
Regulatory Review Costs				
Transfers:				
Annualized Monetized ($million/year)	912	2021	7	2022–2026
	933	2021	3	2022–2026
From Whom to Whom	Transfers from Federal Government to DME Suppliers			
Annualized Monetized($million/year)	219	2021	7	2022–2026
	224	2021	3	2022–2026
From Whom to Whom	Transfers from Medicare Beneficiaries to DME Suppliers			
Annualized Monetized ($million/year)	28	2021	7	2022–2026
	28	2021	3	2022–2026
From Whom to Whom	Transfers from State Government to Beneficiaries			

F. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) imposes certain requirements with respect to federal rules that are (1) required to be published as a notice of proposed rulemaking subject to the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b)); and (2) likely to have a significant economic impact on a substantial number of small entities.

Note that the finalized provisions of the May 2018 IFC and the finalized May 2020 COVID–19 IFC impose no burden on a substantial number of small entities. However, the provisions of this final rule that were proposed in the November 2020 proposed rule will have a positive impact on DMEPOS suppliers. This rule will increase DMEPOS supplier revenues for furnishing DMEPOS items and services subject to the fee schedule adjustments in rural and non-contiguous areas. As compared to the baseline, the revenues for DMEPOS suppliers will be higher due to the 50/50 blended fee schedule adjustments in rural and non-contiguous areas.

The 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, we estimate that almost all DMEPOS suppliers are small entities, as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year).

According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards,* DME suppliers may fall into either the North American Industrial Classification System (NAICS) code 532291 and Home Health Equipment Rental code 44610, Pharmacies and Drug Stores. The SBA defines Pharmacies and Drug Stores as businesses having less than $30 million and Home Health Equipment Rental as businesses having less than $35 million in annual receipts.

TABLE 5—DMEPOS SUPPLIERS SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/small entity threshold (million)	Total small businesses
446110 ...	Pharmacies and Drug Stores	$30	18,503
532291 ...	Home Health Equipment Rental	35	673

Source: 2012 Economic Census.

Since we are uncertain of the DMEPOS suppliers' composition, we sought comments from the public to aid in understanding the various industries that supply DMEPOS products. So far, we have identified only the two industries in Table 5.

TABLE 6—DMEPOS SUPPLIERS CONCENTRATION RATIOS

[(NAICS 532292) home health equipment rental]

Firm size (by receipts)	Firm count	% of small firms (%)	Total average revenue	Average revenue per firm to total average revenue (%)
SMALL FIRMS	673	100.0	$42,468,578	100
<100,000	57	8.47	$45,912	0.11
100,000–499,999	207	30.76	$287,647	0.68
500,000–999,999	137	20.36	$722,080	1.70
1,000,000–2,499,999	148	21.99	$1,599,811	3.77
2,500,000–4,999,999	64	9.51	$3,430,781	8.08
5,000,000–7,499,999	16	2.38	$5,599,563	13.19
7,500,000–9,999,999	15	2.23	$8,909,267	20.98
10,000,000–14,999,999	12	1.78	$10,715,917	25.23
15,000,000–19,999,999	10	1.49	$11,157,600	26.27
20,000,000–24,999,999	3	0.45	NA	NA
25,000,000–29,999,999	2	0.30	NA	NA
30,000,000–34,999,999	2	0.30	NA	NA
LARGE FIRMS:				
Receipts >$35 Million	46	NA	NA	NA

Source: 2012 County Business Patterns and 2012 Economic Census.

Average revenue data are not included for the Home Health Equipment Rentals (NAICS 532291) for firms greater than 20,000,000 in receipts. Moreover, no revenue data are available for large firms in Home Heath Equipment Rentals Industry.

TABLE 7—DMEPOS SUPPLIERS CONCENTRATION RATIOS

[NAICS 446110 pharmacies and drug stores]

Firm size (by receipts)	Firm count	% of small firms (%)	Total average revenue	Average revenue per firm to total average revenue (%)
SMALL FIRMS	18,503	100.0	$89,692,509.68	100
<100,000	751	0.04	$48,023.97	0.05
100,000–499,999	2,060	0.11	$283,085.44	0.32
500,000–999,999	1,919	0.10	$740,942.68	0.83
1,000,000–2,499,999	5,767	0.31	$1,742,084.10	1.94
2,500,000–4,999,999	5,094	0.27	$3,556,077.54	3.96
5,000,000–7,499,999	1,638	0.09	$6,068,161.78	6.77
7,500,000–9,999,999	583	0.03	$8,544,548.89	9.53
10,000,000–14,999,999	432	0.02	$11,705,081.02	13.05
15,000,000–19,999,999	147	0.01	$16,415,476.19	18.30
20,000,000–24,999,999	68	0.00	$20,211,073.53	22.53
25,000,000–29,999,999	44	0.00	$20,377,954.55	22.72
LARGE FIRMS:				
Receipts >$30 Million	349	NA	NA	NA

Source: 2012 County Business Patterns and 2012 Economic Census.

Tables 6 and 7 show that the economic impacts are disproportionate for small firms. Moreover, these tables show the revenues for each of the size categories, and the revenue impact per small entity. For example, in table 6, 57 of the smallest firms earn only 0.11 percent of the revenue in its industry; while, in table 7, 751 of the smallest firm earn only 0.05 percent of the revenue in its industry.

Therefore, as can be seen in Tables 6 and 7, almost all DMEPOS suppliers are small entities as that term is used in the RFA.[27] Additionally, Tables 6 and 7 show the disproportionate impacts among firms, and between small and large firms. In Table 6 and 7, each industry, Pharmacies and Drug Stores and Home Health Equipment, Rental firm size (by receipts), firm count, percentage of small firms, total average revenue, and percentage of average revenue to total revenue of small firms were estimated separately to determine the DMEPOS concentration ratios. Note, there are missing data. See footnotes in Table 6.

For purposes of the RFA, approximately 98.15 percent of pharmacies and drugs stores (18,503/18,852) and 93.60 percent of home health equipment rental (673/719) firms are considered small businesses according to the SBA's size standards with total revenues of $30 and $35 million or less respectively in any 1 year. Individuals and states are not included in the definition of a small entity.

This rule does not affect health care enterprises operated by small government entities such as counties or towns with populations 50,000 or less. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. The RFA threshold analysis, therefore, indicates

[27] Note, the entire population of DMEPOS suppliers is not known at this time. However, based on our experience, the majority of DMEPOS suppliers are covered in the two industries identified.

that there is not a significant economic impact on a substantial number of small entities. As shown in Table 6, the average total revenue earned by the DMEPOS Home Health Equipment Rental industry is approximately $42,468,578 million and the total transfer costs amount to approximately $6.261 billion, which is only 0.67 percent. Additionally, as shown in Table 7, the average total revenue earned by DMEPOS Pharmacies and Drugs Stores is approximately $89,692,509.68 million and the total transfer costs amount to approximately $6.030 billion, which is 1.49 percent. As a result, we believe that this 3 percent threshold (the threshold used by the Department of Health and Human Services to determine a significance threshold under the RFA) will not be reached for both the Home Health Equipment Rental industry and the Pharmacies and Drugs Stores industry mentioned in this rule. Furthermore, the regulation review costs mentioned previously, is *de minimis* and will not impose any additional burden on these small businesses.

Even though a substantial number of small suppliers will benefit from the 50/50 blended fee schedule amounts in rural and non-contiguous non-CBAs, we do not believe that this regulation will result in a significant economic impact on a substantial number of small entities. Therefore, the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 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, updated annually for inflation. In 2021, that threshold is approximately $158 million. This final rule imposes mandates that will result in anticipated costs to state, local and Tribal governments or private sector, but the transfer costs will be less than the threshold. As a result, this final rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $158 million in any one year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does impose costs on state or local governments, the requirements of Executive Order 13132 are applicable.

The State governments' Medicaid payments in aggregate for dual eligible beneficiaries will increase by an estimated $150 million from CY 2022 to CY 2026.

I. Congressional Review Act

This final 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 22, 2021.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 414 as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER SERVICES

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

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 2. Section 414.114 is added to subpart C to read as follows:

§ 414.114 Procedures for making benefit category determinations and payment determinations for new PEN items and services covered under the prosthetic device benefit; splints and casts; and IOLs inserted in a physician's office covered under the prosthetic device benefit.

(a) *Definitions.* For the purpose of this subpart:

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of a prosthetic device at section 1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services that may be covered and paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit.

(2) If a preliminary determination is made that the item or service is parenteral or enteral nutrients, supplies, and equipment covered under the prosthetic device benefit, splints and casts or other devices used for reductions of fractures or dislocations, or IOLs inserted in a physician's office covered under the prosthetic device benefit, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(4) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

■ 3. Section 414.210 is amended by revising paragraphs (g)(1)(v) and (g)(2) and adding paragraph (g)(9)(vi) to read as follows:

§ 414.210 General payment rules.

* * * * *

(g) * * *

(1) * * *

(v) For items and services furnished before February 28, 2022, the fee schedule amount for all areas within a state that are defined as rural areas for the purposes of this subpart is adjusted to 110 percent of the national average price determined under paragraph (g)(1)(ii) of this section.

(2) Payment adjustments for areas outside the contiguous United States and for items furnished on or after February 28, 2022 in rural areas within the contiguous United States using information from competitive bidding programs.

(i) For an item or service subject to the programs under subpart F, the fee schedule amounts for areas outside the contiguous United States (Alaska, Hawaii, and U.S. territories) for items and services furnished from January 1, 2016, through December 31, 2020 are reduced to the greater of—

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

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

(ii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for areas outside the contiguous United States for items and services furnished on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

(A) Fifty percent of the greater of the average of the single payment amounts for the item or service for CBAs outside the contiguous United States or 110 percent of the national average price for the item or service determined under paragraph (g)(1)(ii) of this section; and

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

(iii) For an item or service subject to the programs under subpart F of this part, the fee schedule amounts for rural areas within the contiguous United States for items and services furnished on or after <AMDPAR>, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, is adjusted to equal the sum of—

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

(B) Fifty percent of the fee schedule amount for the area in effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors specified in sections 1834(a)(14), 1834(h)(4), and 1842(s)(1)(B) of the Act, respectively, for durable medical equipment and supplies, off-the-shelf orthotics, and enteral nutrients, supplies, and equipment.

* * * * *

(9) * * *

(vi) For items and services furnished in all areas with dates of service on or after February 28, 2022, or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, whichever is later, based on the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section.

* * * * *

■ 4. Section 414.240 is added to subpart D to read as follows:

§ 414.240 Procedures for making benefit category determinations and payment determinations for new durable medical equipment, prosthetic devices, orthotics and prosthetics, surgical dressings, and therapeutic shoes and inserts.

(a) *Definitions.* For the purpose of this subpart—

Benefit category determination means a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Act, a prosthetic device at section 1861(s)(8) of the Act and further defined under section 1834(h)(4) of the Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute.

(b) *General rule.* The procedures for determining whether new items and services addressed in a request for a HCPCS Level II code(s) or by other means meet the definition of items and services paid for in accordance with this subpart are as follows:

(1) At the start of a HCPCS coding cycle, CMS performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Act, and, if not excluded by statute, whether the item or service is durable medical equipment, a prosthetic device as further defined under section 1834(h)(4) of the Act, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert.

(2) If a preliminary determination is made that the item or service is durable medical equipment, a prosthetic device, an orthotic or prosthetic, a surgical dressing, or a therapeutic shoe or insert, CMS makes a preliminary payment determination for the item or service.

(3) CMS posts preliminary benefit category determinations and payment determinations on *CMS.gov* approximately 2 weeks prior to a public meeting.

(4) After consideration of public consultation provided at a public meeting on preliminary benefit category determinations and payment determinations for items and services, CMS establishes the benefit category determinations and payment determinations for items and services through program instructions.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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