



[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1738-P]

RIN 0938-AU17

Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish 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 for items 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 Social Security Act, whichever is later; application evaluation processes and other procedures related to Healthcare Common Procedure Coding System (HCPCS) Level II code applications; and 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 proposes to classify continuous glucose monitors (CGMs) as DME under Medicare Part B and establish fee schedule amounts

for these items and related supplies and accessories. Also, this proposed rule would expand the scope of the Medicare Part B benefit for DME by revising the interpretation of the “appropriate for use in the home” requirement in the definition of DME specifically for certain drugs or biologicals infused in the home using an external infusion pump. This proposed rule would also make conforming changes to the regulations related to implementation of section 106 of the Further Consolidated Appropriations Act, 2020.

DATES: To be assured consideration, comments must be received at one of the addresses specified in the ADDRESSES section, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1738-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may send written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1738-P,
P.O. Box 8013,
Baltimore, MD 21244-8010.

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

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

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1738-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT:

DMEPOS@cms.hhs.gov or Alexander Ullman, 410-786-9671, for issues related to the DMEPOS payment policy.

HCPCS@cms.hhs.gov or Kim Campbell, 410-786-2289, for issues related to HCPCS.

HomeInfusionPolicy@cms.hhs.gov for issues related to home infusion therapy services payment policy.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Website as soon as possible after they

have been received: <http://www.regulations.gov>. Follow the search instructions on that Website to view public comments.

I. Executive Summary

A. Purpose

This proposed rule contains proposals 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, classification and payment for CGMs under the Part B benefit for DME to establish the benefit category and payment rules for these items, and the HCPCS Level II code application process to increase transparency and gather public input on proposed code application procedures. This proposed rule would expand the scope of the Medicare Part B benefit for DME by revising the interpretation of the “appropriate use in the home” requirement in the definition of DME at 42 CFR 414.202. External infusion pumps used to administer certain drugs or biologicals in the home would meet the definition of DME in cases where assistance in the patient’s home from a skilled home infusion therapy supplier is necessary during the infusion and these home infusion therapy services are separately covered and paid for by Medicare under the home infusion therapy services benefit. This proposed rule would also make conforming changes to the regulations related to implementation of section 106 of the Further Consolidated Appropriations Act, 2020.

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

The purpose of this proposal 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 April 1, 2021 or the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (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 II.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. CMS previously established transition rules for phasing in the fee schedule adjustments under 42 CFR 414.210(g)(9), and these rules address the phase in of the fee schedule adjustments for items furnished through December 31, 2020. The purpose of this proposal is to establish revised DMEPOS 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 PHE for COVID-19, whichever is later.

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 address our intent to finalize and address comments received on the May 11, 2018 interim final rule (83 FR 21912) entitled “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” including

comments related to the conforming amendment excluding infusion drugs from the DMEPOS CBP.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

CMS establishes and maintains certain codes under the HCPCS Level II and is responsible for making decisions about additions, revisions, and discontinuations to those codes. This proposed rule proposes application procedures and evaluation processes for external HCPCS Level II code applications related to drug or biological products, and non-drug, non-biological items and services, as defined in this proposed rule.

4. 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 proposal 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). CMS decided to expand these procedures to all new items and services in 2005. We are proposing to codify in regulation 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 current CMS practice, the proposed procedures will incorporate public consultation on these determinations.

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 Title XVIII. 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 will need to determine what payment rules would apply to the item if other statutory criteria for coverage of the item are met, such as whether the item or service meets the reasonable and necessary criteria under section 1862(a)(1)(A) of the Act.

Therefore, we are proposing procedures 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, in order to promote transparency, continue our longstanding practice of establishing coverage and payment 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 soon after they are identified through the HCPCS code application process, and prevent delays in access to new technologies 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.

5. Classification and Payment for Continuous Glucose Monitors under Medicare Part B

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

6. Expanded Classification of External Infusion Pumps as DME

The purpose of this proposed rule is to revise our interpretation of the “appropriate for use in the home” requirement at 42 CFR 414.202 as it applies to certain external infusion pumps. We are proposing 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. The home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump. Under our proposal, if an individual or caregiver is unable to safely and effectively administer certain infusion drugs, such drugs could be covered as supplies necessary for the effective use of an external infusion pump under the DME benefit if the criteria listed previously

is satisfied (and, presumably, the external infusion pump satisfies all other relevant statutory and regulatory requirements for DME).

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs from the CBP

Section 106 of the Further Consolidated Appropriations Act, 2020 excludes complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories from the DMEPOS CBP as well as from fee schedule adjustments based on information from the DMEPOS CBP. This provision became effective January 1, 2020, and we are currently implementing this provision through program instructions, as authorized by section 106 of the Further Consolidated Appropriations Act, 2020. This rule proposes to make conforming changes to the regulations to reflect section 106 of the Further Consolidated Appropriations Act, 2020.

B. Summary of the Major Provisions

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

This rule proposes to revise § 414.210(g)(2) and (9) to establish the fee schedule adjustment methodologies 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-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

We indicate in this rule our plan to finalize the May 11, 2018 interim final rule (83 FR 21912) entitled “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” that resumed the transitional 50/50 blended rates for items furnished in rural areas and noncontiguous areas from June 1, 2018 through December 31, 2018, including the conforming amendment to exclude infusion drugs from the DMEPOS CBP.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

This proposed rule proposes application procedures and evaluation processes for external HCPCS Level II code applications:

- *Coding cycles for code applications:* This rule proposes specific coding cycles for drug or biological products, and non-drug, non-biological items and services, as defined in this proposed rule, including timeframes for application submission and final decisions; and additional procedures and exceptions to these proposed processes.

- *Processes for Evaluating Coding Applications:* This rule proposes processes that CMS would use to evaluate code applications to determine whether to add, revise, or discontinue a code for drug or biological products, and non-drug, non-biological items and services, as defined in this proposed rule.

4. 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

This proposed rule would 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, to determine how payment for the item of service would be made, and to obtain public consultation on these determinations.

5. Classification and Payment for Continuous Glucose Monitors under Medicare Part B

This rule proposes to classify all CGMs as DME and addresses the payment for different types of CGMs, as well as supplies and accessories used with CGMs. Additional determinations regarding whether a CGM is covered in accordance with section 1862(a)(1)(A) of the Act, or is otherwise excluded under Title XVIII, will be made by DME MACs using the local coverage determination process or during the Medicare claim-by-claim review process.

6. Expanded Classification of External Infusion Pumps as DME

We propose to interpret the “appropriate for use in the home” requirement within the definition of DME at 42 CFR 414.202 to be met for certain external infusion pump 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 possible route of administration, at least once per month, for the drug. The home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the

Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump.

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain other Manual Wheelchairs from the DMEPOS CBP

This rule proposes to revise the definition of “item” under the CBP at 42 CFR 414.402 to exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories as required by section 106(a) of the Further Consolidated Appropriations Act, 2020.

C. Summary of Cost and Benefits

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

We estimate that the payment methodologies described in section I.B.1. of this proposed rule would have no fiscal impact because the Office of the Actuary has determined that this provision neither increases nor decreases spending from what is assumed in the FY 2021 President’s Budget.

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

As we are signaling an intent to finalize an IFC that was already promulgated in 2018, there would be no fiscal impacts associated with this policy. The fiscal impacts of this IFC are considered to have already occurred.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

This rule proposes to continue certain existing code application policies and processes and proposes certain new coding policies and procedures. All proposed policies and procedures

are assumed to have no fiscal impact when considered against the FY 2021 President's Budget baseline.

4. 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

This rule proposes to establish 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 and is assumed to have an indeterminable fiscal impact due to the unique considerations given to establishing payment for specific items.

5. Classification and Payment for Continuous Glucose Monitors under Medicare Part B

This rule proposes to classify all CGMs as DME and addresses the payment for different types of CGMs. This classification is assumed to have no fiscal impact when considered against the FY 2021 President's Budget baseline.

6. Expanded Classification of External Infusion Pumps as DME

This rule proposes that an external infusion pump would be considered "appropriate for use in the home" in accordance with the definition of DME at 42 CFR 414.202 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 possible route of administration, at least once per month, for the drug. The home infusion therapy benefit

is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump. This expanded classification is assumed to be a small savings to Medicare in CY 2021 when considered against the FY 2021 President's Budget baseline.

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain other Manual Wheelchairs from the DMEPOS CBP

This rule proposes to revise the definition of "item" at 42 CFR 414.402 to exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories as required by section 106(a) of the Further Consolidated Appropriations Act, 2020 and is assumed to have no fiscal impact. These conforming changes to the regulations have no impact since the exclusion of these items from the CBP is mandated by the statute.

II. 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 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for contract award purposes in order 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.

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?#>

We refer to areas in which the CBP is not or has not been implemented as non-competitive bidding areas (non-CBAs). There are currently no CBAs due to a gap period in the DMEPOS CBP, however, we use the term “former CBAs” to refer to the areas that were formerly CBAs prior to the gap in the CBP, in order to distinguish those areas from “non-CBAs.” More information on why there are currently no CBAs can be found in the November 14, 2018 final rule entitled “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 entitled “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 entitled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable 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), CMS determines 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 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 midpoint 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 recomputed. 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, CMS 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 CMS would monitor the impact of the

³ For further discussion regarding adjustments to SPAs to address price inversions, we refer readers to the CY 2017 ESRD PPS DMEPOS final rule, entitled Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model, 81 FR 77937 (November 4, 2016).

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).

4. 21st Century Cures Act

Section 16007(a) of the 21st Century Cures Act (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 11, 2018 interim final rule with comment period entitled “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,” 83 FR 21912 through 21925 (hereinafter 2018 Interim Final Rule), 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 2018 Interim Final Rule (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 CMS 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 CMS 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.

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 Social Security 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 interim final rule with comment period that we published in the May 8, 2020 **Federal Register** entitled “Medicare and Medicaid Programs; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.”

B. Current Issues

We are now proposing 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. Though the transition rules under 42 CFR 414.210(g)(9) expire 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)) expire after January 1, 2021, and before April 1, 2021. In other words, 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 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 March 31, 2021.

1. Section 16008 of the Cures Act Analysis

As discussed, section 16008 of the Cures Act requires that we 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 Accordance 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 oral 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

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

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

⁵ <https://www.cqrc.org/img/CQRCCostSurveyWhitePaperMay2015Final.pdf>

⁶ <https://www.hrsa.gov/rural-health/about-us/definition/index.html>

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. CMS refers 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.

In general, we continue to receive feedback from industry stakeholders expressing their belief that the fully adjusted fee schedule amounts are too low and are having an adverse impact on beneficiary access to items and services furnished in rural 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 have been closely monitoring beneficiary health outcomes and access to DMEPOS items. 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 2018 while

⁷ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/afspuf>

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 have continued 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 have seen 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 slightly from 3.6 to 3.9 percent and monthly days in nursing homes remained unchanged. Finally, we note 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).

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).

We have updated some of the travel distance data used in our previous travel distance analysis with data from 2018, which is the most recent full year of data with CBAs. In reviewing the data from 2018, we found that the same trends we presented in the CY 2019 ESRD PPS

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).

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 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
CBAAs	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 travel distance data updated by partial 2019 data spanning January through November 2019. 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. However, there are currently no CBAs due to the gap period in the DMEPOS CBP, allowing any Medicare-enrolled DMEPOS suppliers to furnish DMEPOS items and services. We still reviewed data from former CBAs, as we believe the decrease in average travel distance in the former CBAs is additional confirmation that travel distances are generally greater in CBAs while a CBP is in effect, when compared to non-CBAs. We believe 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. Now that there is 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 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 note that we also 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. 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 un-adjusted 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 reviewing updated data from 2018, we found that in most cases, the average volume of items and services furnished by suppliers was higher in CBAs than in non-CBAs. 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.

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. 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. 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.

However, to determine what effect, if any, our payment amounts have had on the number of billing suppliers, 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). 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 note 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, we reviewed data depicting how many non-CBA counties are being served by only one oxygen supplier. 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 in seeking to prevent beneficiary access issues.

2. DMEPOS Fee Schedule Adjustment Impact Monitoring Data

In addition to the various Cures Act factors, we have also been monitoring other metrics we believe are important in measuring the impacts of our payment policies. In reviewing claims data processed through mid-November in 2018 and 2019, we found 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). Keep in mind that the 2019 claims data is not yet complete, so the number of allowed services will be greater than what is reported here, but the final rate of assignment will likely not change much if at all.

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. 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, we examined what effect, if any, paying the blended rates in rural and non-contiguous non-CBAs had on utilization of DME. 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 Interim Final Rule (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, assignment 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 seek 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

<p>Cost</p>	<ul style="list-style-type: none"> • 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.
<p>Volume</p>	<ul style="list-style-type: none"> • CBAs generally have higher volume than non-CBAs. • Total services per supplier continued to increase in 2018 and 2019 in non-CBAs.

<p>Number of Suppliers</p>	<ul style="list-style-type: none">• 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
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	more than half of the single-supplier counties were in Puerto Rico.
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* http://www.medpac.gov/docs/default-source/commentletters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf?sfvrsn=0

C. Provisions of the Proposed Regulations

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 are proposing to revise §414.210(g) to establish three different methodologies for adjusting fee schedule amounts for DMEPOS items and services included in more than ten 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. We are proposing 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). With respect to items and services furnished in no more than ten competitive bidding programs, we are proposing 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. 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 are proposing to continue paying the 50/50 blended rates in non-contiguous non-CBAs, but are proposing 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 are proposing 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. 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.

Second, we are proposing to continue paying the 50/50 blended rates in rural contiguous areas, but are proposing 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 are proposing 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 are also revising §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 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.

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 are proposing that the fee schedule amounts be equal to 100 percent of the adjusted payment amount established under §414.210(g)(1)(iv) .

Accordingly, we are proposing 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).

Thus under our proposal, CMS would 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 believe 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 believe that this proposal, which proposes 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.

The purpose of the 50/50 blend is to ensure payment rates are sufficient to maintain access to DME in areas where suppliers often furnish a lower volume of DME, such as rural areas of the country and non-contiguous areas.

The proposed fee schedule adjustment methodologies rely on SPAs generated by the CBP. CMS recently announced that it will only award Round 2021 CBP contracts to bidders in

the OTS back braces and OTS knee braces product categories.¹¹ CMS will 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 will not have any new SPAs for these items and services. As a result, we are 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. 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 would 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 are considering extending the rules at §414.210(g)(10), until such product categories are competitively bid again in a future round of the CBP. In this situation, the proposed fee schedule adjustments discussed previously in this proposed rule would only apply to OTS back braces and OTS knee braces furnished in non-CBAs on or after April 1, 2021.

In short, 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, 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

¹¹ The link to the announcement is <https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf>.

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 are proposing in this proposed rule in §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 welcomes 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 invite 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.

3. Alternatives Considered but not Proposed

We considered, but are not proposing, three alternatives to our proposals and we are seeking comments on these alternatives:

a. 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. Specifically, we considered proposing 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 section 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 section 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.¹² 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 should 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.

¹² <https://www.cqrc.org/img/CQRCCostSurveyWhitePaperMay2015Final.pdf>

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).

b. 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. 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.

c. 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 recently announced that it will only award Round 2021 CBP contracts to bidders in the OTS back braces and OTS knee braces product categories. CMS will 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 will not have any new SPAs for these items and services. As a result, under this alternative, we are seriously considering 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 have essentially been removed from Round 2021 of the CBP. Specifically, for items and services included in product categories that have essentially been removed from Round 2021 of the CBP, CMS would consider 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 consider adjusting 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. 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. For items and services included in product categories that have essentially 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, CMS would adjust the fee schedule amounts for such items and services in accordance with the adjustment methodologies outlined in this proposed rule; CMS 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.

We are seeking comments on these alternative methodologies and our proposed methodologies. For instance, we would be interested to learn if there are benefits or downsides to our proposals that we did not consider or discuss in this proposed rule.

III. 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

On May 11, 2018 we published an interim final rule (83 FR 21912) in the **Federal Register** entitled “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” (which we will refer to as the “2018 Interim Final Rule”). We solicited comments on the 2018 Interim Final Rule, but because we have not yet responded to the comments we received, we are signaling our intent to do so in the final rule.

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 2018 Interim Final Rule, 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 2018 Interim Final Rule, 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 are necessary (83 FR 21918

through 21919). We intend to respond to the comments we received on these issues in the final rule.

IV. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

A. Background

1. Origin and Purpose of HCPCS

Section 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under Medicare Part B unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under that part. In order to process claims and determine payment for items and services under Medicare, we need a way to appropriately identify the items and services billed. As discussed later in this section, we have established certain codes for providers and suppliers to use to identify items and services on claims. Medicare receives over 1 billion electronic claims per year.

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to identify particular items and services on claims submitted to Medicare, Medicaid, and other health insurance programs in a consistent and orderly manner. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of Current Procedural Terminology (CPT®) codes.¹³ The HCPCS Level II code set is

¹³ The CPT® is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Decisions regarding the addition, deletion, or revisions of CPT® codes are made and published by the American Medical Association (AMA) through the CPT® Editorial Panel. More information on CPT® codes can be found at www.ama-assn.org/about/cpt-editorial-panel/cpt-code-process.

used primarily to identify items, services, supplies, and equipment that are not identified by CPT® codes. The HCPCS Level II codes were originally created for use by government insurers including Medicare.¹⁴ On August 17, 2000, HHS published a final rule (65 FR 50312) in which it adopted HCPCS Level II codes as the standard code set to be used by all payers for, among other things, health care equipment and supplies not described by CPT® codes, for use in Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions (45 CFR 162.1002).¹⁵ The HCPCS Level II coding system was selected as the standard code set, in part, because of its wide acceptance among both public and private insurers. With few exceptions,¹⁶ HCPCS Level II codes are maintained by CMS, which is responsible for making decisions about additions, revisions, and discontinuations to the codes. CMS maintains the code set for Medicare but, because HCPCS Level II is a standard code set designated for use under HIPAA by all payers, CMS also considers the needs of other payers, including both government and private insurers, in establishing and maintaining codes.

The procedures by which the public submits and CMS evaluates external code applications to modify the HCPCS Level II code set have been primarily included in guidance documents released on the CMS website at

¹⁴ The code set was previously called the HCFA (Health Care Financing Administration) Common Procedure Coding System, after the previous name of the Agency, before it became known as the Healthcare Common Procedure Coding System as it is known today.

¹⁵ Through subtitle F of Title II of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191), Congress added to Title XI of the Social Security Act a new Part C, entitled “Administrative Simplification.” HIPAA requires the Secretary to adopt standards for code sets for the electronic transactions, including health care claims transactions, for which the Secretary has adopted a standard.

¹⁶ The Code on Dental Procedures and Nomenclature (CDT® code) represents a separate medical code set adopted under HIPAA. See 45 CFR 162.1002. Based on alpha-numeric format, they are considered HCPCS Level II series D-codes but are maintained, copyrighted, licensed and published separately by the American Dental Association. More information on CDT® codes can be found at <https://www.ada.org/en/publications/cdt>.

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>. We update and release the HCPCS Level II dataset files to our contractors and the public via our website on a quarterly basis. Although the HCPCS Level II code set is a coding system used to identify categories of items and services, it is not a methodology or system for making coverage or payment determinations for individual items and services, and the existence or absence of a code does not, of itself, determine coverage or non-coverage for the corresponding item or service.

HCPCS Level II codes are alpha-numeric codes that begin with an alphabetical letter followed by four numeric digits. Currently, there are almost 8,000 HCPCS Level II codes that represent categories of like items and services. Each code includes a text descriptor (code text) that identifies the category of items and services encompassed in the code. HCPCS Level II codes are generally organized into lettered categories that loosely describe the types of codes under that letter;¹⁷ however the lettered categories are not dispositive, meaning that they are not all inclusive of the types of items and services described in the heading for each lettered category.

2. External HCPCS Level II Code Applications

Interested parties seeking to modify the HCPCS Level II code set may submit an application, as available on CMS' website, that requests to add a code, revise an existing code, or discontinue an existing code. The types of items and services subject to the external HCPCS

¹⁷ A-codes: Transportation Services, Medical and Surgical Supplies, Miscellaneous; B-codes: Enteral and Parenteral Therapy; C-codes: Hospital Outpatient Prospective Payment System; D-codes: Dental Procedures; E-codes: Durable Medical Equipment; G-codes: Temporary Codes for Procedures and Professional Services; H-codes: Rehabilitative Services; J-codes: Drugs Administered Other Than Oral Method, Chemotherapy Drugs; K-codes: Medicare National Codes for DMEPOS; L-codes: Orthotics, and Prosthetics; M-codes: Medical Services; P-codes: Pathology and Laboratory Services; Q-codes: Medicare National Codes; R-codes: Diagnostic Radiology Services; S-codes: Non-Medicare National Codes; T-codes: State Medicaid Agency Codes; U-codes: Clinical Laboratory Tests; and V-codes: Vision and Hearing Services.

Level II code application procedures and evaluation processes proposed in this rule are described in section IV.B. of this proposed rule. The information collection activity is approved under OMB control number 0938-1042. In recent years, approximately 150 code applications typically have been submitted to CMS annually from the public. As part of our external HCPCS Level II code application process, we establish deadlines for when code applications need to be submitted by the public and post those deadlines on CMS' HCPCS website.

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). In November 2001, we issued a notice announcing the establishment of public meetings for making coding and payment determinations for new DME beginning in 2002 (66 FR 58743 through 58745). We also issued a notice on March 25, 2005, stating that the public meeting process previously limited to DME was expanded to include all new public requests for revisions to the HCPCS Level II codes (70 FR 15340). This change was intended to provide more opportunities for the public to become aware of and provide comment on code applications and changes under consideration, as well as opportunities for CMS to gather public input. Given the expansion of the public meeting process, we scheduled additional annual public meetings for 2005 and subsequent years.

Public meetings have provided a forum for interested parties to make oral presentations and to submit written comments in response to preliminary HCPCS Level II coding

recommendations¹⁸ for new DME, as well as for other items and services included in the public meeting. The dates for the public meetings are announced in the **Federal Register**. Agenda items for the meetings are published in advance of the public meeting. The public meeting agendas generally have included descriptions of the coding requests under consideration, the applicant, the name of the item or service, our preliminary HCPCS Level II coding recommendations and rationale, as well as preliminary Medicare payment recommendations.¹⁹ We publish the public meeting agendas on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

Prior to 2020, CMS received and reviewed HCPCS Level II code applications and typically made related coding changes annually, including releasing updated coding files. However, CMS' quarterly systems release process gave CMS the flexibility to review applications and make codes effective quarterly in response to claims processing needs, which it used in very limited circumstances. In November 2019, we announced updates to our HCPCS Level II coding procedures to enable shorter and more frequent HCPCS Level II code application cycles beginning in January 2020 as part of our initiative to facilitate launching new products into the marketplace for providers and patients.²⁰ Specifically, we implemented a process whereby HCPCS Level II code applications for DMEPOS and other non-drug, non-biological items and services are submitted and reviewed no less frequently than bi-annually; and HCPCS

¹⁸ CMS has also previously referred to preliminary recommendations as preliminary decisions. Hereinafter, in section IV. of this proposed rule, we will use the term preliminary recommendation.

¹⁹ Preliminary Medicare payment recommendations (also referred to as preliminary Medicare payment determinations) are discussed in more detail in section V.A.2. of this proposed rule.

²⁰ HCPCS – General Information. Announcement of Shorter Coding Cycle Procedures, Applications, and Deadlines for 2020. Available at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>.

Level II code applications for drugs and biological products are submitted and reviewed no less frequently than quarterly (hereinafter also referred to as bi-annual and quarterly coding cycles, respectively).²¹

Prior to 2020, we included code applications for drugs and biological products in the HCPCS public meeting process, even though not required under section 531(b) of BIPA. In order to achieve the additional time savings necessary to implement coding for the majority of drugs and biological products for which we receive code applications on a quarterly cycle, in November 2019, we updated our HCPCS Level II coding procedures such that beginning January 1, 2020, we no longer conduct public meetings as part of our HCPCS Level II code application process for drugs and biological products.²² Although code applications for drugs and biological products are no longer included in the public meetings, the 2020 coding procedures provide an opportunity for applicants to resubmit a code application for a drug or biological product in a subsequent quarterly coding cycle, which offers individual applicants who are dissatisfied with our coding decisions in one quarterly cycle an opportunity to reapply in the next or a subsequent quarterly cycle.

We also announced that beginning in 2020, consistent with implementing shorter and more frequent HCPCS coding cycles, we will release decisions on coding actions on a quarterly

²¹ HCPCS – General Information. Announcement of Shorter Coding Cycle Procedures, Applications, and Deadlines for 2020, available at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>; Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, Rev. September 16, 2020, available at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>.

²² Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, revised November 26, 2019.

basis in the same format as we previously announced annual decisions.²³ These actions are available on the CMS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>. We note that each payer effectuates the changes to the code sets on its own timeframes. For Medicare, unless otherwise announced or specified, Table 4 sets forth the coding timeframes for the 2020 coding cycles. We refer readers to the CMS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo> for the most recent updates and revisions to these timeframes.

TABLE 4: 2020 SCHEDULE FOR HCPCS LEVEL II CODING CYCLES

Application Topic	Coding Cycle	Application Deadline	Preliminary Recommendation Publication	Public Meeting	Final Decision Publication	Coding Changes Effective Date
DMEPOS and Other Non-Drug, Non-Biological Items and Services	Bi-annual 1	1/06/2020	May 2020	June 1 and 2, 2020**	July 2020	10/01/2020
DMEPOS and Other Non-Drug, Non-Biological Items and Services	Bi-annual 2	6/29/2020	Approximately 2 weeks prior to the Public Meeting in Fall 2020	Fall 2020	January 2021 or earlier	4/01/2021
Drugs and Biological Products	Q1	1/06/2020	N/A*	N/A*	April 2020	7/01/2020
Drugs and Biological Products	Q2	4/06/2020	N/A*	N/A*	July 2020	10/01/2020
Drugs and Biological Products	Q3	6/29/2020	N/A*	N/A*	October 2020	1/01/2021
Drugs and Biological Products	Q4	9/21/2020	N/A*	N/A*	January 2021 or earlier	4/01/2021

Announced in the **Federal Register at 85 FR 21859.

* As further explained, although we previously included code applications for drugs and biological products in our HCPCS public meeting processes, we are not doing so in 2020 in order to achieve the additional time savings necessary to implement coding for the vast majority of drugs and biological products on a quarterly cycle.

As explained in more detail in section IV.B.2. of this proposed rule, there are three types of modifications to the HCPCS Level II code set that can be requested by the public under this process using the application form available on CMS' website: (1) the addition of a HCPCS Level II code; (2) a revision to the long descriptor language (code text) of an existing HCPCS Level II code; and (3) the discontinuation of an existing HCPCS Level II code. The current

²³ Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, Rev. September 16, 2020, available at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>.

HCPCS Level II code application and instructions can be found on the CMS HCPCS website at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions.²⁴ Anyone may submit an application. We outline procedures we use to make coding decisions for certain items and services that are coded in the HCPCS Level II code set in a document entitled “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,” available on our website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>.²⁵ Summaries of external HCPCS code applications with our final coding decisions and rationale are made available on our website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>. Separately, Quarterly Update releases of the full HCPCS Level II code set are made available on our website at <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets>.

B. Proposals for HCPCS Level II Coding Procedures

To increase transparency and gather stakeholder input, we are proposing in this proposed rule to codify certain policies and procedures regarding the submission and evaluation of external HCPCS Level II code applications. Consistent with our current practices, the proposed external HCPCS Level II code application process applies to products paid separately as drugs or biologicals (defined later in the section and in proposed 42 CFR 414.8(a)(2)),²⁶ and non-drug,

²⁴ Updated September 2020.

²⁵ Updated September 2020.

²⁶ Note, in prior code documents on our website, we used the reference “drugs and biological products” (see “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,” available at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>).

non-biological items and services (defined later in the section and in proposed 42 CFR 414.8(a)(1)).²⁷

For purposes of section IV.B. of this proposed rule, the term “products paid separately as drugs or biologicals” refers to products that are separately payable by Medicare under Part B (and potentially by other payers, such as private insurers) as drugs or biologicals as that term is defined in section 1861(t) of the Act. These products typically fall into one or more of the following three categories: (1) products furnished incident to a physician’s services under sections 1861(s)(2)(A) and (B) of the Act, excluding products that are usually self-administered (for example, tablets, capsules, oral solutions, disposable inhalers); (2) products administered via a covered item of DME; and (3) other categories of products for which there is another Part B benefit category as specified by statute or regulations (for example, drug or biological products described elsewhere in section 1861(s) of the Act, such as immunosuppressive drugs (at section 1861(s)(2)(J) of the Act); hemophilia blood clotting factors (at section 1861(s)(2)(I) of the Act); certain oral anticancer drugs (at section 1861(s)(2)(Q) of the Act); certain oral antiemetic drugs (at section 1861(s)(2)(T) of the Act); pneumococcal pneumonia, influenza and hepatitis B vaccines (at section 1861(s)(10) of the Act)). For ease of reference, when discussing products paid separately as drugs or biologicals in this proposed rule, we will generally refer to these as “drug or biological products.” The proposed code application and evaluation processes for drug or biological products are described in section IV.B. of this proposed rule.

²⁷ Note, in prior code documents on the website, we used the reference “DMEPOS and other non-drug, non-biological items and services” in our “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,” available at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>.

For purposes of the proposals regarding HCPCS Level II coding procedures in section IV.B. of this proposed rule, the term “non-drug, non-biological items and services” refers to items and services that Medicare (and potentially other payers, such as private insurers) typically pay separately²⁸ and that are described in the following list,²⁹ as well as certain items and services that are not covered under Medicare (as described in the following list):

- Medical and surgical supplies, such as splints and casts described in section 1861(s)(5) of the Act and therapeutic shoes described in section 1861(s)(12) of the Act.
- Dialysis supplies and equipment such as those described in section 1861(s)(2)(F) of the Act.³⁰
- Ostomy and urological supplies such as those described in section 1861(s)(8) of the Act.
- Surgical dressings such as those described in section 1861(s)(5) of the Act.
- Prosthetics (artificial legs, arms, and eyes) such as those described in section 1861(s)(9) of the Act and prosthetic devices such as those described in section 1861(s)(8) of the Act.
- Orthotics (leg, arm, back, and neck braces) such as those described in section 1861(s)(9) of the Act.

²⁸ Items and services that are separately payable would not be included in a bundled payment. We discuss this in more detail in section IV.B.2 of this proposed rule.

²⁹ The statutory citations and corresponding definitions are not intended to be strict definitions of the items and services in these categories or the categories themselves, but are intended for purposes of describing the types of non-drug, non-biological items and services that are subject to the HCPCS Level II code application process.

³⁰ Beginning January 1, 2011, all renal dialysis services defined under 42 CFR § 413.171 are paid under the ESRD PPS, and therefore, we do not pay separately for most dialysis supplies and equipment. However, the transitional drug add-on payment adjustment (TDAPA) and the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES), available under the ESRD PPS (42 CFR 413.234 and 413.236), require separate coding for certain items and services that are eligible for a payment adjustment.

- Enteral/parenteral nutrition such as those described in section 1842(s)(2) of the Act.
- Durable Medical Equipment (and related accessories and supplies other than drugs), such as oxygen and oxygen equipment, wheelchairs, infusion pumps, and nebulizers such as those described in sections 1861(s)(6) and 1861(n) of the Act.
- Vision items and services, such as prosthetic lenses described in section 1861(s)(8) of the Act.
- Other items and services that are statutorily excluded from Medicare coverage for which CMS or other government or private insurers have identified a claims processing need for a HCPCS Level II code, such as hearing aids which are excluded from coverage by section 1862(a)(7) of the Act.

We note that these are the general categories of non-drug, non-biological items and services currently listed in the HCPCS Level II code application³¹ on our website. For purposes of this proposed rule, the term non-drug, non-biological items and services does not include drugs covered under the DME benefit as supplies put directly into DME, such as a nebulizer or infusion pump, to achieve the therapeutic benefit of the DME (such drugs, as noted previously, are considered “drug or biological products” under this proposed rule), but does include gaseous or liquid oxygen put into oxygen equipment (tanks or other containers).

The proposed code application procedures and evaluation processes in section IV.B of this proposed rule would not apply to other items and services described in procedural codes for oral health and dentistry that begin with the letter “D” (CDT® codes), which are published,

³¹ HCPCS Code Application, Question #3.

copyrighted, and licensed by the American Dental Association (ADA) and are not maintained by CMS, nor items and services coded by CMS internally that are not based on an external application request and are based exclusively on Medicare claims processing needs.

1. Proposed HCPCS Level II Coding Cycles and Related Policies

As discussed in section IV.A.2. of this proposed rule, beginning in January 2020, the following coding cycles for HCPCS Level II code applications apply: (1) for non-drug, non-biological items and services, coding cycles begin no less frequently than bi-annually; and (2) for drug or biological products, coding cycles begin no less frequently than quarterly. As discussed in more detail later in the section, we propose to codify these coding cycles and certain related policies for code applications for non-drug, non-biological items and services, and for drug or biological products. We propose to add new sections §§ 414.8 and 414.9 to set forth these proposed policies.

a. Coding Cycles for Non-drug, Non-biological Items and Services

We propose that for HCPCS Level II code applications for non-drug, non-biological items and services, we would continue to begin a new coding cycle for such code applications no less frequently than bi-annually. Subject to the exceptions proposed and explained later in this section, we also propose that for each coding cycle for non-drug, non-biological items and services, we would continue to: (1) establish a deadline for submitting code applications in or around January or June each year (depending on the cycle) on the CMS website or in another manner; (2) issue preliminary recommendations (a preliminary recommendation may also include questions or requests for additional information that could help CMS in reaching a final decision) on code applications that will be addressed at the public meeting on the CMS website or in another manner prior to the relevant public meeting; (3) hold public meetings to provide the

public with an opportunity to become aware of and provide input on code applications and preliminary recommendations under consideration for that coding cycle; and (4) issue final coding decisions on the CMS website or in another manner within approximately 6 months of the code application deadline. Consistent with our current practice, coding changes would become effective approximately 3 months after issuance of the final coding decision. We propose to add new § 414.8(b), (c), (d) and (e) to set forth these proposed procedures.

We currently post all of our final coding decisions on the CMS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>. We believe these proposed bi-annual coding cycles for non-drug, non-biological items and services allow us sufficient time to issue preliminary recommendations in advance of the public meetings and to meet the statutory requirement under section 531(b) of BIPA that we permit public consultation on coding determinations for new DME (which we currently accomplish through our public meetings), while also being responsive to previous stakeholder feedback requesting faster coding decisions. We note that even though section 531(b) of BIPA requires procedures for coding determinations for new DME that permit public consultation, as explained in section IV.A.2. of this proposed rule, we previously expanded public meetings to include all new HCPCS Level II code applications because we believe it is helpful to obtain public input on code applications for as many items and services as possible. Therefore, we are proposing at §§ 414.8(d) and 414.8(b), to continue to include not only code applications for new DME items and services in the public meetings, but also code applications for all non-drug, non-biological items and services and to follow the bi-annual coding cycle schedule for them.

We also considered proposing coding cycles of no less frequently than quarterly for non-drug, non-biological items and services. While quarterly cycles for non-drug, non-biological

items and services could provide for faster coding decisions on these items and services and would align with our proposal for quarterly coding cycles for drug or biological products, as further discussed in section IV.B.1.b. of this proposed rule, we believe quarterly coding cycles would not allow us sufficient time to evaluate the applications for all non-drug, non-biological items and services, issue preliminary recommendations, hold public meetings, and issue final coding decisions. All of these activities would require more than 3 months to complete. As described earlier in this section, we are proposing to continue seeking public input at our public meetings on preliminary recommendations issued for all non-drug, non-biological items and services under consideration in a given bi-annual coding cycle, and not just for new DME items and services. In addition, in our experience, applications for non-drug, non-biological items and services tend to be more complex or require more research and review time than code applications for drug or biological products, and therefore we typically need more than 3 months for their evaluation. For example, non-drug and non-biological items and services may not be regulated by the Food and Drug Administration (FDA) and therefore, the manufacturer may not conduct clinical studies and in that case we may not receive clinical studies with the HCPCS Level II code application. Thus, applications for such items and services would require independent review and research by CMS to evaluate, for example, whether the item or service has functional or clinical differences compared to other similar items and services already described in the code set and thus, we would need more time to gather such information, if available, and review the code application. By contrast, as described in section IV.B.1.b. of this proposed rule, drug or biological products are regulated by the FDA and code applications for approved drug or biological products include detailed FDA documentation, which typically include clinical information and studies that assist us in evaluating the application. Thus,

typically we require less time to assess such applications than many of the applications for non-drug, non-biological items and services. As a result, while we are proposing quarterly coding cycles for drug or biological products, we believe bi-annual cycles are more appropriate for applications for non-drug, non-biological items and services.

We also propose at §414.8(e)(3), consistent with our current practice, that in circumstances where code applications for non-drug, non-biological items or services raise complex or significant issues or considerations and we determine that additional time is needed to evaluate such applications, we may delay issuing a preliminary recommendation and therefore delay the final coding decision. We note that a decision to delay a preliminary recommendation would have the effect of pushing the code application to the next coding cycle for further determination. In addition, after issuing a preliminary recommendation, we may delay issuing the final coding decision. These delays may be for one or more coding cycles (depending on the nature and timing of the issues raised). While we make every effort to complete our review and issue final coding decisions for all timely and complete code applications within the applicable coding cycle, there are occasions where additional time and evaluation are necessary to fully assess certain applications because the code application raises complex or significant issues or considerations. These circumstances would include, but are not limited to, situations where the code application involves a significant policy consideration (for example, a unique issue related to a specific item or service or group of items or services, such as appropriate coding for combination products that include a drug and a service component), involves a significant claims processing consideration (for example, operational issues arising from a coding action requiring significant revisions to the claims processing system, such as re-tooling to add another character to the price field to accommodate higher prices than contemplated when the system was

established, including determining whether the claims processing system change could be made, and in what timeframe, to ensure that the coding solution would be viable, or whether an alternative solution needs to be implemented before publishing new codes), or requires in-depth clinical or other research.

We note that under our current process, we also may delay issuing preliminary recommendations and final coding decisions on code applications because we need additional time to evaluate the applications. We note that this occurs infrequently, and we believe it is important to continue this practice to allow us sufficient time to evaluate and determine appropriate coding actions on certain applications. While we expect to make a final coding decision within the next coding cycle in most instances where we determine such delays are necessary, we may further delay issuing a preliminary recommendation and final coding decision, or a final coding decision after a preliminary recommendation, to subsequent coding cycles. We expect extended delays would be rare and would only occur if necessary due to significant complexities arising from an application that requires additional consideration and time to come to a preliminary recommendation or final coding decision. We believe the ability to extend our evaluation of an application in limited circumstances for more than one bi-annual coding cycle may be necessary to account for potential significant complexities presented by individual applications, particularly in light of the proposed bi-annual coding cycles, so that we can continue to ensure we have sufficient time as well as information needed to determine the most appropriate coding action. Therefore, we propose that, where additional time and evaluation are necessary to fully assess an application (including in the circumstances described earlier), we may delay issuing a preliminary recommendation, and therefore, the final coding decision, or after making a preliminary recommendation, we may delay issuing a final coding

decision alone, on the application for one or more coding cycles. We propose to add new § 414.8(e)(3) to set forth this proposed policy. We note that prior to a final coding decision, miscellaneous codes are available for assignment by insurers, if they deem appropriate, to allow suppliers to begin billing for an item or service as soon as it receives FDA marketing authorization for those items and services that require such marketing authorization, or as soon as it begins marketing for those items and services that do not require FDA marketing authorization, including during the HCPCS code application review process.

In cases in which we determine that we need additional time to make a preliminary recommendation, we propose that we would continue our current practice of issuing a determination that additional time is needed to evaluate a particular application, either on the CMS website or in another manner, at the same time that we issue preliminary recommendations for other items and services included in that coding cycle (see proposed § 414.8(e)(3)(iii)). We also may seek additional information from the applicant or other sources or both as we continue to consider the application, which is consistent with our current practice.

In cases in which a preliminary recommendation is issued, but we later determine that we need additional time to come to a final coding decision, we propose to continue our current practice of issuing a determination that additional time is needed to evaluate a particular application, either on the CMS website or in another manner, at the same time that we issue final coding decisions for other items and services included in that coding cycle (see proposed § 414.8(e)(3)(iii)). In such cases, we propose to continue to evaluate that application in the next coding cycle and note that per proposed § 414.8(e)(3) it could be delayed into additional subsequent cycles. We may seek additional information from the applicant or other sources or both as we continue to consider the application.

b. Coding Cycles for Drug or Biological Products

We propose that for HCPCS Level II code applications for drug or biological products, we would continue to begin new coding cycles for such code applications no less frequently than quarterly. Subject to the exceptions proposed and explained later in this section, we also propose that for each coding cycle for applications for drug or biological products, we would continue to: (1) establish (on the CMS website or in another manner) a deadline for submitting code applications, which would occur in or around January, April, June, or September each year depending on the cycle; and (2) issue final coding decisions on the CMS website or in another manner, within approximately 3 months of the code application deadline. Coding changes would become effective approximately 3 months after issuance of the final coding decisions. We currently post summaries of the applications with our final coding decisions on the CMS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>. We propose to codify these procedures at proposed § 414.8(b), (c)(2), and (e).

The proposed quarterly coding cycles for drug or biological products are responsive to previous stakeholder feedback requesting faster coding cycles for such products. We also believe that faster coding cycles may facilitate and expedite claims processing and launching new products into the marketplace for providers and patients. We believe that quarterly cycles are appropriate for most drug or biological product applications because it is our experience that drug or biological product applications tend to be more straightforward and take less time to assess than many of the applications for non-drug, non-biological items and services. Most separately paid Part B drugs are paid using the methodology in section 1847A of the Act, and the code evaluation process for many drug or biological products is based on Medicare statutory requirements consistent with section 1847A of the Act. Specifically, section 1847A of the Act

requires different payment methodologies for single source drugs, multiple source drugs, and biological products (including biosimilar biological products), which, in turn, necessitates separate codes for purposes of facilitating separate payment amounts. The use of separate codes for this purpose is discussed further in subregulatory guidance published in 2007 (https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf). In most cases, information pertaining to the need for separate payment amounts for drug or biological products under section 1847A is driven by factors such as the FDA approval pathway (for example, a Biologics License Application (BLA), New Drug Application (NDA), or Abbreviated New Drug Application (ANDA)) as well as Therapeutic Equivalence ratings as provided in section 1847A(c)(6)(C). Information on these factors is easy to obtain using public sources such as Daily Med (<https://dailymed.nlm.nih.gov/dailymed/index.cfm>), the Orange Book (<https://www.accessdata.fda.gov/scripts/cder/ob/>), and the Purple Book (<https://purplebooksearch.fda.gov/>). In addition, the FDA approval processes for drug or biological products, and the accompanying documentation provided with external HCPCS Level II code applications for those products, which includes clinical data, information relevant to the safety profile, clinical indications for use, contraindications, and appropriate use or dosing intervals and other information, helps us evaluate those applications faster and tends to allow CMS to make final coding decisions about the program need for a code and the information required for a code descriptor without the need for public input. The proposed procedures for evaluating drug or biological product code applications are discussed in more detail in section IV.B.2. of this proposed rule. For situations where more detailed information may be required to support coding decisions pertaining to an external code application, for example if we are not

able to immediately establish whether the drug is separately payable under Part B, we may delay the final coding decision to a subsequent coding cycle as proposed later in this section.

Furthermore, except for code applications that are resubmitted for reevaluation as provided in proposed § 414.9(b), and code applications where a decision is delayed under proposed § 414.8(e)(3) that present program, policy, or implementation concerns or complexities, or otherwise raise questions that public input could help to address (see proposed § 414.8(d)(4)(ii)), we propose that, consistent with our current procedures, we would not hold public meetings or issue preliminary recommendations for drug or biological product code applications. Because of the additional time needed to prepare for and hold the public meetings, we believe it would not be feasible to include public meetings within the quarterly cycles. We note that there is no statutory requirement for public consultation on drug or biological product coding determinations. We propose to set forth this proposed policy at new § 414.8(d)(4). We refer readers to section IV.B.1.d. of this proposed rule where we propose to add drug or biological product applications to a bi-annual public meeting agenda if an applicant is dissatisfied with a prior final coding decision and submits an application for reevaluation. We refer readers to later in this section where we propose that we may add drug or biological product applications to a bi-annual public meeting if the code applications are delayed and present program, policy, or implementation concerns or complexities, or otherwise raise questions that public input could help to address.

We also considered coding cycles of no less frequently than bi-annually for applications for drug or biological products, which would align with our proposal for bi-annual coding cycles for non-drug, non-biological items and services discussed in section IV.B.1.a. of this proposed rule and enable us to include all drug or biological product applications in the public meeting

process. While we understand there is value in providing an opportunity for the public to submit input and for CMS to consider public input on all applications, we also believe that by expediting coding decisions for drug or biological products and the incorporation of such products in the claims processing system, quarterly coding cycles for drug or biological product applications may facilitate patient and provider access to new products. In addition, as explained previously, we believe that generally, we can make well-informed HCPCS Level II coding decisions for drug or biological products based on the information contained in the code applications without a public meeting given that applications for such products are largely evaluated based on Medicare statutory requirements consistent with section 1847A of the Act, and the code applications include detailed FDA documentation, as discussed earlier in this section. Given these considerations, we believe that more expeditious coding for these products outweighs the benefit of including such applications in the public meeting process.

As noted, the trade-off for conducting public meetings for applications for drug or biological products would be longer coding cycles, such as bi-annual cycles, to accommodate the time required to prepare preliminary recommendations and conduct public meetings, evaluate public input received from the public meetings, and reach final coding decisions for such applications. We seek comments on whether it would be appropriate or preferable to instead adopt coding cycles of no less frequently than bi-annually for drug or biological product code applications, which would enable us to issue preliminary recommendations and solicit public input at public meetings on all such products for a given coding cycle.

For applications for drug or biological products, we propose at § 414.8(e)(3) that, consistent with our current practice, in circumstances where the code application raises complex or significant issues or considerations and we determine that additional time is needed to

evaluate the code application, we may delay issuing a final coding decision by one or more coding cycles. While we will make every effort to complete our review of all timely and complete code applications within the applicable coding cycle, there will be occasions where additional time and evaluation are necessary to fully assess certain applications because the application raises complex or significant issues or considerations. These circumstances would include, but are not limited to, situations where the code application involves a significant policy consideration (for example, a unique issue related to a specific drug or biological product or group of drug or biological products), or a significant claims processing consideration (for example, operational issues arising from a coding action requiring significant revisions to the claims processing system); or the code application requires in-depth clinical or other research (for example, if we are not able to immediately establish whether the drug is separately payable under Part B). Based on coding experience with Part B drugs since the implementation of section 1847A of the Act, we anticipate that these situations would be particularly rare for drug or biological product applications, which tend to be more straightforward than applications for non-drug, non-biological items and services, as explained earlier in this section. While in most instances where we determine such a delay is necessary we expect to make a final coding decision within the next coding cycle, we propose that in certain circumstances, we may further delay issuing a final coding decision into a subsequent coding cycle. We expect this would be a rare occurrence, and would only be done if necessary due to significant complexities arising from an application that requires additional consideration and time to come to a final coding decision. We believe the ability to extend our evaluation of an application in limited circumstances for more than one coding cycle may be necessary to account for potential significant complexities presented by individual applications, particularly in light of the proposed

shorter coding cycles, so that we can continue to ensure we have sufficient time, as well as information needed, to determine the most appropriate coding action. We propose to set forth this proposed policy at new § 414.8(e)(3). As is our current practice, we also propose that we would continue to issue a determination that additional time is needed to evaluate a particular application on the CMS website or in another manner at the same time that we issue final coding decisions for drug or biological products included in that coding cycle, in the same way as described in section IV.B.1.a. of this proposed rule for non-drug, non-biological items and services (see proposed § 414.8(e)(3)(iii)). We reiterate that we believe such delays would occur infrequently, and we would make every effort to complete our review and issue final coding decisions for all timely and complete code applications within the applicable coding cycle.

Additionally, in some of these situations where we delay a final coding decision we propose at § 414.8(d)(4)(ii) that we may also add the application to the agenda for a public meeting, in order for CMS to obtain further input and public discussion of the application. We would add an application for a drug or biological product to a public meeting agenda only when we believe that an individual application requires additional consideration because it presents program, policy, or implementation concerns or complexities, or otherwise raises questions that public input could help to address, such as where we believe we may need input from other external sources such as clinicians or other users of the product. For example, we believe it may be helpful to gather public input when a request to code a new drug that is similar to other drugs categorized within existing HCPCS Level II codes would involve modifying, discontinuing existing codes, or replacing those existing codes with new ones. In these types of circumstances, gathering public input through the public meeting process could facilitate our review of the application and assist in reaching an appropriate coding decision. If an application is put on a

public meeting, we propose that we would issue a preliminary recommendation prior to that public meeting. In order to provide sufficient time to prepare for the public meeting, we would not be able to include the application on a public meeting in the quarter in which it is submitted, even if regular bi-annual public meetings were held in that quarter. In other words, if an application for a drug or biological product is included in a public meeting it would need to follow the bi-annual cycle schedule and would also be subject to the proposals that allow for delay of preliminary recommendations and final coding decisions for one or more cycles under new § 414.8(e)(3). Given that including a drug or biological product code application on a public meeting agenda could result in delaying a final coding decision more than one quarterly cycle given the bi-annual public meeting timelines, we would weigh the benefit of and need for receiving public input with the interests of making final coding decisions as quickly as possible when deciding whether to put a drug or biological product code application on a public meeting agenda. For instance, while we may determine that we need to delay a final coding decision on an application for a drug or biological product to consider complexities or other concerns internally, if we do not believe public input is needed, we may decide not to place the application on a public meeting agenda, which would give flexibility to potentially come to a final coding decision in the next quarterly coding cycle. For example, if an application is submitted by the deadline in the second quarterly coding cycle, which has an application deadline around April, and we decide to delay the final decision, if we also decide to put the application on a public meeting agenda, the earliest public meeting it could be placed on would be the public meeting for the second bi-annual cycle, which would necessarily delay the final decision at least two quarterly cycles. However, if the final decision is delayed but it is not placed on a public meeting agenda it may be possible to come to a final decision within the next quarterly cycle,

depending on the circumstances. Our goal is to make every attempt to make final coding decisions as quickly as possible and avoid unnecessary delays. We note that any determination to include an application in a public meeting would be initiated by CMS based on the considerations described in this section and would not be granted based on requests from an applicant.

We also seek public comment on whether there may be other circumstances under which it may be appropriate for CMS to decide to include a drug or biological product application in a public meeting (for example, when an applicant requests to add such an application to the public meeting process; or other particular circumstances where a public meeting would be important). However, we note that unless the addition of an application for drug or biological product to a public meeting agenda is a rare occurrence, we believe that the operational burden of accommodating public meetings for these products could make it infeasible for CMS to carry out a quarterly coding review cycle for drug or biological product applications. Consequently, if stakeholders favor public meetings for the review of applications for drug or biological products on other than a very infrequent basis, it is likely that we would need to consider implementing bi-annual coding cycles for all drug or biological product applications, including a public meeting component.

As an alternative to including the code applications described at proposed § 414.8(d)(4)(ii) in a public meeting, we considered soliciting public input for such applications through the CMS website (rather than a public meeting). We considered that such a web-based public input process would occur bi-annually, as the public meetings do, and would include posting on CMS' HCPCS website either a preliminary HCPCS coding recommendation, one or more coding options for which we are seeking feedback, one or more questions, or other requests

for comment or information that would help CMS formulate a coding decision. We considered that this process could be applied to the same types of code applications we propose at § 414.8(d)(4)(ii) to include in a public meeting, that is, where we determine to delay a decision on a code application and we determine the application requires additional consideration because it presents program, policy, or implementation concerns or complexities, or otherwise raises questions that public input could help to address. We considered that a 15-calendar day period for public input could be applied under such a process, with the comment window beginning on the date that the public would be invited to comment on the CMS website. We note that a 15-calendar day period is approximately the same amount of time we currently provide for submitting public input on preliminary recommendations issued for non-drug, non-biological code applications in the public meeting agenda (which is generally posted approximately two weeks prior to the associated public meeting), including written and oral comments related to public meetings, if received by the end of the public meeting at which the relevant application is discussed. Similar to the proposal to add select drug or biological product applications to the public meeting process, in order to provide sufficient time to prepare either a preliminary HCPCS coding recommendation, one or more coding options for which we are seeking feedback, one or more questions, or other requests for comment or information that would help CMS formulate a coding decision, we believe that we would not be able to put an application through such a web-based public input process in the same quarter in which the application is submitted and would need to follow the bi-annual cycle schedule. We considered that we would also similarly weigh the benefit of and need for receiving public input through such a web-based process with the interests of making final coding decisions as quickly as possible when deciding whether to put a drug or biological product code application through such a web-based public

input process, given the potential that a final decision may be delayed more than two quarters depending on the timing of the bi-annual public input periods. While we are not proposing in § 414.8(d)(4)(ii) a web-based public input process for drug or biological product code applications described in that proposed provision, we seek comment on the alternative we considered (as discussed previously) to solicit public input for such drug or biological product applications through the CMS website (rather than in a public meeting). We also seek comment on whether there may be other specific circumstances in which public input via such a web-based public input process may be useful, considering that under the shorter coding cycles only a limited number of applications could be accommodated.

c. Proposed Requirements for Applications to be Considered in a Coding Cycle

Consistent with our current procedures and requirements for HCPCS Level II code applications, we propose at new § 414.9(a) that to be considered in a given coding cycle, an application must be timely and complete. We further propose that an application that is not timely and complete would be declined by CMS but may be submitted by the applicant in a subsequent coding cycle. We propose at new § 414.9(a)(1) that an application is timely if it is submitted to CMS by the applicable code application submission deadline specified by CMS for each coding cycle, which CMS posts on its website or in another manner, or as specified in proposed § 414.9(a)(3). We propose at new § 414.9(a)(2)(i) that an application would be considered complete if it includes, by the applicable code application submission deadline, the applicable information and documentation required in proposed § 414.9, and meets the administrative elements as specified by the application instructions issued by CMS and posted on the CMS website (for example, it includes answers to all of the application questions, includes required FDA documentation, and is within the page limit). We also propose at new §

414.9(a)(2)(ii) that, consistent with our current practice, for an application to be complete, the applicant provide FDA documentation of the item's current classification, as applicable, as well as FDA marketing authorization documentation, or provide the regulation number under 21 CFR parts 862 through 892 for a device exempted from the premarket notification requirement. If a device exceeds the limitations to the exemptions under 21 CFR parts 862 through 892 of the device classification regulations, the appropriate marketing authorization documentation must be submitted to CMS as part of the application. We propose that FDA documentation of the item's current classification, as applicable, and FDA marketing authorization documentation, or the regulation number under 21 CFR parts 862 through 892 for a device exempted from the 510(k) requirement would be required to be submitted with the code application by the relevant HCPCS Level II code application deadline, for an application to be complete.

Additionally, for biosimilar biological products, we propose to allow a 10-business day extension past the application deadline to provide a complete application, including FDA marketing authorization documentation, if the proposed criteria discussed later in this section are met. Under the annual coding cycle prior to 2020, for drug or biological product code applications, we provided a 3-month extension for submission of FDA marketing authorization documentation and to provide updates to the application based on the FDA marketing authorization documentation. However, the shorter quarterly coding cycles for drug or biological product applications cannot accommodate a 3-month extension for submission of FDA marketing authorization documentation and to update the application based on that documentation, as was previously offered under the annual coding cycle, and thus, beginning in 2020, we eliminated the 3-month extension to enable the quarterly coding cycles for drug or biological products. Therefore, currently, in order for an application to be complete, code

applications must be submitted by the application deadline with the aforementioned FDA documentation. Under the shorter quarterly coding cycles, applicants who are unable to submit a complete application, including the required FDA marketing authorization documentation, by the application deadline for a given coding cycle would be able to submit the application and required FDA marketing authorization documentation for the next quarterly cycle, provided the application is complete by the next coding cycle's application deadline. We note that under our previous annual coding process prior to 2020, the next opportunity to submit was the next annual coding cycle.

Our recent changes to the coding cycles were designed to facilitate more rapid coding, which could be frustrated if required FDA documentation is unavailable for a large number of applications at the deadline because the items have not yet received FDA marketing authorization, or if a lengthy extension is allowed in order to provide such documentation. We have concerns about the impact of extending the submission deadline for required FDA marketing authorization documentation and the impact that not having the documentation would have on the ability to provide complete information in the rest of the application and how that could further compress the amount of time available to process applications. We also have concerns about allowing deadline extensions for all drug or biological product code applications given our resources and the compressed review timeframe under shorter quarterly coding cycles. If we were to consider extensions to accommodate submission of required FDA documentation for all drug or biological product code applications, we believe that this would potentially strain our resources and possibly hinder our ability to thoroughly evaluate applications and issue final coding decisions in a timely manner. Therefore, we do not believe an extension for the submission for required FDA documentation would be feasible for all drug or biological product

applications. However, we recognize that there may be instances in which an extension to accommodate the submission of required FDA documentation past the quarterly application deadline for certain items and services could serve broader Medicare programmatic goals, particularly where expedited coding could facilitate and expedite claims processing, without straining our resources and possibly hindering our ability to thoroughly evaluate and issue final coding decisions for all the applications we receive in a given coding cycle.

Stakeholders have mentioned biosimilar biological products as a type of product that might warrant an extension for submitting required FDA documentation beyond the code application deadline while still allowing a coding decision to be made within a particular coding cycle to facilitate faster coding for such products. A biosimilar biological product is a biological product that is highly similar to and has no clinically meaningful differences in terms of safety, purity, and potency from an FDA-approved biological reference product.³² In the Revisions to the Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018 final rule (CY 2018 PFS and Other Revisions to Part B final rule) (82 FR 53186) we finalized a policy to separately code and pay for biosimilar biological products under Medicare Part B. In that final rule, we noted that we were persuaded that there is a program need for assigning Part B biosimilar biological products into separate HCPCS codes, and specifically that the policy would address concerns about a stronger marketplace, access to these drugs in the United States marketplace, provider and patient choice and competition. As stated in the CY 2018 PFS and Other Revisions to Part B final rule (82 FR 53186), we believe that the change in

³² See section 351(i)(2) of the Public Health Service Act.

policy encourages the innovation needed to bring more products to the market by encouraging greater manufacturer participation in the marketplace and the introduction of more biosimilar biological products, thus creating a stable and robust market, driving competition and decreasing uncertainty about access and payment. Additionally, we stated we believe that the policy provides physicians with greater certainty about biosimilar payment and that, in turn, that will affect utilization of biosimilar biological products, creating more demand that would help increase competition (82 FR 53186). We also anticipated greater access to biosimilar biological products and that more price competition between more products would occur. Finally, as stated in the CY 2018 PFS and Other Revisions to Part B final rule (82 FR 53186), we believed the change in policy could lead to additional savings for Medicare and its beneficiaries over the long-term by increasing the utilization of products that are less expensive than reference biologicals. We believe that providing a code application deadline extension for biosimilar biological products to accommodate the submission of required FDA documentation past the application deadline would similarly support the goal of a competitive market because it will facilitate faster assignment of a separate HCPCS code, which we believe will increase the availability of and access to biosimilar biological products. We also believe that providing an extension for submitting the required FDA documentation for biosimilar biological products will help further the President's initiative to promote access to generics and biosimilar biological products in order to lower prescription drug costs for all Americans.³³ We believe this 10-business day extension would be helpful for manufacturers of biosimilar biological products

³³ See "Increasing Access to Generics and Biosimilars in Medicare" (Feb. 5, 2020) available at <https://www.cms.gov/blog/increasing-access-generics-and-biosimilars-medicare>.

seeking a HCPCS Level II code who receive their FDA marketing authorization just after the deadline for submitting an application in a given coding cycle, and because we do not currently receive many applications for biosimilar biological products, we do not believe this extension would impact our ability to review all the applications and issue final coding decisions in a particular coding cycle. We do not believe an extension longer than 10-business days would be feasible given the number of applications we receive in a coding cycle and the resources for evaluating those applications. We note that if we were to begin receiving a large number of applications for biosimilar biological products within the 10-business day extension period in a coding cycle, and the number of applications negatively impacted our timely review of all of the applications we received, we might decide to reconsider this proposed policy, if finalized.

Thus we propose to add a new policy at new § 414.9(a)(3) that would establish a 10-business day extension past the code application deadline for submitting a complete application, including FDA marketing authorization documentation, for biosimilar biological products. We propose that this extension would apply only if the following proposed criteria are met: (1) the marketing authorization documentation is dated between the first day of the extension period and no later than the last day of the extension period; and (2) the applicant submits a complete application to CMS by the last day of the extension period. We believe these proposed limitations are necessary to limit the deadline extension only to those applicants that receive marketing authorization after the regular quarterly application deadline and before the end of the extension period. We believe a 10-business day extension would be an adequate and reasonable amount of time for applicants, given the proposed shorter quarterly coding cycles, while still allowing enough time for CMS to evaluate the code application and generally make a final coding decision within the quarterly coding cycle. We also considered an extension of up to 3

weeks. Because there are only a limited number of days in the quarterly coding cycle to evaluate the applications and because we are usually already heavily involved in application review by that point, we believe it would be very difficult for us to provide an extension beyond 10 business days and still be able to make a final coding decision in the quarterly coding cycle. Given implementation of shorter, quarterly coding cycles, we believe it is reasonable to have applicants submit a full and complete application in the next coding cycle when complete documentation cannot be submitted by the 10-business day extension after the code application deadline. We also considered extensions shorter than 10 business days, but we believe shorter extensions might not make a meaningful difference for applicants to receive an FDA decision and submit the required documentation to CMS.

Also, while we do not believe an application deadline extension to accommodate later submission of required FDA documentation would be feasible for all drug or biological product applications given our resources and the compressed review timeframe under shorter coding cycles, we seek comment on other potential circumstances that could warrant such a deadline extension within the quarterly coding cycles (for example, for particular drugs or drug classes). We note however that our ability to accommodate any extension is based on our expectation that the extension would impact only a limited number of applications. If the number of applications that are submitted to CMS within an extension period becomes too large, we may need to reevaluate the policy, if finalized. We also seek comment on the appropriate length of an extension for those circumstances, taking into consideration that one possible approach to address requests for more lengthy extensions, or a higher volume of applications submitted within an extension period, may be a longer coding cycle (for example, a bi-annual coding cycle) for all drug or biological product applications. We also seek comment on the impact of product

launch delays for biosimilar biological products once they are approved by the FDA. A number of biosimilar biological products have not been launched immediately after their approval by the FDA, thus we seek comment on whether a 10-day deadline extension is necessary.

Consistent with current practice, we also propose at new § 414.9(a)(2)(iii) that in order for applications for non-drug, non-biological items or services that are not subject to marketing authorization under the Federal Food Drug & Cosmetic Act (FD&C Act) or Public Health Service Act (PHSA) to be considered complete, the application must include evidence that the item or service is available in the U.S. market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline specified by CMS. Prior to 2020, we had a requirement for 3 months of marketing activity at the time of the application deadline to create or revise a code for non-drug items, although an insurer could assign a miscellaneous code for use until such time as a coding decision is made.³⁴ Beginning in 2020, we adjusted the marketing criteria to only require evidence that the item or service is available in the U.S. market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline, to improve the speed of beneficiary access to new items and services, and applied this policy to non-drug items that are not regulated by the FDA. We believe it is important that non-

³⁴ HCPCS Level II codes include “miscellaneous/not otherwise classified” codes. Historically, these codes have been used when a supplier is submitting a bill for an item or service for which there is no existing code that adequately describes the item or service being billed. If a supplier or manufacturer has been advised to use a miscellaneous code (also known as unlisted code, unclassified code, or not otherwise specified code) because there is no existing code that describes the item or service but the supplier or manufacturer believes that a new code is needed, then the supplier or manufacturer may submit an application to add a new HCPCS Level II code. Significantly, miscellaneous codes allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the FDA in the absence of a specific HCPCS code – including during the period when a request for a new code is being considered under the HCPCS code review process. In addition, to avoid the inefficiency and administrative burden of assigning distinct codes, miscellaneous codes also may be used for items or services that are rarely furnished or for which few claims are expected to be submitted.

drug, non-biological items not subject to marketing authorization under the FD&C Act or PHSA be available in the U.S. market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline as some measure of assurance that the item is available for prescription or use and thus is ready to receive a HCPCS Level II code. We believe this minimizes the chance of adding unnecessary codes or making updates to the code set that may not be useful, thus promoting administrative simplification and minimizing burden on insurers, providers, coders, and other users of the HCPCS code set. As discussed in more detail in section IV.B.2. of this proposed rule, a major goal of an effective code set is to strike a balance between sufficiently identifying and differentiating items and services and producing a manageable system and set of codes for users to efficiently submit and process claims. When a new code is added, updates must be disseminated, policies and coding manuals revised, and medical records, billing software, and other systems changes are necessary to accommodate the new and revised codes. In addition, coders, providers, and suppliers have to be educated on and prepared for changes in codes to ensure they are accurately utilizing the appropriate code that best describes a specific item or services. By contrast, given the rigorous FDA marketing authorization processes, requirements for clinical data, and the user fees generally associated with the FDA marketing authorization processes, CMS believes that manufacturers of items that are subject to FDA marketing authorization intend to market the product that is the subject of the code application and as such we do not require evidence that these items are available in the U.S. market for use and purchase at the time of the relevant code application deadline. We note however that even if an item or service that is subject to FDA marketing authorization is not available on the U.S. market at the time of the application submission deadline, as noted in

proposed § 414.9(a)(2), all such code applications must include the applicable FDA documentation and other information outlined in § 414.9(a)(2), to be complete.

As described earlier in this subsection and at proposed § 414.9(a), we are proposing to decline applications received after the applicable deadline or that are incomplete. Applications that are declined because they are not submitted by the applicable deadline or are incomplete may be submitted in a subsequent coding cycle provided they are timely and complete by the applicable deadline for the subsequent coding cycle. We also considered allowing applicants to supplement incomplete applications after the application deadline for minor deficiencies or missing information that is insubstantial, such as a missing brochure or clinical study that is referenced by the applicant but not included as an attachment to the application. We weighed the benefits of accommodating the submission of such supplemental information within a coding cycle in cases where there are minor deficiencies, against the need for applicants to submit timely, complete applications. Given the shorter coding cycles we currently implement (which we propose to continue, as previously discussed), we believe it would be difficult to follow-up with numerous applicants within a cycle for missing information, and thus, we propose that an application must be timely and complete, in accordance with the criteria described earlier in this section, in order for the application to be considered and reviewed in a coding cycle. However, we seek comment on whether we should allow certain supplemental information to be submitted after the application deadline and in what circumstances (including requirements or timeframes we should impose for accepting additional information), recognizing that CMS would only have a limited amount of time and resources for following up about and obtaining missing information from applicants and may also have limited opportunities to consider supplemental information in the course of the coding review cycle. Please note that we would continue to allow applicants to

supplement a complete application with additional materials up to the time of close of business on the date of the public meeting at which the application is discussed, as is our current policy.

d. Proposed Application Resubmission and Reevaluation

As outlined in the HCPCS Level II Coding Procedures document posted on our website at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS>, we currently allow any applicant who is dissatisfied with our final coding decision to resubmit an application for a previously considered item or service in a subsequent coding cycle for us to reevaluate the final coding decision. Under our current policy, we allow applicants to resubmit HCPCS Level II code applications without limitation for items and services on which we previously reached a final coding decision. Although we have stated in our past guidance that previously unavailable information, additional explanations, or significant new information that supports such a reevaluation request may be helpful in informing CMS about why the prior decision should be changed, many resubmitted applications do not contain new information or specify a clear basis for us to reevaluate the previously submitted information or reconsider the prior final coding decision. As a result, we have spent time and resources reviewing applications that are resubmitted with substantially similar information, without a clear understanding of whether there is something new or whether aspects of the information previously submitted should be considered differently, such that it would warrant a change to our prior final coding decision. We are proposing to continue to allow applicants to resubmit code applications for reevaluation of prior final coding decisions. However, in the interest of reaching an appropriate coding decision and supporting efficient and expeditious review of all code applications that are resubmitted, we are proposing certain limitations and additional policies related to reevaluations of coding decisions.

We propose at new § 414.9(b)(1) that an applicant who is dissatisfied with a final coding decision on an initial code application may resubmit their application for reevaluation by CMS no more than two times. We propose that any application resubmitted for reevaluation must be timely and complete as specified in proposed § 414.9(a) and must include-- (1) a description of the previous application submission(s); (2) a copy of the prior final coding decision(s); and (3) an explanation of the applicant's reason for disagreement with the prior final coding decision(s). The first time an applicant resubmits an application for reevaluation by CMS, we would not require, but would strongly encourage, that the applicant submit new information with the application. As we state in our current guidance, previously unavailable information, additional explanations, or significant new information that supports such a reevaluation request may be helpful in informing CMS about why the prior decision should be changed.

In addition, at proposed § 414.9(b), we propose that if an applicant is dissatisfied after our initial reevaluation of our prior final coding decision, we would allow one additional opportunity for the applicant to resubmit the application for reevaluation of the first resubmission decision. For a second application resubmission and reevaluation, we propose at § 414.9(b)(2) that, in addition to the information and documentation required to be submitted with both resubmissions under proposed § 414.9(b)(1), the application also must include the following: (1) significant new information, defined as information that was not previously submitted to CMS with respect to the application that directly relates to the reason for the prior final coding decision(s) and could potentially change the final coding decision, and (2) an explanation of how the significant new information addresses and directly relates to the reason(s) for the previous final coding decision(s) and supports the request for a different coding decision. By significant new information, we mean information not previously submitted to CMS (for example, it was

not included in the prior application, and not submitted as a supplement to the prior application or in response to a preliminary recommendation issued for a prior public meeting up to the time of close of business on the date of the CMS HCPCS public meeting at which the application is discussed), and that directly relates to the reason for the prior final coding decision(s) (for example, significant new information could be a newly published relevant clinical study that supports a claim of a significant therapeutic distinction made, but unsupported, in the prior code application, or additional information that supports a claim in an initial application that the product performs a significantly different clinical function not captured in the current code set). The nature of the prior final coding decisions also would be relevant in determining whether the new information submitted would be considered significant new information within the meaning of this proposal. As in the example described previously, a new or additional clinical study may be considered significant new information if the previous final coding decision(s) directly relates to an unsupported claim of significant therapeutic distinction. If significant new information is not submitted with the second resubmission, or if the applicant does not provide the other information required to be provided with both resubmissions (as set forth at proposed § 414.9(b)(1) and (2)), we would decline to reevaluate the application. We note that for an application to be considered for reevaluation it must be for the same item or service originally submitted, and it must be based on the same request made in the initial code application. For example, if an item receives a new indication that was not a part of the original application, a new and separate application would be required if the applicant seeks to address the new indication because the review of such an application would require new and different considerations.

We believe that requiring applicants to include significant new information (and satisfy the additional requirements at proposed § 414.9(b)(1) and (b)(2)) when an application is resubmitted for a second reevaluation balances our desire to afford applicants another opportunity to seek a reevaluation when they believe a final coding decision should be changed and the recognition that it takes time and resources to reevaluate applications that are submitted multiple times, especially when those applications are submitted without a clear indication of whether there is new information that should impact CMS's decision, or whether aspects of the information previously submitted to CMS may be considered differently. We believe that requiring significant new information and other information, as outlined in proposed § 414.9(b)(1) and (b)(2), would enhance the accuracy of our coding decisions and would enable us to focus our limited resources on maintaining continued efficiency and speed in processing applications.

We believe our limitation on the number of times an application can be resubmitted for reevaluation of a final coding decision is reasonable. In the past under the annual coding cycles, applicants have resubmitted applications multiple times in subsequent coding cycles for reevaluation. We believe that this could happen even more often under the shorter more frequent coding cycles, especially for drug or biological product code applications, given the shorter coding cycles. However, we do not believe it would be necessary or appropriate to allow for more than two resubmissions of a code application for reevaluation, especially since under our proposal, resubmissions would include additional information and materials as required by proposed § 414.9(b)(1) and (b)(2) (as previously discussed in this section) and the applications would go through a public meeting process with opportunity to comment on resubmissions (as discussed later in this section). Allowing further opportunities for applicants to resubmit

applications after multiple evaluations of the prior coding decision(s) for the same item or service would strain our resources and is unlikely to result in a different decision (especially given that for the second resubmission, the applicant would be required to provide us with significant new information for our consideration). Therefore, we believe it is important to apply a reasonable limit to the number of times a code application for the same item or service can be resubmitted that takes into account prior opportunities for evaluation, conserves limited resources, and supports successful and timely implementation of shorter and more frequent coding cycles. We also believe that our proposal to place a limit on the number of resubmissions would encourage applicants to fully consider and robustly address the reason for the prior denial of their coding request before resubmitting. It also would decrease the likelihood of resubmission of applications without significant new information that could potentially change the prior coding decision. Therefore, we propose to limit the number of times an applicant may resubmit a code application for the same item or service for reevaluation by CMS to two resubmissions. This limitation would apply to resubmissions of applications for the same item or service with the same FDA marketing authorization submitted with the original application and would continue to apply to a code application for that item or service regardless of whether the applicant or manufacturer undergoes a change of ownership, a new manufacturer begins manufacturing the item or service at issue, there is a change of or new supplier of that item or service, or the item or service is renamed.

In addition, in order to ensure that we have the opportunity to receive and consider additional input that may be helpful for reevaluations, at proposed § 414.9(b)(3), we are proposing to include an application submitted for reevaluation on an agenda for a bi-annual public meeting and to issue a preliminary recommendation (provided the resubmitted application

is timely and complete and meets all other proposed criteria and requirements for consideration under the HCPCS Level II external code application process). We note that this policy would also apply to resubmitted applications for drug or biological products as well as for non-drug and non-biological items and services. For resubmissions of code applications for drug or biological products, we propose at § 414.9(b)(3)(i) that the resubmitted application would not be included in a public meeting or receive a final decision in the quarterly cycle in which the application is submitted. Even if a public meeting falls within the quarterly cycle in which such an application was resubmitted, we would not include the application in a public meeting agenda or issue a preliminary recommendation on such application until at least the following bi-annual cycle. We believe this is necessary because we would need more than approximately 1-month to prepare the preliminary recommendation before including an application on a public meeting agenda. For example, if a drug or biological product application were submitted for reevaluation for the second quarterly cycle of the year (application deadline around April), the preliminary recommendation for the public meeting that falls in that cycle would need to be prepared for May, which we believe would not allow us sufficient time to complete a preliminary recommendation. In addition, consistent with the policy that would apply to initial code applications, we propose at § 414.9(b)(3)(ii) that preliminary recommendations and final decisions for applications that are resubmitted for reevaluation may be delayed as described in § 414.8(e)(3).

We seek comments on the proposals discussed in this section.

2. Proposed Evaluation of HCPCS Level II Code Applications

As explained earlier in section IV.A.2. of this proposed rule, interested parties seeking to modify the HCPCS Level II code set may submit an external HCPCS Level II code application,

as available on CMS' website, that requests to add a code, revise an existing code, or discontinue an existing code. An application to add a code may be submitted when the applicant believes it is appropriate for the item or service that is the subject of the code application to be separately identified by a new HCPCS Level II code. An applicant may submit an application to revise an existing code if the applicant believes that the descriptor of an existing HCPCS Level II code does not adequately describe the subject item or service, and that a modification to the long descriptor language (code text) would provide a more appropriate description of the category of items or services represented by the code. An application to discontinue an existing code may be submitted when the applicant believes that an existing HCPCS Level II code is duplicative of another code or has become obsolete and should be removed from the HCPCS Level II code set. Consistent with these procedures, we propose at § 414.10(b) that an applicant may submit an external HCPCS Level II code application to request the addition of a code, revision of an existing code, or discontinuation of an existing code.

We propose at § 414.10(c) that our evaluation of a code application would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Our evaluation of a code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with modification. CMS may also deny the coding request. CMS's coding action would be set forth in the final coding decision. We propose at § 414.10(h) to continue these procedures. Examples of prior years'

CMS HCPCS Level II coding decisions are publicly available on our HCPCS website at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>.

As set forth at proposed § 414.10(a), the code application evaluation procedures proposed in § 414.10 and described in this section would apply to CMS' evaluation of external HCPCS Level II code applications for drug or biological products and non-drug, non-biological items and services, as described in proposed § 414.8. In this section, we propose the processes by which we would evaluate code applications, depending on the subject of the application and type of modification to the code set requested. Our evaluation of all code applications, however, involves careful consideration of CMS's objectives of maintaining a code set that is manageable for users and that meets the claims processing needs of Medicare, as explained in more detail in this section.

A major goal of an effective code set is to strike a balance between sufficiently identifying and differentiating items and services and producing a manageable system and set of codes for the efficient submission and processing of claims. The HCPCS Level II code set is not intended to be a universal listing of all items and services at a granular, product-specific level. Rather, the HCPCS Level II code set currently contains almost 8,000 separate categories of like items or services that encompass products from different manufacturers. Thus, a code category is generally intended to describe the item or service provided in a way that is general enough so as not to be manufacturer specific. Categorizing items and services in this manner simplifies the submission and processing of claims with a manageable number of codes and thus promotes the goals of administrative simplification and burden reduction as previously discussed.

In striking a balance between sufficiently identifying and differentiating items and services and producing a manageable system and set of codes for the efficient submission and

processing of claims, throughout the proposed evaluation process for code applications, we consider CMS' objective of maintaining a code set that allows for the efficient and timely processing of Medicare claims in accordance with the Medicare statute and regulations that are specific to the items and services for which a code is being requested. As explained in section IV.A.1. of this proposed rule, prior to its adoption under HIPAA as the standard medical data code set for reporting certain items and services not identified by CPT[®] codes in HIPAA standard transactions, HCPCS Level II codes were developed by CMS, then known as HCFA, to standardize the coding systems used to facilitate claims processing and payment for items and services primarily for Medicare. The HCPCS Level II coding system was selected as a standard medical data code set for use in HIPAA standard transactions in part because of its wide acceptance among both public and private payers. We maintain the HCPCS Level II code set primarily to support the claims processing needs of Medicare, recognizing that other payers use HCPCS Level II codes as well.

When we use the term "claims processing need" we are referring to evaluating HCPCS applications in a manner that sufficiently identifies and differentiates items and services but produces a manageable system and set of codes for the efficient submission and processing of Medicare claims in accordance with the Medicare statute and regulations that are specific to the items and services for which a code is being requested. The granularity of what falls within code categories in the HCPCS Level II code set is deeply tied to Medicare's "claims processing need." Similarly, reaching a judgment about whether any two items that fall within the code set are sufficiently different so as to require distinct codes is also always tied to "claims processing need." Several of the more specific proposed criteria for evaluating HCPCS Level II code applications, as described later in this proposed rule, can be understood to encompass an

assessment of Medicare “claims processing need.” Sometimes a Medicare “claims processing need” is driven by Medicare program integrity concerns. A Medicare program integrity need may drive a need to add a HCPCS Level II code to identify an item or service that would otherwise fall outside the scope of the HCPCS Level II code set or may drive a need for a more specific code in order to make it efficient for CMS to distinguish and deny corresponding claims. In general, CMS has a “claims processing need” for each code within the HCPCS Level II taxonomy to adequately describe a corresponding item or service, such that when a related claims form is filed, CMS can understand what the Medicare beneficiary actually received from the provider or supplier, but without the code being overly specific and thereby causing undue administrative burden for CMS (or for other users of the code set, for that matter). In other words, when we review applications for HCPCS Level II coding requests, we evaluate the information offered by the applicant that articulates the reasons why the applicant believes a specific code is warranted, against the information CMS believes is needed to process a claim effectively for a specific item or service, including the information needed to describe that item or service in order to apply Medicare coverage and payment policies, and to minimize program integrity risks. We invite the public to comment on the term “claims processing need” as we use it here and throughout this proposed rule, including in the context of specific provisions of this rule describing the proposed evaluation standards for the review of HCPCS Level II code applications.

a. Proposed Evaluation Process for Applications to Add a Code

In this section, we propose the processes by which we would evaluate code applications to add a code.

(1) Proposed Evaluation Process for Non-Drug, Non-Biological Applications to Add a Code

(a) Proposed Threshold Factors for Evaluating Non-Drug, Non-Biological Applications to Add a Code

As a threshold matter, when an applicant requests to add a code for a non-drug, non-biological item or service, as defined in section IV.B of this proposed rule, we believe it is important to first consider whether the item or service that is the subject of the application is appropriate for inclusion in the HCPCS Level II code set and whether there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set. Consistent with our current practice, we propose at § 414.10(d)(1)(i)-(iii) that we would first determine whether, as a threshold matter, the subject item or service is appropriate for inclusion in the HCPCS Level II code set by assessing whether: (1) the item or service is not appropriate for inclusion in or already coded in a different HIPAA standard medical data code set, such as CPT[®], ICD, or CDT[®]; (2) the item or service is primarily medical in nature; and (3) if applicable, the item has the appropriate marketing authorization from FDA, or is exempt from premarket notification requirements. Consistent with our current practice, we propose at § 414.10(d)(1)(iv) that we would also determine whether, as a threshold matter, there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set.

As discussed in section IV.A. of this proposed rule, not all items and services are appropriate for inclusion in the HCPCS Level II code set maintained by CMS. This is because HIPAA mandated the adoption of certain medical data code sets to standardize the way various types of data are reported during routine transmission of electronic claims, with the HCPCS Level II code set specifically adopted to identify particular items and services, such as healthcare equipment and supplies not described by CPT[®] codes (45 CFR 162.1002). The adoption of

standard national medical data code sets helps to avoid duplication and burden (65 FR 50361). Therefore, as a threshold matter, we believe it is important to determine whether the subject item or service is not appropriate for inclusion in or already coded in a HIPAA standard medical data code set other than the HCPCS Level II code set maintained by CMS, such as CPT[®], ICD, or CDT[®]. For example, although technically part of the HCPCS Level II code set, the CDT[®] code set was adopted under HIPAA as the standard national medical data code set to be maintained by the American Dental Association, for reporting dental items and services supplied to or used by dentists, oral and maxillo-facial surgeons, prosthodontists, and periodontists. Therefore, these items and services are not appropriate for inclusion in the HCPCS Level II code set maintained by CMS.

When we evaluate whether an item or service is appropriate for inclusion in the HCPCS Level II code set, we also take into account the type of item or service, the setting in which it is furnished or used, by whom it is used, and how it is used. For example, an item or service exclusively used or administered in the inpatient hospital setting would not be appropriate for inclusion in the HCPCS Level II code set. Procedures performed during an inpatient stay are identified by ICD-10-PCS codes. In addition, the setting in which the item or service is used or administered and by whom it is used or administered may be considered together when considering whether the item or service is appropriate for inclusion in the HCPCS Level II code set. For example, we consider whether an item or service is typically physician-administered in a physician's office versus self-administered by the patient in the home. Procedures performed by physicians or other health care professionals when performed in a physician's office are typically described by CPT[®] codes. We also note that an item or service that is the subject of a HCPCS Level II code application could already be captured by a specific code or a

comprehensive code used to identify a group of related items and services in another code set such as supplies that are used during an already coded procedure. As part of this assessment, we consider whether a particular item or service, or a component of an item or service, is included in a bundled payment³⁵ and coded in a different HIPAA standard medical data code set because separate reporting and billing of a bundled item or service could be duplicative.

Consistent with our current practice, we also propose to assess, as a threshold consideration, whether the subject item or service is primarily medical in nature. The HCPCS Level II code set is a standard medical data code set adopted under HIPAA for describing and identifying healthcare equipment and supplies in electronic healthcare transactions (45 CFR 162.1002). The HCPCS Level II code set is not intended to be a universal or exhaustive listing of all items and services on the market, and is generally reserved for medical items and services, since HCPCS Level II codes generally represent categories of like healthcare items and services for health insurer claims processing purposes. As such, we believe it is important to evaluate whether the item or service for which an applicant is requesting coding action is primarily medical in nature. For purposes of this proposed threshold factor, an item or service would be considered “primarily medical in nature” when it is primarily and customarily used to serve a medical (diagnostic or therapeutic) purpose, and is generally not useful in the absence of an illness or injury. If the primary or customary use of an item or service is not for a

³⁵ A bundled payment methodology involves the combining or “bundling” items and services together for single rate or payment amount (an all-inclusive payment amount), such that individual items and services are not billed and paid for individually. This is common in many Medicare prospective payment systems, though the constellation of bundled items and services and underlying payment methodologies vary (for example, a bundled payment may be based on expected costs of the items and services furnished to a beneficiary during an episode of care). When bundled payment methodologies apply, we must ensure that duplicate payment is not made by Medicare (that is, that items and services are not “unbundled” and billed and paid for separately).

medical (diagnostic or therapeutic) purpose, then it would not be considered primarily medical in nature, even if the item or service could be used in a healthcare setting or in a way that assists a patient. For example, while an air conditioner may have a remote medical (therapeutic) use of lowering room temperature to reduce fluid loss in a cardiac patient and to maintain the proper fluid balance, the primary and customary use of the air conditioner is for a non-medical purpose – that is, the item is generally used by anyone, regardless of an existing medical condition, to stay cool in a way that is not for the diagnosis or treatment of an illness or injury. Furthermore, an air conditioner is useful in the absence of an illness or injury, and thus, an air conditioner would not be considered “primarily medical in nature” for purposes of this proposed threshold factor. Other examples of items that may be used by a person with a medical disease or condition, but that we would not consider primarily medical in nature for purposes of this proposed threshold factor due to their common usage for non-medical purposes include: mirrors used for self-examination; drinking straws (including elongated straws) used to assist with reach; and wearable garments, such as shirts, pants, headbands and belts, even if the styling of the garment permits easier access to IV insertion sites or dialysis shunts, or keeps a body part dry when worn in the shower or swimming pool. The information that applicants include in the code application facilitates our assessment of this proposed threshold factor; applicants describe how the item or service is primarily and customarily used to serve a medical purpose and explain whether the item or service is useful in the absence of an illness or injury.

Consistent with our current practice, we also propose to assess, as a threshold consideration, whether the item that is the subject of the code application has the appropriate marketing authorization from FDA, or is exempt from premarket notification requirements, if applicable. We believe it would be inappropriate and premature to consider potential coding

action for an item that does not yet have the appropriate marketing authorization from FDA or a claimed exemption from such requirements. We require applicants to provide documentation of marketing authorization by FDA at the time the application is submitted, and also request information regarding the date the item was granted such marketing authorization, at the time the application is submitted. We also require applicants to explain the basis for any claimed exemptions from FDA premarket notification requirements, with specific citations to the regulation number under 21 CFR parts 862 through 892 as appropriate. Our assessment of this proposed threshold factor involves verifying that the documentation and information provided by the applicant matches the item or service that is the subject of the code application. We seek input from FDA should we have any questions about the documentation and information provided by the applicant.

Consistent with our current practice, we also propose to assess, as a threshold matter, whether there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set. Given our objective, as explained earlier in section IV.B.2. of this proposed rule, of maintaining a code set that meets the claims processing needs of Medicare, we believe it is important to first ensure that Medicare has a claims processing need to identify the subject item or service with a HCPCS Level II code.

The determination of whether a HCPCS Level II code to identify the subject item or service is needed for claims processing purposes would depend on the individual facts and circumstances presented by each application. As we stated previously, we propose at § 414.10(c) that our evaluation of a code application would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal

employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made or the evidence produced by the applicant. Consistent with current practice, this includes information obtained from and evaluations conducted by federal employees comprising a team generally known as the CMS HCPCS Workgroup. This is an internal workgroup composed of federal government officials representing the major components of CMS, as well as other employees from pertinent Federal agencies, including the Department of Veterans Affairs and the Defense Health Agency, which includes policy, product, and claims processing experts. The Workgroup discusses whether coding requests warrant a change to the HCPCS Level II code set, and informs CMS' decisions relative to the claims processing needs of Medicare. We also take into consideration any pertinent information that may have been received from code applicants and their representatives and other stakeholders, including government insurers and the general public, through HCPCS public meetings.

Consistent with our current practice, we propose at § 414.10(d)(1) that if we determine that the subject item or service satisfies all the factors at proposed § 414.10(d)(1)(i) through (iv), discussed previously, we would further evaluate the applicant's coding request under the process proposed in § 414.10(d)(4) and discussed later in section IV.B.2.a.(1)(b) of this proposed rule, to determine whether it would be appropriate to add a code for the item or service.

Furthermore, given our objective of maintaining a code set that meets the claims processing needs of Medicare, we propose at § 414.10(d)(2) that if one or more of the proposed factors under § 414.10(d)(1)(i)-(iii) are not met but the proposed factor in § 414.10(d)(1)(iv) is met, we would further evaluate the applicant's coding request under the process proposed in § 414.10(d)(4). We believe it would be premature to deny the application when a Medicare

claims processing need exists. For instance, Medicare may need to separately identify a non-covered, previously non-coded item or service that has been frequently miscoded using an existing specific or miscellaneous HCPCS Level II code, which could result in inappropriate payment. As an example, we created code A4467 (“Belt, strap, sleeve, garment, or covering, any type”) to identify certain items that were not found to be primarily medical in nature and thus not appropriate for inclusion in the HCPCS Level II code set, but that had been miscoded under miscellaneous or other existing HCPCS Level II codes for DME, resulting in erroneous payment. To ensure the accuracy of Medicare claims, code A4467 was established to separately identify these particular items in order to prevent them from being inappropriately reported through the use of other existing HCPCS Level II codes. In this way, separately identifying these items clarifies to coders that the particular item is not described by a different existing HCPCS Level II code. As another example, we may need a code to distinguish items statutorily excluded under Medicare, such as certain contact lenses, similarly to avoid miscoding and ensure more accurate claims processing. Thus, consistent with our current practice, we believe it is appropriate to propose the exception at proposed § 414.10(d)(2).

We propose at § 414.10(d)(3) that if the application satisfies neither proposed § 414.10(d)(1) nor § 414.10(d)(2), we would not further evaluate the applicant’s coding request under the process proposed in § 414.10(d)(4) and thus would not modify the HCPCS Level II code set in response to the coding request. If we determine that the subject item or service is only appropriately coded in a code set other than the HCPCS Level II code set, such as CPT®, ICD, or CDT®, we would, where appropriate, redirect the applicant to the other code set.

(b) Proposed Process for Further Evaluating Non-Drug, Non-Biological Applications to Add a Code

If the application satisfies proposed § 414.10(d)(1) or (d)(2), the focus of our evaluation then shifts from whether the subject item or service is appropriate for inclusion in the HCPCS Level II code set to the appropriate placement within the HCPCS Level II code set. Under this proposed evaluation process, we would further evaluate an applicant's coding request by assessing the functional and clinical differences of the subject item or service compared to other similar items or services already described in the HCPCS Level II code set, and determine based on our assessment of those differences, whether it would be appropriate to take coding action to add a new code to identify the subject item or service or revise the descriptor of an existing code category to clarify that the subject item or service is captured by the existing code category, or to take no coding action due to the availability of an existing code category that adequately describes the subject item or service. As explained in more detail in this section, we assess these differences due to the nature of HCPCS Level II codes, which generally represent categories of like items or services, grouped together at the broadest level, on the basis of performing the same or similar function for a patient. This is because, as previously noted in this section, the HCPCS Level II code set is not intended to be a universal listing of all items and services at a granular, product-specific level. Additionally, the information submitted by the applicant in the code application facilitates our determination of appropriate coding action. In the code application, applicants describe the item or service that is the subject of the code application, such as what the item or service does, how it is used, the patient population for which the item or service is clinically indicated; the medical benefit of the item or service to the patient, such as the clinical outcome resulting from the use of the item or service; and the reason why the applicant believes existing codes do not adequately describe the item or service.

As explained in more detail later in this section, we propose at § 414.10(d)(4) to assess:

(1) whether the subject item or service performs a significantly different clinical function compared to other items or services described by the HCPCS Level II code set; and (2) whether the use of the subject item or service results in a significant therapeutic distinction compared to the use of other similar items or services described by the HCPCS Level II code set.

Furthermore, as discussed later in this section, we propose to consider whether a new HCPCS Level II code to separately identify the subject item or service is needed by Medicare to facilitate claims processing. These proposed factors balance our desire to facilitate patient access to innovative items or services with our consideration of CMS' objectives of maintaining a code set that is manageable for users and that meets the claims processing needs of Medicare.

(i) Significantly Different Clinical Function

As previously discussed, codes generally represent categories of like items and services, grouped together at the broadest level, on the basis of performing the same or similar clinical function for a patient. In order to evaluate what code category is appropriate for an item or service, we need to evaluate the clinical function performed for the patient and how the item or service addresses their condition. Therefore, our evaluation of applications to add a code begins with identifying and assessing the clinical function of the item or service that is the subject of the code application. Broadly speaking, the clinical function performed by an item or service refers to what the item or service does for a patient. It can also be understood as the general function of the item or service in the body, or the intended purpose of the item or service in the delivery of care. Clinical function can also refer to the overall treatment provided to a patient through the use of the item or service. For example, the clinical function of positive airway pressure is respiratory ventilation, and the clinical function of an electrode is to conduct electricity. As

explained earlier, applicants are requested to provide information to facilitate our assessment of clinical function, such as fully explaining what the subject item or service does, how it is used, and the patient population for which the item or service is clinically indicated.

In most cases, items and services are developed in a way that is evolutionary or iterative – that is, they are developed in a way that results in new items or services that still retain similar features or functionalities as those performed by previous iterations or versions, such that they may not be so different from those already described by the code set. When evaluating whether a new code is appropriate for the subject item or service, we look to see if an existing code adequately captures the clinical function of the item or service, or whether the clinical function of the item or service is so distinct or dissimilar from the clinical functions performed by other items or services currently described by the HCPCS Level II code set that it cannot be categorized in an existing code category with other items or services. We believe a new code may be warranted if we determine that the subject item or service performs a clinical function that is not performed by any other items and services currently categorized in the HCPCS Level II code set – that is, a clinical function that is considered first-of-kind for purposes of HCPCS Level II coding. Because the clinical function would not be performed by other items or services already categorized in the code set, there would be no existing HCPCS Level II code to describe such an item or service. Thus, consistent with our current practice, we propose at § 414.10(d)(4)(i) that we would evaluate whether the item or service that is the subject of the code application performs a significantly different clinical function as compared to other items and services described by the HCPCS Level II code set, and that an item or service is considered to perform a significantly different clinical function if it performs a clinical function that is not performed by any other item or service currently described by the code set. If we determine that

an item or service performs a significantly different clinical function, we further assess whether there is a claims processing need on the part of Medicare to identify that particular item or service based on its clinical function with a new code on a HIPAA standard claim. Thus, we propose at § 414.10(d)(5)(i) that a new code would be warranted if we determine that the item or service that is the subject of the code application performs a significantly different clinical function as compared to other items and services described by the HCPCS Level II code set, and we find there is a claims processing need to separately identify the item or service with a new code to facilitate payment under Medicare.

An example of this can be shown by code Q0480, “Driver for use with pneumatic ventricular assist device, replacement only,” which at the time a code was requested, was an item performing a first-of-kind clinical function not previously captured by the code set and for which there was a demonstrated claims processing need. This device was the first mechanical heart pump with replaceable external components authorized by FDA as a destination therapy so the patient would not have to remain in the hospital while awaiting a transplant, and we issued a new code to identify this device.

(ii) Significant Therapeutic Distinction

Codes represent categories of similar items or services, grouped together at the broadest level, on the basis of performing the same or similar clinical function. Items or services identified in the same code may differ in some respects, for example in the mechanism of operation. We recognize that differences between items or services that perform the same or similar clinical function, such as a difference in mechanism of operation, may result in a significantly improved medical benefit or significantly different medical benefit for patients. We believe it is important for insurers to be able to differentiate and separately identify such items

and services to facilitate claims adjudication. As such, and subject to CMS finding there is a claims processing need under proposed § 414.10(d)(5)(i), we believe that when the item or service that is the subject of the code application operates differently than other similar items or services described in existing codes, and that difference in operation results in a significantly improved or significantly different medical benefit for patients (as defined later in the section), the difference between the subject item or service and other similar items or services would be meaningful enough to warrant a differential coding based on significant therapeutic distinction. Differential coding on the basis of significant therapeutic distinction also reflects our desire to facilitate patient access to the advantages and benefits of innovative items or services by ensuring codes are available to providers and suppliers to use.

Under current guidance,³⁶ a significant therapeutic distinction is shown when the subject item or service results in an improved medical benefit (for example, a significantly improved medical outcome or a significantly superior clinical outcome) when compared with the use of other similar items or services that would otherwise share an existing code category. Requests for modifications to the HCPCS Level II code set based on claims of significant therapeutic distinction are reviewed on a case-by-case basis, taking into consideration clinical information provided by the applicant and others that may support or refute the claim(s) made by the applicant. An applicant should provide the best available information in support of the claim(s). Greater weight is given to more methodologically rigorous and scientifically reliable evidence. Process indicators, such as improved compliance, convenience, and personal preference are

³⁶ See “HCPCS Decision Tree For External Requests to Add or Revise Codes,” available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS_Decision_Tree_and_Definitions.pdf

considered significant therapeutic distinctions only to the extent that they result in demonstrably improved clinical outcomes.

The application seeks information from the applicant to enable us to assess whether the subject item or service results in a significant therapeutic distinction. Applicants are requested to identify currently coded items or services that perform the same or similar medical function as the subject item or service. Applicants are then requested to identify the differences between the subject item or service or its operation and the currently coded items or services, which would result in a significantly improved medical outcome or significantly superior clinical outcome.

In this proposed rule, we are proposing to broaden opportunities to identify a significant therapeutic distinction by also considering whether the use of the subject item or service results in a significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set. Thus, we propose at § 414.10(d)(4)(ii) that a significant therapeutic distinction is shown when the use of that item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

We propose at § 414.10(d)(4)(ii)(A) that we would determine that the use of an item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set if we find that it meets any of the criteria at proposed § 414.10(d)(4)(ii)(A), as further described later in the section. We note that proposed § 414.10(d)(4)(ii)(A) sets forth a framework that is based on the same general criteria that CMS currently uses for determining substantial clinical improvement for purposes of the Inpatient Prospective Payment System (IPPS) New Technology Add-On Payment (NTAP) (42 CFR 412.87(b)(1)), subject to

modifications that we are proposing for purposes of evaluating a significant therapeutic distinction claim for a HCPCS Level II code application. We believe that the same general framework used to evaluate whether a service or technology represents a substantial clinical improvement for purposes of the NTAP, as modified here, may also reasonably be used to evaluate whether the use of an item or service results in a significantly improved or significantly different medical benefit for the purpose of evaluating HCPCS Level II code applications. In both the HCPCS Level II context and the NTAP context, the framework allows for reaching a comparative determination about the therapeutic effect of a designated item or service, and whether this represents an advance over other items and services.

While we believe the same framework used for determining substantial clinical improvement for purposes of the IPPS NTAP would be generally appropriate for determining significant therapeutic distinction (significantly improved or significantly different medical benefit) in the context of evaluating a HCPCS Level II code application, we are seeking comment, as indicated in the bullet points later in the section, regarding whether certain factors would appropriately apply in the context of evaluating HCPCS Level II code applications, or whether they should be modified or eliminated for the purpose of determining significant therapeutic distinction. As reflected in proposed § 414.10(d)(4)(ii)(A), CMS would determine that the use of an item or service results in a significantly improved or significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set, if it finds any of the following:

- The item or service that is the subject of the code application offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments (for purposes of determining significant therapeutic distinction, this may include, for example,

persons for whom currently available treatments may be contraindicated, such as persons who may be allergic to those treatments or for whom those treatments may be toxic or harmful based on compromised renal or liver function or other co-morbid condition; or for specific populations for whom a currently available treatment or dosage is contraindicated, based on FDA-approved labeling, related to age, comorbid condition or concurrent treatment that could impact the results of the treatment; or for whom other treatments must be first tried and failed, as per FDA-approved labeling).

- The item or service that is the subject of the code application offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the item or service to make a diagnosis affects the management of the patient. We are seeking public comment regarding whether and under what circumstances this factor might be appropriately applied to HCPCS Level II code applications. We note that diagnostic tests and lab tests are generally not coded in the HCPCS Level II code set. Diagnostic tests and lab tests are not typically administered in patients' homes; and when administered in a physician's office, they are included in the procedure, and would not be separately payable using HCPCS Level II codes, and therefore a HCPCS Level II code would not be needed for Medicare claims adjudication.

- A demonstration of one or more of the following outcomes.

- ++ A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

- ++ A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

- ++ A decreased number of future hospitalizations or physician visits.

++ A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.

++ An improvement in one or more activities of daily living.

++ An improved quality of life.

++ A demonstrated greater medication adherence or compliance. With regard to this factor in particular, we are seeking comment regarding whether it is useful or appropriate to include improved medication adherence or compliance as a factor in evaluating HCPCS Level II code applications for non-drug, non-biological items and services for the purposes of determining significant therapeutic distinction. We note that medication adherence or compliance, by itself, is an interim measure, and not a clinical end point. While greater adherence or compliance might potentially lead to a clinical end point, those end points are already identified earlier in the list of outcomes. If CMS decides to adopt this factor as proposed, it would substantially modify the current standard CMS uses to evaluate whether the use of a non-drug, non-biological item or service demonstrates a significant therapeutic distinction. Generally, process indicators (such as improved compliance) have been considered significant therapeutic distinctions only to the extent that they result in demonstrably improved clinical outcomes (for example, improved mortality or morbidity).

- The totality of the information otherwise demonstrates that the use of the item or service results in a significantly improved or a significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set.

When determining whether the use of the item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other

similar items or services described in the HCPCS Level II code set, we propose at § 414.10(d)(4)(ii)(B) that we may consider instances where the use of the item or service may substantially improve or substantially change the medical benefit realized by a specific subpopulation of patients with the medical condition for whom the item or service is used, based on a common characteristic shared by the subpopulation (for example, allergic sensitivity to a currently available alternative treatment item) that impacts the medical benefit of the subject item or service. To offer another example, a significantly improved or significantly different medical benefit may be demonstrated where the use of an item or service, when compared to a currently available alternative item or service that is currently described in the HCPCS code set, provides a differential benefit to a subset of patients, based on patient characteristics typically needed to use the item or service (such as strength, functionality, and cognitive ability) and the manner in which the item or service is typically used. For example, certain prosthetics or orthotics, such as a heavy prosthetic leg with features that enable quicker gait, use on rough terrain, or on steep inclines might potentially be suitable for a strong patient, but may be more than a frail elderly patient could use or might need. A finding of significantly different medical benefit for such a prosthetic or orthotic item might be supported on the basis that the item provides a differential benefit for strong patients.

In determining whether the use of item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, we propose at § 414.10(d)(4)(ii)(C) that we would make this determination without regard to the prevalence among Medicare beneficiaries of the underlying medical condition treated or diagnosed by the item or service that is the subject of the code application. In particular, we would not consider a low prevalence rate for the

underlying medical condition as a factor weighing against an item or service that is the subject of the code application, for the purpose of our evaluating whether there is a significantly improved or significantly different medical benefit associated with use of the item or service.

Additionally, when determining whether the item or service would meet the criterion of conferring a significant therapeutic distinction, we propose at § 414.10(d)(4)(ii)(D) that an item's designation under the FDA Breakthrough Devices Program and marketing authorization for the indication that received such designation will be given substantial weight in the consideration. Under this voluntary program, FDA evaluates certain devices and device-led combination products that “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.”^{37,38} When FDA grants a designation under the Breakthrough Devices Program, FDA has considered whether or not the underlying device (or device-led combination) meets one of several additional criteria, including the criterion of offering “significant advantages over existing approved or cleared alternatives,” as by “reduc[ing] or eliminat[ing] the need for hospitalization, improv[ing] patient quality of life, facilitat[ing] patients’ ability to manage their own care (such as through self-directed personal assistance), or establish[ing] long-term clinical efficiencies.”³⁹ In sum, we believe that when an FDA Breakthrough Devices designation has been granted, this strongly suggests that use of the device results in a significantly improved medical benefit as compared to the use of other items and services for the purpose of meeting the significant therapeutic distinction factor under the

³⁷ 21 U.S.C. 360e-3.

³⁸ FDA, Final Guidance, Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff (December 18, 2018). Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program>.

³⁹ Ibid.

HCPCS Level II code evaluation process. Therefore, proof that a device has received an FDA Breakthrough Devices designation will be given substantial weight as CMS considers whether the device meets the significant therapeutic distinction factor under the HCPCS Level II code evaluation process. As such, we propose at § 414.10(d)(4)(ii)(D) that when an application to add a code relates to a device that has already received an FDA Breakthrough Device designation and marketing authorization for the indication for which the device was granted FDA Breakthrough Device designation, then proof of that FDA designation and authorization will be given substantial weight as CMS considers whether the device meets the significant therapeutic distinction factor proposed at § 414.10(d)(4)(ii). The aim of this proposal is to recognize that an FDA Breakthrough Device designation offers supporting evidence that can help to strengthen a claim of significant therapeutic distinction.

We propose at § 414.10(d)(4)(ii)(E) that if an applicant seeks a new code on the basis that the use of the item or service results in a significant therapeutic distinction, the application must contain sufficient information and supporting documentation to support a claim of significant therapeutic distinction. We further propose at § 414.10(d)(4)(ii)(E) that CMS would consider the totality of the circumstances when making a determination that the use of an item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set. It is important that applicants provide sufficient information and documentation so that we can understand the scientific basis for the applicant's claim of significant therapeutic distinction and perform an adequate, evidence-based assessment regarding whether this factor is met.

Applicants should provide the best available information to support their claim of significant

therapeutic distinction, including copies of all articles that result from systematic analysis of the available literature, as well as any unfavorable articles with appropriate rebuttal or explanation.

Published or unpublished information from sources from within the United States or elsewhere may be submitted by the applicant to help substantiate their claim that the use of an item or service results in a significantly improved or a significantly different medical benefit, when compared with the use of other similar items or services described in the HCPCS Level II code set. Although we are not proposing to require specific types of support, greater weight will be given to more methodologically rigorous and scientifically reliable evidence. Information sources may include the following: clinical trials, peer reviewed journal articles, study results, meta-analyses, consensus statements, white papers, patient surveys, case studies, reports, systematic literature reviews, letters from major healthcare associations, editorials and letters to the editor, public comments, and other appropriate information sources.

Some examples of past findings that a claim of significant therapeutic distinction is not substantiated include where the applicant specified a clinical indication for, or associated a clinical indication with, the item or service that was not cleared, approved, or otherwise given marketing authorization by FDA, or that is not scientifically supported. Other examples of unsubstantiated claims of significant therapeutic distinction include claims for which the evidence provided is inconclusive or weak (anecdotal, or not methodologically rigorous or reliable); the supporting information provided does not include the actual product or service that is the subject of the code application; the supporting documentation or the applicant's claim is not specifically addressed in or conflicts with other information found in the information packet submitted for review; or the supporting information addresses interim measures and not clinical end points.

We propose at § 414.10(c), our evaluation of an application to add a code would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made or the evidence provided by the applicant.

We propose at § 414.10(d)(5)(i) that if we determine that (1) the item or service that is the subject of the application performs a significantly different clinical function when compared to other items or services described in the HCPCS Level II code set (as specified under § 414.10(d)(4)(i)), or the use of the item or service results in a significant therapeutic distinction when compared to the use of other similar items or services described by the HCPCS Level II code set (as specified under § 414.10(d)(4)(ii)), and (2) there is a claims processing need to separately identify the item or service with a new code to facilitate payment under Medicare, we would create a new code to identify the item or service.

We also propose at § 414.10(d)(5)(ii) that if the conditions in § 414.10(d)(5)(i) are not met, we would not create a new code. Further, we propose at § 414.10(d)(6) that if we find that revisions to the descriptor of an existing code category are appropriate to account for minor distinctions between the subject item or service and other items or services described by the existing code category and to clarify that the subject item or service is included in the existing code category, then we would revise the descriptor rather than add a new code.

As proposed in § 414.10(h), our evaluation of the applicant's code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with

modification; or a denial of the coding request. Any coding action taken on an applicant's request would be set forth in the final coding decision.

(2) Proposed Evaluation Process for Drug or Biological Product Applications to Add a Code

There is no HIPAA standard medical data code set designated for reporting drug or biological products for non-retail pharmacy transactions – that is, as described previously, products that are paid separately as drugs or biologicals. In non-retail pharmacy transactions, the choice of code set for drugs or biologicals is governed by specific payer needs. Drug or biological products for which providers or suppliers seek payment that is separate from payments for procedures or other bundled services might be reported on claims in non-retail pharmacy transactions using the National Drug Code (NDC) set, HCPCS Level II code set, or both, however the Medicare Part B claims payment system utilizes HCPCS level II codes to pay these claims. As stated in section IV.B. of this proposed rule, for the purposes of section IV of this proposed rule, the term “products paid separately as drugs or biologicals” refers to products that are separately payable under Medicare Part B (and potentially by other payers) as drugs or biologicals as that term is defined in section 1861(t) of the Act. These products typically fall into one or more of the following three categories: (1) products furnished incident to a physician's services under sections 1861(s)(2)(A) and (B) of the Act, excluding products that are usually self-administered (for example, tablets, capsules, oral solutions, disposable inhalers); (2) products administered via a covered item of DME; and (3) other categories of products for which there is another Part B benefit category as specified by statute or regulations (for example, drug or biological products described elsewhere in section 1861(s) of the Act, such as immunosuppressive drugs (at section 1861(s)(2)(J)); hemophilia blood clotting factors (at section 1861(s)(2)(I)); certain oral anticancer drugs (at section 1861(s)(2)(Q) of the Act); certain oral

antiemetic drugs (at section 1861(s)(2)(T) of the Act); pneumococcal pneumonia, influenza and hepatitis B vaccines (at section 1861(s)(10) of the Act). As described previously, for ease of reference, when discussing products paid separately as drugs or biologicals in this rule, we will generally refer to these as “drug or biological products.”

Similar to applications for non-drug, non-biological items or services, we believe it is important for CMS to first consider whether the drug or biological product that is the subject of an application to add a code is appropriate for the HCPCS Level II code set. Consistent with our current practice, we propose at § 414.10(e)(1) that we would first determine whether, as a threshold matter, the subject drug or biological product is appropriate for the HCPCS Level II code set by assessing whether: (1) the product is not appropriate for inclusion or already coded in a different HIPAA code set, such as CPT®; (2) the product is primarily medical in nature; (3) if applicable, the product has the appropriate marketing authorization from FDA; and (4) there is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set.

CPT® codes and codes from other code sets do not frequently describe drug or biological products paid under Medicare Part B. Few CPT® codes are listed in the Medicare payment files, such as the ASP Drug Pricing files, where CPT® codes typically describe vaccines (influenza, pneumococcal pneumonia, and hepatitis B vaccines) that are paid under Part B based on their average wholesale price (AWP) per requirements in section 1842(o) of the Act. When CPT® codes do not adequately describe drug or biological products, HCPCS Level II codes have been developed and are used to bill for them, particularly when there is a Medicare program need for such codes. Also, CPT® codes that may describe drug or biological products may not be sufficiently precise to distinguish between situations where separate payment for a drug or

biological product is necessary, such as certain hepatitis B immune globulin products approved under separate BLAs, that require separately calculated payment allowances under section 1847A of the Act (as operationalized by the program instruction that is discussed in the next paragraph). Separate billing and payment codes allow for the products approved under different BLAs to be paid separately, consistent with section 1847A of the Act. Also, in general, the CPT® code set focuses primarily on services, like procedures, rather than separately payable drugs that are used in Medicare Part B settings.

Payment for most drug or biological products under Medicare Part B is described in section 1842(o) of the Act. This provision provides for payments based on the average wholesale price (AWP) for products such as vaccines, as well as payments based on section 1847A of the Act. Section 1847A of the Act includes payments based on the average sales price (ASP), and most Medicare Part B drugs are paid based on the ASP. Section 1847A of the Act defines terms such as multiple source drugs, single source drugs, and biologicals, and specifies how payment for each of them is to be determined, and also authorizes CMS to assign individual drug or biological products (for example products identified at the National Drug Code level) to billing and payment codes so that code-specific payment amounts may be assigned. Section 1847A is implemented by regulation at 42 CFR 414.904. However, section 1847A(c)(5)(C of the Act) also permits the use of program instruction for the implementation of section 1847A of the Act, notwithstanding any other provision of law. In 2007, CMS issued a program instruction explaining how coding and pricing of multiple source drugs, single source drugs, and biologicals has been operationalized (https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf).

Section 1847A of the Act and its corresponding regulations and program instructions have driven a claims processing program need for using HCPCS Level II codes to report Part B drug or biological products where CPT® codes do not exist or are insufficiently precise to be used for this purpose. CMS has made payment determinations for Part B drug or biological products identified in external coding applications on a case by case basis in accordance with statutory requirements, such as those in section 1847A(b) of the Act, that specify different payment amounts for single source drugs, multiple source drugs, and biologicals (including biosimilar biological products), and CMS has also made coding determinations to facilitate implementation of separate pricing of drug or biological products, as necessary, as discussed in the 2007 program instruction. For example, in that program instruction, CMS stated that “the payment limit under Section 1847A for that biological product...will be based on the pricing information for products produced or distributed under the applicable FDA approval.” Thus, a biological product with its own unique BLA that is administered incident to a physician’s services and not bundled with payments for other services would typically be priced and paid under its own HCPCS code, meaning that CMS would typically assign NDCs associated with the product to a unique HCPCS code. Because most Part B drugs are paid using the methodologies in section 1847A of the Act, these provisions have driven Part B drug coding since the implementation of the Medicare Modernization Act. However, other statutory provisions, such as the requirement in Section 1842(o)(1)(A)(iv) to base payment for certain vaccines on AWP, also create coding needs, for example the development of new codes or revisions of existing codes when existing CPT® codes are insufficiently precise for Part B payment.

Once we determine that the HCPCS Level II code set is the appropriate code set for the product that is the subject of the application, we then evaluate an application to determine the

appropriate HCPCS Level II coding action on the code application – that is, whether it would be appropriate to take coding action to add a new code to identify the subject product, or revise the descriptor of an existing code category to clarify that the subject product is captured by the existing code category, or to take no coding action due to the availability of an existing code category that adequately describes the subject product. We use the evaluation factors described in the bullet points later in this section to determine whether separate payment for the product may be made under Part B, how that payment is made (for example, separate payment under a specific statutory requirement), and the coding action appropriate to implement the payment (including facilitating separate payment, if necessary) based on statutory requirements, such as those in sections 1842(o) or 1847A of the Act, applicable regulations pertaining to Part B drug payment such as 42 CFR part 414 Subparts J and K, and program instructions pertaining to section 1847A of the Act, such as the 2007 guidance cited in this proposed rule.

Consistent with our current practice, we propose at § 414.10(e)(2) that if CMS determines that the factors set forth in § 414.10(e)(1) are met, then CMS next determines, for purposes of claims processing (and payment), whether an existing code adequately describes a product, or whether a revision to the descriptor of an existing code category is appropriate, or whether a new code is necessary. In making this determination, we would consider applicable Medicare Part B statutory and regulatory payment requirements, program instructions, and information, such as the following: (1) sections 1842(o) and 1847A of the Act; (2) 42 CFR part 414 subparts J and K; (3) program instructions implementing section 1847A of the Act; and (4) information from the code application and other applicable sources such as FDA, drug compendia, the manufacturer, and scientific literature. As noted previously, consistent with our current practice, we propose at § 414.10(c) that our evaluation of a code application would be

based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Consistent with the foregoing and as proposed at § 414.10(e)(2)(iv), such research and information may be drawn from a range of outside sources relevant to the application, such as FDA, drug compendia, the manufacturer, and scientific literature. Based on such information and the statutory and regulatory requirements and payment instructions described in § 414.10(e)(2), we would determine whether an existing code adequately describes a product for the purpose of claims processing (and payment), or whether a revision to the descriptor of an existing code category is appropriate, or whether a new code is necessary. This includes determining whether Medicare Part B billing and payment for the product can be accomplished under existing codes, whether revisions to existing codes are necessary, or whether new codes are necessary.

As a whole, the information in the bullet points described later in this section is used to determine appropriate coding action for the product that is the subject of the code application. This information is obtained from the code applications (and information and documentation that is submitted with the code application) and from other sources such as FDA, drug compendia, the manufacturer (or applicant), and scientific literature. We propose at § 414.10(e)(3) to evaluate each application to determine: (1) whether the product is separately payable under Medicare Part B as a drug or biological product; and (2) whether the product is a single source drug, multiple source drug, biological, or biosimilar biological product for purposes of section

1847A of the Act, or if other specific payment provisions such as those in sections 1842(o)(1)(A) or (F) of the Act apply.

While there is some overlap between the information used to make these determinations, the following paragraphs briefly describe how certain factors, that is information in the groups of bullet points later in this section, are used to make these determinations and describe the framework for the decision-making process on external code applications. Under this framework, the information in the groups of bullet points is assessed as a whole to determine a coding action, specifically whether to create a new code that would typically result in separate payment for a product provided that the product is covered under Part B, revise the descriptor of an existing code in response to an application, for example to make clear that the product in the application is described by an existing code or to better distinguish existing codes from a new code resulting from an application. Alternatively, we may decide to take no coding action, for example if the product is never or rarely paid separately under Part B.

The following information is used primarily to determine whether the product is separately payable as a drug or biological under Medicare Part B, and is also used to begin the process of determining the appropriate coding action on an application for a drug or biological product:

- The active ingredient(s) and drug name(s) of the product and other potentially similar drug or biological products in existing Level II HCPCS codes.
- The product's labeling and description, including whether there are differences between the product and previously coded products, such as the salt form; whether the product includes any additional ingredients when compared to previously coded products; and the indications for which the product is used.

- Prescribing information, setting-of-use and other information found in FDA-required prescription drug labeling.

The active ingredient(s), drug name(s), product labeling, and description assist CMS in first identifying the product. The active ingredient(s), drug name(s), product labeling and description also help to inform CMS's evaluation under § 414.10 (e)(2), (e)(3) and (e)(4), and this information guides CMS in determining whether there are any comparable products that are described by existing Level II HCPCS codes.

The prescribing information and setting of use information help CMS to understand where the product is used and whether the product is separately payable under Medicare Part B (and therefore whether a HCPCS Level II code is appropriate for the product). Some products are used in settings where drug or biological products generally are not separately payable under Medicare Part B and a HCPCS Level II code is not likely to be necessary. Examples of situations where a HCPCS Level II code would not be necessary include: products furnished exclusively in an inpatient hospital and paid exclusively under Part A; products furnished in retail pharmacy, such as a self-administered drug, like an orally administered antihypertensive drug, that is not covered under a Part B benefit category. Such products would not require a HCPCS Level II code for separate payment under Medicare Part B. However, in cases where the information provided in response to the bullet points described previously is insufficient to allow CMS to determine whether the product is separately payable as a drug or biological under Medicare Part B, other information discussed later in the section, such as the route and method of administration, dosage, and frequency, may also be used by CMS to assist with a determination about whether the product is separately payable under Medicare Part B. This additional

information may also potentially be used to distinguish the product from other potentially similar products that are not paid separately under Part B.

In addition to the information in the previous bullet point list of items, the following information is used to help determine whether the product is a single source drug, multiple source drug, biological product, or biosimilar biological product for purposes of section 1847A or if other specific payment provisions, such as those in sections 1842 (o)(1)(A) or (F) of the Act apply:

- FDA approval, including the date of approval and how the FDA regulates the product, for example whether it is approved as a drug, biological product, or biosimilar biological product.
- Therapeutic equivalence ratings as provided in section 1847A(c)(6)(C), if applicable.
- Date of first sale in the United States.
- Active ingredient(s) and labeling information
- Product information such as trade or brand name; nonproprietary drug name(s) and National Drug Code (NDC) or other applicable drug product identifier, if one exists.
- Packaging and labeling that indicates how the drug is supplied, including the How Supplied/storage and handling section in prescribing information.

FDA approval information, therapeutic equivalence rating as provided in section 1847A(c)(6)(C) (if applicable), and date of first sale in the United States help us to determine whether the product may be paid under section 1847A of the Act and whether the product satisfies the definition of multiple source drugs, single source drugs, and biological products as the definitions have been operationalized by program instruction under the authority of section 1847A of the Act. While this information primarily pertains to products paid under section

1847A of the Act, it also helps us evaluate other products, such as flu, pneumococcal, and hepatitis B vaccines, which are paid based on AWP per section 1842(o) of the Act and to identify situations where it would be appropriate to add a new code or revise an existing code for such products to facilitate payment, for example if existing codes (including CPT[®] codes used for Part B vaccines) are not sufficiently clear or do not sufficiently distinguish between similar products that have significant price or payment differences and thus may be candidates for separate codes and payment determinations.

The active ingredients and labeling information, product information such as trade or brand name(s); nonproprietary drug name(s) and National Drug Code (NDC) or other applicable drug product identifier, if one exists, and packaging and labeling that indicates how the drug is supplied also help us to accurately identify a product for the purpose of making a coding decision for that product. If a new code is necessary, for example when a product is approved under a new BLA, in most cases the active ingredient(s) will play a major role in the development of a code descriptor, and other information, such as packaging and other product information, can be used to refine the descriptor and to help select an amount of drug for the descriptor, as necessary. Also, all of this information can be used to determine if an existing code adequately describes the product without further revision or whether revisions would be necessary to the descriptor of an existing code to accommodate the product. For example, if a product that is the subject of a code application is described by an existing biological drug code, is approved under the same BLA as other products assigned to that code, and uses the same trade name, a new code would probably not be necessary because the existing code could be used without modification. However, at times a revision to the descriptor of one or more existing codes may be made, for example, to include a new trade name in the descriptor, to better distinguish between other similar codes.

The following information is used to help CMS determine whether it is appropriate to add a new code or revise an existing code in situations where the information in the bullet points described previously is not sufficient to allow CMS to make a coding determination on an application. The following information is used to further clarify the similarities and differences between the products that are the subject of a code application and products described in existing codes, to determine whether the product that is the subject of a code application is adequately described by an existing code. The information helps CMS to determine whether it is appropriate to add a new code or revise an existing code(s) consistent with discussion in the previous paragraph, for the purpose of claims processing and facilitating payment under Medicare Part B:

- Indications for use.
- Mechanism of action.
- Dosage, frequency, route, and method of administration.
- Other drugs (including those with different proprietary names) that are marketed with the same active ingredient(s) or use the same drug name(s).
- FDA labeling and compendia information (aspects not already listed in previous bullet points, such as pharmacokinetics, contraindications, warnings, drug interactions, and adverse reactions).
- Billing information, like any third-party payers that pay for the product; any codes that are currently being billed to those payers for the product; and existing policies of third-party payers for reporting the product (if available) to compare how other payers are paying for the product.

Drawing on all of the foregoing information and considerations, and consistent with our current review process, we propose at § 414.10(e)(4) that after reviewing an application to add a HCPCS Level II code for a drug or biological product, and after considering the factors listed in § 414.40(e)(1) through (e)(3), CMS will then make a determination about whether the appropriate action is to add a code, revise a code, or take no coding action, in response to that application.

In addition, we propose at § 414.10(e)(5) to continue to use code descriptors with drug amounts that correspond to quantities of a drug or biological product that are smaller than, for example, the product's package size or usual adult dose, where appropriate. The quantities of drug or biological products described by HCPCS Level II code descriptors often vary. Some are based on the size of typical adult doses of a drug or biological product. Many older HCPCS Level II codes, particularly codes that became effective before the implementation of ASP-based payments, have code descriptors reflecting quantities that correspond to available package amounts, such as 500 mg for cefazolin. Cefazolin is an injectable first generation cephalosporin antibiotic that has been available for decades as an inexpensive generic product and can be billed under HCPCS code J0690, injection, cefazolin sodium, 500 mg. Dosage adjustments for typical adult doses of cefazolin are often made in increments of 500 mg, so the code descriptor quantity for cefazolin corresponds well to its frequently used doses (and their multiples, such as 1 gram, 1.5 grams, and 2 grams). However, many newer and much more expensive drug or biological products, such as those used to treat cancer, require weight-based dosing, and dosage adjustments for individuals are made in much smaller increments, such as a milligram or a fraction of a milligram. Thus, many newer HCPCS Level II codes have code descriptors reflecting quantities that are less than the smallest available package size. Decisions about the

code descriptor quantities in these cases generally have been based on the factors discussed in the preceding bullet points, including indications, the active ingredient(s), dosage, and route of administration, packaging, and how the drug is supplied as indicated in labeling. We propose to continue to use smaller quantities in the code descriptors for drug or biological products, as appropriate and discussed in this paragraph, to facilitate more accurate billing, particularly for products that must be dosed based on the patient's weight, and for products where dosing must be adjusted in small increments, due to factors such as age, a patient's ability to metabolize or excrete a drug, toxicity, or response. Improvements in billing accuracy by the use of smaller quantities in descriptors will also facilitate the accurate tracking of payments for discarded drugs (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf> section 40). In situations where the discarded drug policy does not apply, this approach can help minimize out of pocket costs for drugs that are not administered. For example, if the amount of drug or biological specified in the code descriptor for a single HCPCS billing unit of a drug uses a quantity of 500mg and the patient is given 550mg, that patient would be billed for two billing units or 1000mg of the drug. The use of a smaller quantity in the descriptor, such as 10mg, would permit billing for exactly 550mg.

b. Proposed Evaluation Process for Non-Drug, Non-Biological and Drug or Biological

Applications to Revise an Existing Code

An applicant may submit an application to revise an existing code if the applicant believes that the descriptor of an existing HCPCS Level II code does not adequately describe the item or service that is the subject of the code application, and that a modification to the long descriptor language (code text) would provide a better description of the category of items or services represented by the code. Applicants provide the language currently used in the

descriptor of an existing HCPCS Level II code and the language that the applicant suggests to use as the descriptor.

When evaluating whether the requested revision provides a better description of the category of items or services represented by a code, we consider whether there is a Medicare claims processing need for the requested revision. For example, a revision may be considered when a claims processing need has been identified to improve the descriptor to clarify that the existing code also describes a newer or different version of an item or service which performs the same clinical function as other items or services included in the existing code category.

When evaluating applications to revise an existing code, we also consider whether the requested revision is appropriate given the nature and purpose of the HCPCS Level II code set. For example, we do not believe that a request to include information in the descriptor for the purposes of tracking or data analysis would be appropriate unless there is a Medicare claims processing need to do so, because the primary purpose of HCPCS Level II code set is to facilitate efficient claims processing. We also consider the nature of the code set, because HCPCS Level II codes generally represent categories of similar items or services, and are generally intended to describe an item or service provided or performed in way that is general enough so as not to be manufacturer specific. Where multiple like items or services are grouped together in a single HCPCS Level II code category, the corresponding descriptor uses language to describe the entire category of items or services at the collective, rather than product-specific, level. Thus, the suggested language should be applicable to the entire category of items or services, rather than only to the item or service that is the subject of the code application.

We propose at § 414.10(c) that our evaluation of an application to revise an existing code would be based on information contained in the code application and supporting material, any

comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Consistent with our current practice, we propose at § 414.10(f) that if we determine that the revised descriptor language suggested by the applicant would provide a more appropriate description of the category of items or services, as discussed earlier in this section, we would revise the descriptor accordingly. As proposed in § 414.10(h), our evaluation of the applicant's code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with modification; or a denial of the coding request. Any coding action taken on an applicant's request would be set forth in the final coding decision.

c. Proposed Evaluation Process for Non-Drug, Non-Biological and Drug or Biological Applications to Discontinue an Existing Code

To maintain a manageable and efficient coding system, HCPCS Level II codes that are no longer needed may be removed from the code set. An application to discontinue an existing code may be submitted when the applicant believes that an existing HCPCS Level II code is duplicative of another code or has become obsolete and should be removed from the HCPCS Level II code set.

When evaluating applications to discontinue an existing code, we determine whether the code is duplicative of another code in the code set, or has become obsolete, and we have no further expectation that the same or similar item or service will be marketed at a later date, such that there is no longer a claims processing need to retain the existing code. A code that is duplicative of another code because it is superseded by a more specific code, for example, would

no longer be utilized to process claims. The presence of a duplicative code could potentially result in erroneous billing.

We also consider whether a code has become obsolete by evaluating the availability of the item or service, or category of items or services, described by the code. In order to avoid removing a code prematurely, we would first determine that each item or service described by the code is no longer marketed, and that there does not appear to be an intent to market. For example, before discontinuing a code for a product that has been discontinued, we would first determine that there is no remaining stock available – in other words, we would determine that the stock has been depleted, with no expectation of the stock being refilled, and thus there would be no need to retain the code for future claims processing. We would make this determination based on information provided by the applicant, as well as through information we gather from our own market surveillance and claims examination. Before making this determination or taking action on a particular application to discontinue a code, we also consider the possibility of the same or similar item or service reappearing on the market at a later date by the same or different manufacturer, and we may retain the code for a period of time for this reason.

We propose at § 414.10(c) that our evaluation of an application to discontinue an existing code would be based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information we may obtain independently that may support or refute the claims made by or the evidence provided by the applicant. Consistent with our current practice, we propose at § 414.10(g) to discontinue an existing code when we find that the code is duplicative of another code or has become obsolete and we have no further expectation that the same or similar item or

service will be marketed at a later date. As proposed in § 414.10(h), our evaluation of the applicant's code application may result in a coding decision that reflects the applicant's coding request in whole, in part, or with modification; or a denial of the coding request. Any coding action taken on an applicant's request would be set forth in the final coding decision.

We seek comment on the proposed processes described in this section for evaluating applications to add a code, to revise an existing code, and to discontinue an existing code.

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 proposed 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 mandated the establishment of procedures that permit public consultation on coding and payment determinations for new DME under Medicare Part B of title XVIII of the Act in a manner consistent with the procedures established for implementing coding modifications to ICD-9-CM. Accordingly, we host 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 section IV., we propose to continue holding these public meetings for non-drug, non-biological items and services and, in limited circumstances, for drug or biological products (as defined and discussed in section IV of this proposed rule) that are associated with external requests for HCPCS codes. External requests for HCPCS codes are made by submitting a HCPCS application available on the CMS.gov website at the following address:

https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions

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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.

In order 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

In order to increase transparency and structure around the process for obtaining public consultation on benefit category and payment determinations for these items and services, we

believe 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 this proposed rule, we recently revised our coding cycle for requests for HCPCS Level II codes to implement shorter and more frequent coding application cycles.⁴⁰ 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 under these new bi-annual coding cycles. We believe that continuing to establish payment determinations, which, as a condition precedent, 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.

C. Provisions of the Proposed Regulation

We are proposing 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 propose to include these procedures under

⁴⁰ CMS, Announcement of Shorter Coding Cycle Procedures, Applications, and Deadlines for 2020, HCPCS – General Information. Available at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>.

both subparts C and D. We are proposing 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. This proposal generally reflects the procedures that have been used by CMS since 2005, however, we are proposing 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 are proposing 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. 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 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 the purpose of these proposed procedures and § 414.114, we are proposing 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 are also proposing 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. 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 the purpose of these proposed procedures and § 414.240, we are proposing 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

Social Security Act, a prosthetic device at section 1861(s)(8) of the Social Security 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 Social Security 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 are proposing 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 subparts 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. We are proposing that the 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 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, an analysis is performed by CMS to determine if the item or service is statutorily excluded from coverage under Medicare under any of the provisions at section 1862 of the Act, and, if not excluded by statute, the analysis looks to see 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 about the item or service from several sources is considered as part of this analysis 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 granted marketing authorization by the FDA. This step could take anywhere from 1-week to 1 or 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 take anywhere from 1-week to 1 or 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 §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 or payment determinations made for the item or service, the benefit category or payment determinations are established through program instructions issued to the Medicare Administrative Contractors.

It is important to note 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 seek 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 note 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 note 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.

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 are proposing to replace a Ruling issued in January of 2017 (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 order to be covered, an item must meet the requirements of section 1862(a)(1)(A) of the Act, which precludes payment for any items and services that are 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’ 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. In order 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 (P.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 state-wide 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 in order to be considered DME. This 3-year minimum lifetime requirement was established in a final rule published in the November 10, 2011 **Federal Register** entitled: 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 that are part 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, CMS issued CMS-1682-R articulating the CMS policy concerning the classification of 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 by 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. 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 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 FDA, while some newer CGM models are class II devices that do not require premarket approval by FDA. 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 in 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 a 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 then displayed on a dedicated receiver (or type of monitor), an insulin infusion pump, or a compatible mobile device (smart phone, smart watch, tablet, etc.). The receiver 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 classifies CGM display devices as DME if they have been approved by 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 a patient uses to check their glucose levels and trends that must be verified by use of a blood glucose monitor in order 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.

C. Current Issues

Beneficiaries are continuing to use adjunctive or “non-therapeutic” CGMs to help manage their diabetes, and claims submitted for this equipment and its related supplies and accessories are being denied in accordance with CMS-1682-R. We believe classification of CGMs in general is an important issue to address again in notice and comment rulemaking. In this proposed rule we revisit the question of whether CGMs (both adjunctive and non-

adjunctive), and their accessories and supplies meet the five requirements or prongs of the definition of DME at 42 CFR 414.202.

1. Requirements of DME Definition

(a) Ability to Withstand Repeated Use

As discussed in CMS-1682-R, we view the receiver that converts the glucose readings from the disposable sensors and displays the readings in a graph showing the continuous change in the trend of glucose levels as the CGM component that performs the primary medical function of self-monitoring of glucose levels and that therefore, the receiver is the component that must be durable or withstand repeated use in order for the CGM as a whole to be classified as DME. The receiver for all CGM systems (both adjunctive and non-adjunctive) 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 in order to meet the definition of DME. As noted previously, for multicomponent equipment (that is, a system of durable and nondurable components), the component that performs the medically necessary function of the equipment must be durable in order for the device to be considered DME. The blood glucose monitor reads the glucose level on the test strip and displays the reading for the patient. CGM receivers operate in a similar fashion and, unlike the glucose sensor component,

which must be replaced every 7 to 14 days, we believe the receiver does meet the 3-year minimum lifetime requirement. In the case of one manufacturer, reliability analysis data from an engineering firm that evaluated the receiver component of the CGM system predicted a lifetime of greater than 3 years for the receiver. Therefore, we believe that the receiver, both for adjunctive and non-adjunctive CGMs, has an expected life of at least 3 years.

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

As noted previously, in CMS-1682-R, we concluded that adjunctive CGMs are not primarily and customarily used to serve a medical purpose. We are proposing to change our determination with regard to whether adjunctive CGMs are primarily and customarily used to serve a medical purpose. The agency's determination that devices like these are not primarily and customarily used to serve a medical purpose has been rejected by several district courts. The district courts hearing these cases have rejected the determination that adjunctive CGMs are not primarily and customarily used to serve a medical purpose. *See, e.g., Finigan v. Burwell*, 189 F. Supp. 3d 201 (D. Mass. 2016); *Whitcomb v. Hargan*, Case No. 17-cv-14, 2017 U.S. Dist. LEXIS 216571 (E.D. Wis. Oct. 26, 2017); *Lewis v. Azar*, 308 F. Supp. 3d 574 (D. Mass. 2018).

CGMs are used by patients to monitor their glucose levels, which can help them to manage their diabetes and make diabetes treatment decisions such as determining what and when to eat and changes in insulin dosage. We are proposing that CGM systems that have not been approved by FDA for use in making these 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. We now believe that because adjunctive CGMs can provide information about potential changes in glucose levels while a beneficiary is sleeping and is not using a blood glucose monitor, these

CGMs are primarily and customarily used to serve a medical purpose. Specifically, these CGMs serve a medical purpose by helping patients to avoid potential episodes of hypoglycemia or hyperglycemia, despite the fact that fingerstick blood glucose verification is still required for use in making diabetes treatment decisions. Currently, Medicare does not cover adjunctive CGMs because such CGMs are not DME, per CMS-1682-R. CMS is proposing to change this policy issued under CMS-1682-R; all CGMs (adjunctive and non-adjunctive) would be considered DME, effective April 1, 2021.

(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.⁴¹ 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. CMS is now proposing 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

⁴¹ <https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center>

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. If a Medicare beneficiary is using durable CGM equipment that meets the Medicare definition of DME, but also 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 primarily using their covered DME item 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.

(e) Appropriate for Use in the Home

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.

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 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 granted marketing authorization by 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 propose 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 do not believe these supplies and accessories are comparable to the supplies and accessories for blood glucose monitors, and there is a significant difference in the cost, lifetimes, and types of supplies and accessories used with the various types of CGMs. Namely, some sensors last for 7 days while others last for 14 days, some CGM systems require certain additional accessories such as transmitters or additional supplies such as calibration supplies while others do not. We believe all CGM receivers essentially serve the same purpose as a blood glucose monitor in interpreting and displaying glucose levels from disposable supplies. However, the disposable supplies for CGMs are very different from the disposable supplies used with a blood glucose monitor, so we do not believe that the 1986/87 average reasonable charges for supplies used with a blood glucose monitor should be used to establish the fee schedule amounts for supplies used with a CGM. In addition, the supplies used with the three types of CGMs currently on the market are also very different. For this reason, we are proposing 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 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 April 1, 2021.

As aforementioned, adjunctive and “non-therapeutic” CGMs also work with disposable batteries, sensors, and transmitters to automatically send glucose readings to the receiver on a 24-hour basis, but have not been granted marketing authorization for use in place of a blood glucose monitor. As such, if a beneficiary uses one of these CGMs, the beneficiary and 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 propose 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 are proposing

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 are proposing 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 propose 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.

Again, we believe that the types of CGM supplies and accessories used with the three different types of CGM systems currently on the market warrants three separate fee schedule amounts for the different monthly supplies and accessories for these three types of systems.

C. Provisions of the Proposed Rule

We are proposing to classify all CGM systems that use a receiver that meets the definition of DME as DME. We are proposing that a CGM system would need to be granted marketing authorization by FDA, but its FDA-required labeling would not need to indicate that the CGM is appropriate or indicated for use in place of a blood glucose monitor for making diabetes treatment decisions in order to be classified as DME. Therefore, we are now proposing to classify CGM systems that are adjunctive and non-adjunctive as DME. We are also proposing

to establish Medicare fee schedule amounts for CGM receivers/monitors using 1986/87 average reasonable charges for comparable blood glucose monitors updated in accordance with section 1834(a) (14) of the Act. Finally, we propose to establish separate monthly fee schedule amounts for calendar year 2021 for the supplies and accessories used with the three different types of class II and class III CGMs on the market as of the date of publication of this proposed rule based on the following amounts with the addition of the applicable update factors for 2021 to be determined later this year: \$222.77 (class II) and \$259.20 (class III) for supplies and accessories necessary for the effective use of automatic, non-adjunctive CGMs; \$175.62 (class II) and \$198.77 (class III) for supplies and accessories necessary for the effective use of automatic, adjunctive CGMs; and \$46.86 (class II) and \$52.01 (class III) for supplies and accessories necessary for the effective use of manual, non-adjunctive CGMs.

VII. Expanded Classification of External Infusion Pumps as DME

In section 5012 of the 21st Century Cures Act, Congress amended section 1861(s)(2) of the Act, and added subsections 1834(u) and 1861(iii) of the Act, to establish a new Medicare home infusion therapy services benefit to cover certain professional services associated with the provision of home infusion therapy. Congress defined “home infusion drug[s]” at section 1861(iii)(3)(C) of the Act as “a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)),” excluding insulin pump systems and self-administered drugs or biologicals on a self-administered drug exclusion list. See 42 U.S.C. § 1395x(iii)(3)(C).

In light of the new Medicare home infusion therapy services benefit to cover certain professional services associated with the provision of home infusion therapy, we propose to

expand the scope of the Medicare Part B benefit for durable medical equipment (DME) by revising the interpretation of the “appropriate for use in the home” requirement within the definition of DME at 42 CFR 414.202 specifically for certain drugs or biologicals infused in the home using an external infusion pump. It is important to note that the home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump.

In order for an external infusion pump and associated supplies to be covered under the Part B DME benefit, the pump must, among other statutory and regulatory requirements, be “appropriate for use in the home.” See 42 CFR 414.202. In practice, CMS has interpreted this requirement within the definition of DME at 42 CFR 414.202 as limiting coverable DME items to those items which can be used by a patient or caregiver in the home without the assistance of a healthcare professional. We propose to interpret this requirement to be met for an external infusion pump 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 possible route of administration, at least once per month, for the drug. We will use the first requirement in our proposed standard to identify the drugs or biologicals that a beneficiary or caregiver or both is unable to safely and effectively administer in the home, per the FDA-required labeling. The second requirement addresses the necessary

services furnished by a qualified home infusion therapy supplier, which are covered by Medicare under the home infusion therapy benefit, and which would provide for the safe and effective administration of the drug or biological in the home. Our justification for the third requirement in our proposed standard is based on our belief that the FDA-required labeling must specify that a drug may be infused via an external infusion pump on a regular basis or over a set period of time at prescribed intervals because DME is a rental benefit. Medicare payment for an external infusion pump classified as DME is typically made over the course of 13 months under a capped rental payment; title for the pump transfers to the beneficiary after 13 months of continuous use. Medicare payment for drugs or biologicals infused through an item of DME is typically made consistent with section 1847A of the Act. Therefore, we propose that in a situation in which a beneficiary or caregiver or both is unable to safely and effectively administer certain drugs or biologicals, the external infusion pump through which such drugs or biologicals are administered could satisfy the definition of DME if all three of the requirements described previously are met. The drug or biological could then be covered as a supply under the DME benefit.

Related to the third requirement in our proposed standard, we are seeking comment on our proposed plan to take into account whether the FDA required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug; we welcome input on alternative standards or factors DME MACs could use when making this determination.

If finalized, the proposed change would result in a greater number of drugs or biologicals being covered as supplies under the DME benefit. The proposed change could also affect home infusion therapy services. We solicit comments on our proposal to reinterpret the “appropriate

for use in home” requirement at 42 CFR 414.202, which would expand beneficiary access to drugs or biologicals infused in the home using and external infusion pump.

In particular, we solicit comment on whether our proposal would be adequate to expand access to medically appropriate home infusion drugs administered through external infusion pumps and home infusion therapy furnished by qualified home infusion therapy suppliers. We note that in order to receive services under the Medicare home infusion therapy benefit, section 1861(iii)(2)(B) of the Act requires the individual to be under a plan of care that describes the type, amount, and duration of home infusion therapy services and such plan must be established and reviewed by a physician in coordination with the furnishing of home infusion drugs. Therefore, the patient’s physician must coordinate, as needed, with the DME supplier and a qualified home infusion therapy supplier (if different from the DME supplier) when establishing and reviewing the home infusion therapy plan of care. Additionally, we solicit public comment with regard to whether there are any additional issues that CMS should consider to ensure effective and safe delivery of home infusion drugs administered through an external infusion pump to beneficiaries in their homes. We note that the DME and home infusion therapy benefit categories are separate Medicare benefit categories defined by statute, which may be quite different from how home infusion drugs administered through external infusion pumps are covered, delivered, and paid for under private insurance arrangements and private networks of providers. We further note that Medicare beneficiaries generally have choices regarding their site of care treatment options. If drug infusion therapy in the home setting is an available option to a beneficiary, coordination among physicians, home infusion therapy suppliers, and DME suppliers is important to achieving positive health outcomes.

Increased access and choice for beneficiaries in need of home infusion drugs is an important component of moving towards increased value-based care. We request comment on whether the proposed change would be adequate to further this objective.

We note that this proposal, if finalized, would necessitate updates to the local coverage determinations for external infusion pumps by the DME MACs. The DME MACs update local coverage determinations upon receipt and review of an LCD reconsideration request. The DME MACs have instructions about LCD reconsideration requests on their websites, and we anticipate that manufacturers, suppliers, and others would approach the DME MACs in this manner requesting that drugs or biologicals be included in the LCDs for external infusion pumps. This proposal, if finalized, should not be construed as CMS staff and Medical Officers taking on the responsibility for evaluating requests and making determinations on which drugs or biologicals satisfy the “appropriate for use in the home” criteria in addition to or in lieu of DME MAC process for updates to LCDs. Consistent with long standing practice, the DME MACs are responsible for maintaining the list of eligible drugs that can be infused using an external infusion pump. In summary, we welcome comments on these issues and in particular--

- On our proposal to interpret the “appropriate for use in home” requirement at 42 CFR 414.202, which would expand beneficiary access to drugs or biologicals infused in the home using an external infusion pump;

- On whether our proposal would be adequate to expand access to medically appropriate home infusion drugs administered through external infusion pumps and home infusion therapy furnished by qualified home infusion therapy suppliers;

- With regard to whether there are any additional issues that CMS should consider to ensure effective and safe delivery of home infusion drugs administered through an external infusion pump to beneficiaries in their homes;
- On whether the proposed change would further the objective of moving towards increased value-based care; and
- On our proposed plan to take into account whether the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug; we welcome input on alternative standards or factors DME MACs could use when making this determination.

VIII. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs from the DMEPOS CBP

The Further Consolidated Appropriations Act, 2020 (Pub.L. 116-94) was signed into law on December 20, 2019. Section 106(a) of the Further Consolidated Appropriations Act, 2020 (Pub.L. 116-94) amends section 1847(a)(2)(A) of the Act to exclude complex rehabilitative manual wheelchairs, certain manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor codes, and related accessories from the DMEPOS CBP. We are therefore proposing to make conforming changes to the definition of “item” under § 414.402 to reflect that these wheelchairs and related accessories are excluded from the DMEPOS CBP. We are proposing to edit the definition of item in § 414.402 to exclude “power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs”.

In addition, section 106(b) of the Further Consolidated Appropriations Act, 2020 mandates that, during the period beginning on January 1, 2020 and ending June 30, 2021, the adjustments to the Medicare fee schedule amounts for certain DME based on information from competitive bidding programs not be applied to wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs (HCPCS codes E1161, E1231, E1232, E1233, E1234 and K0005) and certain manual wheelchairs currently described by HCPCS codes E1235, E1236, E1237, E1238, and K0008. We are implementing the changes to the fee schedule amounts for these items through program instructions based on the discretion provided by the Further Consolidated Appropriations Act, 2020.

IX. Collection of Information Requirements

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

As stated earlier, this rule proposes to continue certain existing code application policies and processes and proposes several new coding policies and procedures. However, the new policies and procedures will not have any effect on existing requirements and burden estimates. Specifically, proposed §414.8, §414.9, §414.10, §414.114, and §414.240 all make reference to the Level II HCPCS code application process. The information collection requirements associated with the aforementioned proposed regulations are currently approved under OMB control number 0938-1042 as part of the information collection request “Healthcare Common Procedure Coding System (HCPCS) – Level II Code Modification Request Process (CMS-10224).

X. Response to Comments

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

XI. Regulatory Impact Statement

We have examined the impact of 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), the Congressional Review Act (5 U.S.C. 801-808), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or

planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). These proposed regulations are not economically significant within the meaning of section 3(f)(1) of the Executive Order.

However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed this proposed rule, and the Departments have provided the following assessment of their impact.

A. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Thus, using the 2019 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 \$111.00 per hour, including overhead and fringe benefits. For manufacturers of DMEPOS products, DMEPOS suppliers, and other DMEPOS industry representatives, we assume the same cost of 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 proposed rule. For each entity that reviews this proposed rule, the estimated cost is \$555.00 (5 hours' x \$111.00 per hour.) Therefore, we estimate that the total cost

of closely reviewing this proposed rule is \$360,750 ($\550.00×650 reviewers).⁴² Due to the uncertainty involved with accurately quantifying the administrative costs of reviewing this rule, we solicit comments on this assumption.

We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters or DME suppliers will review this proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons, we anticipate that a little more than 2 percent of the 2018 DME suppliers (650) may review the proposed rule. We further assume that some DME entities will read summaries from trade newsletters, trade associations, and trade law firms within the normal course of staying up with current news, incurring no additional cost. We solicit comments on this assumption.

B. Detailed Discussion of Impacts by Major Provisions

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

The Office of the Actuary has determined that the proposed regulations would neither increase nor decrease spending from what is assumed in the FY 2021 President's Budget. In November 2019 when the budget baseline was estimated based on historic trends the same level of spending in CBAs and also non-CBAs from 2021 onwards. In other words, no explicit assumption for changing this provision was made in the President's budget baseline.

In addition, we seek comments on three alternatives to our proposal that would have fiscal impacts. The first alternative is to pay fully adjusted fee schedule rates in all areas except

⁴² 650 represents a little more than 2 percent of the 2018 number of DME suppliers.

super rural areas or non-contiguous areas and pay 120 percent of the fully adjusted rates in super rural areas and non-contiguous areas. The Office of the Actuary estimates that this alternative would generate \$2.4 billion in Medicare savings and \$0.2 billion in Medicaid savings over 5 years against the FY 2021 President's Budget baseline assuming that the PHE ends by January 2021. The second alternative is to adjust fee schedule amounts for items and services furnished in non-CBAs between 2021 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 generate \$1.8 billion in Medicare savings and \$0.1 billion in Medicaid savings over 5 years against the FY 2021 President's Budget baseline assuming the PHE ends by January 2021. The third alternative addresses a possible payment methodology for certain product categories that were essentially removed from Round 2021 of the CBP. Under this alternative, we would continue the fee schedule adjustment transition rules at §414.210(g)(9) and fee schedule adjustment rules at §414.210(g)(10) for items and services furnished in non-CBAs and CBAs or former CBAs, respectively, for items and services that are essentially removed from Round 2021 of the CBP. Under this alternative, the current fee schedule adjustment methodologies would continue until the next time these items and services are recompeted under the CBP. OACT has estimated that the changes made to the CBP under previous rulemaking (83 FR 57020) would have a minimal impact against the FY 2021 President's Budget baseline; therefore, continuing to use rates set under previous rounds of the CBP to adjust fee schedule amounts would likewise have a minimal impact against the FY 2021 President's Budget baseline since those rates are in line with what OACT assumed would be spent as a result of Round 2021 of the CBP.

The first two alternatives were not proposed primarily due to the assumption that

maintaining the current fee schedule adjustment methodology will provide for better access to DMEPOS items. The third alternative addresses a possible payment methodology for certain product categories that are essentially removed from Round 2021 of the CBP and the fee schedule amounts for such items and services furnished in CBAs, former CBAs, and 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

No fiscal impact has been identified by the Office of the Actuary in the baseline of the FY 2021 President's Budget for these provisions promulgated in 2018.

3. Healthcare Common Procedure Coding System (HCPCS) Level II Code Application Process

This rule proposes to continue certain existing code application policies and processes and proposes certain new coding policies and procedures that are assumed to have no determinable fiscal impact when measured against the FY 2021 President's Budget baseline.

4. 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

This rule proposes to use the existing HCPCS public meeting process for BCDs 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 FY 2021 President's Budget baseline. BCDs are necessary in order to make payment determinations for these new items and services. As an aside, the proposal to incorporate public consultation on BCDs and payment determinations for these new items and

services into the HCPCS public meetings will not affect the ability of manufacturers to make these new items and services. We are proposing to use an already established process (HCPCS public meetings) that has been in use since 2001 for DME and 2005 for other items and services.

5. Classification and Payment for Continuous Glucose Monitors under Medicare Part B

This rule proposes to classify all CGMs as DME and addresses the payment for different types of CGMs. Because we do not anticipate changes in CGM utilization, this proposal is assumed to have no overall fiscal impact when measured against the FY 2021 President's Budget baseline.

6. Expanded Classification of External Infusion Pumps as DME

This proposed rule would expand the scope of the Medicare Part B benefit for DME by revising the interpretation of the "appropriate for use in the home" requirement in the definition of DME at 42 CFR 414.202 specifically for certain drugs or biologicals infused in the home using an external infusion pump 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 possible route of administration, at least once per month, for the drug. It is important to note that the home infusion therapy benefit is only available when a drug or biological is administered through an external infusion pump that is an item of DME. In addition, drugs or biologicals administered through an external infusion pump that is an item of DME can be covered under the Medicare Part B benefit for DME as supplies necessary for the effective use of the external infusion pump. The fiscal impact

of this proposal against the FY 2021 President's Budget is estimated to be a small savings to Medicare in CY 2021.

Beneficiaries have continued access in the outpatient setting to the drugs or biologicals that would be covered as supplies under the DME benefit if this proposal is finalized. Medicare pays for the drugs or biologicals using the same methodology regardless of the setting in which they are administered. However, Medicare would be responsible for a smaller portion of the total costs of administration if this proposal is finalized and a beneficiary chooses to receive home infusion rather than infusion in an outpatient setting because the beneficiary would be responsible for a larger portion of the total costs in the home setting, since there is no cap on the beneficiary cost-sharing for DME as there is in the hospital outpatient setting. The Medicare payments for the external infusion pump, supplies, and professional services (labor) in the home setting is higher than in the outpatient setting, however, the overall impact on Medicare costs is a small savings if the beneficiary chooses the home setting over the hospital outpatient setting. In the outpatient setting, Medicare pays for the supplies, including the costs associated with the use of an external infusion pump, and the professional service in a single payment to the facility. The pump is owned by the facility and not paid for separately by Medicare. Under this proposal, our reinterpretation of the "appropriate for use in the home" requirement would result in more external infusion pumps and supplies, including the drugs or biologicals, being paid for under the DME benefit, while the professional service component of home infusion would be paid under the home infusion therapy services benefit. Medicare payment for an external infusion pump classified as DME is typically made over the course of 13 months under a capped rental payment; title for the pump transfers to the beneficiary after 13 months of continuous use. Medicare would continue to make a monthly payment for supplies (such as tubing, catheters, and

the infusion drugs) for the appropriate use of the external infusion pump for as long as the beneficiary has a medical need for such supplies.

The estimated impact of this proposed policy is based on current utilization, by reviewing Medicare hospital outpatient claims, of the only product known by CMS at this time that is available in the outpatient setting through the use of an external infusion pump and could also be prescribed by a physician for use in the home setting: patisiran. In 2019, 128 beneficiaries utilized this drug and total Medicare payments to facilities for furnishing patisiran was roughly \$26 million. The number of beneficiaries that would shift settings, if this proposal is ultimately finalized, is unknown but a reasonable assumption is that 50 percent - or 64 beneficiaries - would shift settings. CMS estimates that approximately \$235,000 per year in Medicare payment would be paid under the home infusion therapy benefit, as CMS estimates home infusion therapy supplier claims would be paid at the category 3 level for those drugs as described in the CY 2020 Home Health Prospective Payment System (HH PPS) final rule (84 FR 60618) for the home visit. More specifically, CMS estimates that in 2021, a home infusion therapy supplier would come to the home of each of the 64 beneficiaries for one initial visit at a category 3 level of \$320 in payment and 16 subsequent visits at a category 3 level of \$266 in payment per visit, in the first year, if this proposal is finalized. CMS also estimates that \$18 million would be paid to DME suppliers, predominantly based on the costs of the drug and payment for the external infusion pumps. The net impact to Medicare, accounting for enrollment growth and projected payment updates, is estimated to be a savings of roughly \$3 million in CY 2021 if this proposal is finalized. This savings is largely attributable to the differential in cost sharing between the hospital outpatient setting and the home, as described below. Please note that this estimate reflects no assumption for induced utilization of this product or for other products that could

meet the definition of DME currently or that may come to market in the future. CMS asks for public comment on other products that could qualify under this proposed revised interpretation of the definition of DME to further inform our estimates.

We further note the impact on the beneficiary. The beneficiary, in consultation with the physician that develops the plan of care, would have the opportunity to select the home or outpatient setting for infusion, if this proposal is finalized. A fiscal impact on a beneficiary is that the Medicare payments for external infusion pump rental occur in the first 13 months of treatment in the home setting, which may increase up front outlays in cost-sharing for beneficiaries. In addition, hospital outpatient cost sharing is capped at the inpatient deductible, which is currently \$1,408 per service line (which in this case is for each administration of patisiran every 3 weeks). DME, including DME supplies like the drug, and the home infusion therapy benefit have a 20 percent cost sharing, which does not have a cap (or maximum amount). We estimate that patisiran, for example, would have cost sharing of more than \$70,000 per year per beneficiary in the home setting compared to approximately \$24,000 in the hospital outpatient setting. We note that many beneficiaries may have supplemental coverage, like Medigap insurance, from a third-party payer that may mitigate this cost sharing. Infusion of patisiran would also continue to be available in an outpatient setting subject to the per service cap at the inpatient deductible. CMS is also aware that premedication drugs may be necessary to safely and effectively administer certain infusion drugs, and that intravenous forms of the premedication drugs are covered in the hospital outpatient payment. CMS notes that premedication drugs would not be covered as supplies necessary for the use of the external infusion pump under the DME benefit, and therefore, if administered intravenously in the home, are estimated to cost a beneficiary a total of \$3-19 out of pocket per treatment session. We note

that some premedication drugs may also have an oral form and could be covered under Part D or be over-the-counter and non-covered by Medicare.

We seek public comment on the proposed policy, particularly in regard to information about other infusion drugs or biologicals that may be covered as supplies under the DME benefit if this proposal is finalized. We also seek comment on the out-of-pocket costs for beneficiaries who would elect to receive infusion drugs or biologicals in the home rather than the outpatient setting.

7. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain other Manual Wheelchairs from the DMEPOS CBP

This rule proposes conforming changes to the regulations at 42 CFR 414.402 to revise the definition of “item” at 42 CFR 414.402 under the CBP to exclude complex rehabilitative manual wheelchairs and certain other wheelchairs from the CBP and is estimated to have no fiscal impact and is considered in the baseline of the FY 2021 President’s Budget.

C. Regulatory Flexibility Act (RFA)

This proposed rule does not impose a significant impact on small entities or DMEPOS suppliers. As a result, the RFA does not apply to this proposed rule. Nevertheless, the discussion later in this section aims to describe why the proposed rule does not impose a significant impact on small entities. 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 (include 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 Web site 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	Total Small Businesses
446110	Pharmacies and Drug Stores	\$30 million	18,526
532291	Home Health Equipment Rental	\$35 million	673

Source: 2012 Economic Census

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

TABLE 6*: DMEPOS SUPPLIERS CONCENTRATION RATIOS (PHARMACIES AND DRUG STORES AND HOME HEALTH EQUIPMENT RENTAL

Firm Size (by Receipts)	Firm Count	% of Small Firms	Total Avg Rev
SMALL FIRMS	19,199	100.0%	159,052,305
<100,000	808	4.2%	93,936
100,000-499,999	2,267	11.8%	570,733
500,000-999,999	2,056	10.7%	1,463,023
1,000,000-2,499,999	5,915	30.8%	3,341,895
2,500,000-4,999,999	5,158	26.9%	6,986,859
5,000,000-7,499,999	1,654	8.6%	11,667,724
7,500,000-9,999,999	598	3.1%	17,453,816
10,000,000-14,999,999	444	2.3%	22,420,998
15,000,000-19,999,999	157	0.8%	27,573,076
20,000,000-24,999,999	71	0.4%	20,211,074
25,000,000-29,999,999	46	0.2%	20,377,955
30,000,000-34,999,999	25	0.1%	26,891,217
LARGE FIRMS			
Receipts > \$35 Million	326	NA	2,962,532

SOURCE: 2012 County Business Patterns and 2012 Economic Census.

*Total 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 Health Equipment Rentals Industry.

As can be seen in Table 6, almost all DMEPOS suppliers are small entities as that term is used in the RFA⁴³. Additionally, Table 6 shows the disproportionate impacts among firms, and between small and large firms. In Table 6, both industries, Pharmacies and Drug Stores and Home Health Equipment, Rental firm size (by receipts), firm count, % of small firms, and total average revenue were aggregated to determine the DMEPOS concentration ratios. Keep in mind, there are missing data. See footnotes. Nevertheless, the great majority of DMEPOS suppliers are

⁴³ 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.

small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$35 million (see *the Small Business Administration's Web site at <http://www.sba.gov/content/small-business-size-standards>*)).

For purposes of the RFA, approximately 98 percent of pharmacies and drugs stores and home health equipment rental industries are considered small businesses according to the Small Business Administration's size standards with total revenues of \$35 million or less 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 that there is not a significant economic impact on a substantial number of small entities. We do not believe that this threshold will be reached by the requirements in this rule. Recall, the only cost presented is the regulation review cost of \$555 per reviewing firm, which is considered to be a very insignificant cost for the firms.

Since we are uncertain if we have accounted for all the DMEPOS suppliers, we are asking for public comments. We anticipate that additional DMEPOS suppliers not accounted for in this rule are minimal; hence, we do not believe that this regulation will result in a significant impact on a substantial number of small entities. Therefore, the Secretary certifies that this proposed 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 603 of the RFA. For purposes of section

1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area 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.

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 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This proposed rule’s designation under Executive Order 13771 will be informed by comments received.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

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 proposes to amend 42 CFR Chapter IV as follows:

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)(1).

2. Section 414.8 is added to subpart A to read as follows:

§414.8 Healthcare Common Procedure Coding System (HCPCS) Level II code application cycles and procedures.

(a) *Scope.* This section sets forth coding cycles and procedures for external code applications requesting revisions to the HCPCS Level II code set maintained by CMS for the following:

(1) *Non-drug, non-biological items and services.* For purposes of §§414.8, 414.9, and 414.10, non-drug, non-biological items and services are items and services that Medicare (and potentially other payers) typically pay separately, as well as certain items and services that are not covered under Medicare, and that are described as the following:

(i) Medical and surgical supplies, such as splints and casts described in section 1861(s)(5) of the Act and therapeutic shoes described in section 1861(s)(12) of the Act.

(ii) Dialysis supplies and equipment such as those described in section 1861(s)(2)(F) of the Act.

(iii) Ostomy and urological supplies such as those described in section 1861(s)(8) of the Act.

(iv) Surgical dressings, such as those described in section 1861(s)(5) of the Act.

(v) Prosthetics (artificial legs, arms, and eyes) such as those described in section 1861(s)(9) of the Act and prosthetic devices such as those described in section 1861(s)(8) of the Act.

(vi) Orthotics (leg, arm, back, and neck braces) such as those described in section 1861(s)(9) of the Act.

(vii) Enteral/parenteral nutrition such as those described in section 1842(s)(2) of the Act.

(viii) Durable Medical Equipment (and related accessories and supplies other than drugs), such as oxygen and oxygen equipment, wheelchairs, infusion pumps, and nebulizers such as described in sections 1861(s)(6) and 1861(n) of the Act.

(ix) Vision items and services, such as prosthetic lenses described in 1861(s)(8) of the Act.

(x) Other items and services that are statutorily excluded from Medicare coverage for which CMS or other government or private insurers have identified a claims processing need for a HCPCS Level II code, such as hearing aids which are excluded from coverage by section 1862(a)(7) of the Act.

(2) *Drug or biological products.* For purposes of §§414.8, 414.9, and 414.10, these are products that are separately payable by Medicare under Part B as drugs or biologicals as that term is defined in section 1861(t) of the Act.

(b) *Coding cycles.* HCPCS Level II coding cycles begin with the submission deadlines for code applications described in paragraph (c) of this section, followed by a preliminary

recommendation and public meeting as specified in paragraphs (d) and (e) of this section, and the issuance of a final decision described in paragraph (e) of this section. Coding cycles begin no less frequently than--

(1) Bi-annually for non-drug, non-biological items and services; and

(2) Quarterly for drug or biological products.

(c) *Code application deadlines.* HCPCS Level II code application submission deadlines are established on the CMS website or in another manner and are --

(1) In or around January and June of each year for non-drug, non-biological items and services; and

(2) In or around January, April, June, and September each year, for drug or biological products.

(d) *Public meetings.* (1) Public meetings are held to provide the public with notice of, and the opportunity for public input on code applications and preliminary recommendations described in paragraph (e)(1) of this section under consideration by CMS; and for CMS to gather public input regarding these applications and preliminary recommendations.

(2) Public meetings are held during each bi-annual coding cycle.

(3) Subject to paragraph (e)(3) of this section, public meetings are held for all code applications for non-drug, non-biological items and services.

(4) Subject to paragraph (e)(3) of this section, public meetings are held for drug or biological product code applications only under the following circumstances:

(i) The code application is one that was resubmitted for reevaluation as provided in §414.9(b).

(ii) A decision on the code application is delayed under paragraph (e)(3) of this section, and CMS determines it presents program, policy, or implementation concerns or complexities, or otherwise raises questions that public input could help to address.

(e) *Preliminary recommendations, final decisions, and effective dates.*

(1) *Preliminary recommendations.* CMS issues preliminary recommendations, which may include questions or requests for additional information that could help in reaching a final decision, on code applications for items and services included in the public meeting agenda. Except as provided in paragraph (e)(3) of this section and § 414.9(b)(3)(i), preliminary recommendations are posted on the CMS website or issued in another manner, prior to the public meetings described in paragraph (d) of this section.

(2) *Final decisions.* Except as provided in paragraph (e)(3) of this section, final decisions are posted on the CMS website or issued in another manner within approximately--

(i) Six months of the application deadline for non-drug, non-biological items and services; and

(ii) Three months of the application deadline for drug or biological products.

(3) *Delays in making preliminary recommendations or final decisions.* (i) CMS may delay a preliminary recommendation and therefore a final decision, or delay a final decision alone, one or more times into a subsequent coding cycle where a code application raises complex or significant issues or considerations and CMS determines that additional time is needed to evaluate the code application. Such circumstances may include, but are not limited to, situations where the code application involves a significant policy or claims processing consideration, or requires in-depth clinical or other research.

(ii) For code applications (including code applications for drug or biological products) that are resubmitted for reevaluation and placed on a public meeting agenda in accordance with § 414.9(b)(3), CMS may also delay issuing a preliminary recommendation, a final decision, or both into a subsequent quarterly coding cycle.

(iii) Decisions to delay a preliminary recommendation or final decision are issued by CMS, either on the CMS website or in another manner, at the same time that CMS issues the preliminary recommendations or final decisions, as applicable, for other applications during a coding cycle.

(4) Coding changes are effective approximately 3 months after the issuance of the final coding decision.

3. Section 414.9 is added to subpart A to read as follows:

§414.9 HCPCS Level II code application requirements.

(a) *Timely and complete applications.* To be considered in a given HCPCS Level II coding cycle specified in §414.8(b), a code application must be timely and complete. Code applications that are not timely and complete are declined by CMS but may be submitted by the applicant in a subsequent coding cycle.

(1) Applications are timely if submitted to CMS by the applicable code application submission deadline specified by CMS on its website or in another manner, for a given application cycle identified in §414.8(c), or as provided in paragraph (a)(3) of this section.

(2) To be complete, an application must contain the following by the applicable code application submission deadline:

(i) All applicable information and documentation specified in this section, and meet all administrative elements specified by the application instructions issued by CMS and posted on the CMS website.

(ii) FDA documentation of the item's current classification, as applicable, as well as FDA marketing authorization documentation, or the regulation number under 21 CFR parts 862 through 892 for a device exempted from the premarket notification requirement. If a device exceeds the limitations to the exemptions under 21 CFR parts 862 through 892 of the device classification regulations, the appropriate marketing authorization documentation must be submitted as part of the application.

(iii) For applications for non-drug, non-biological items or services that are not subject to marketing authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) or Public Health Service Act (PHSA) to be considered complete, evidence that the item or service is available in the United States market for use and purchase at the time of the relevant HCPCS Level II code application submission deadline specified by CMS.

(3) For biosimilar biological products, CMS allows a 10-business day extension past the code application deadline to provide a complete application as specified in paragraph (a)(2) of this section. This extension applies only if the following criteria are met:

(i) The marketing authorization documentation is dated between the first day of the extension period and no later than the last day of the extension period.

(ii) The applicant submits a complete application to CMS by the last day of the extension period.

(b) *Application resubmission and reevaluation.* (1) An applicant who is dissatisfied with a final coding decision on an initial code application may resubmit their application for

reevaluation by CMS no more than two times. Any application resubmitted for reevaluation by CMS must be timely and complete in accordance with paragraph (a) of this section and must include the following:

- (i) A description of the previous application submission(s).
- (ii) A copy of the prior final code decision(s) with respect to the application.
- (iii) An explanation of the reason for disagreement with the prior final coding decision(s).

(2) For applications resubmitted a second time for reevaluation by CMS, in addition to the information and documentation required in paragraph (b)(1) of this section, the application must include any significant new information as described in paragraphs (b)(1)(i) and (ii) of this section.

(i) Any significant new information which would include information that was not previously submitted to CMS with respect to the application that directly relates to the reason for the prior final coding decision(s) and could potentially change the final coding decision.

(ii) An explanation of how the significant new information addresses and directly relates to the reason(s) for the prior final coding decision(s) and supports the request for a different coding decision.

(3) An application that is resubmitted for reevaluation under this paragraph (b) is included on an agenda for a public meeting as described in §414.8(d) and receives a preliminary recommendation as described in §414.8(e)(1).

(i) An application for a drug or biological product that is resubmitted for reevaluation will not be included in a public meeting or receive a final decision in the quarterly cycle in which the application is submitted.

(ii) Preliminary recommendations and final decisions for applications that are resubmitted for reevaluation may be delayed as described in §414.8(e)(3).

4. Section 414.10 is added to subpart A to read as follows:

§ 414.10 HCPCS Level II Processes for evaluating code applications.

(a) *Scope.* This section sets forth the processes for evaluating external HCPCS Level II code applications for drug or biological products and non-drug, non-biological items and services, as described in § 414.8.

(b) *Coding request.* An applicant may submit an external HCPCS Level II code application to request the addition of a code, revision of an existing code, or discontinuation of an existing code.

(c) *Sources of information.* CMS' evaluation of a code application is based on information contained in the application and supporting material, any comments received through the public meeting process as applicable, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information obtained independently by CMS that may support or refute the claims made or the evidence produced by the applicant.

(d) *Evaluation of non-drug, non-biological applications to add a code.*

(1) Except as provided in paragraph (d)(2) of this section, a request to add a code is further evaluated under paragraph (d)(4) of this section if CMS determines the following –

(i) The item or service is not appropriate for inclusion in or already coded in a different HIPAA standard medical data code set, such as CPT®, ICD, or CDT®;

(ii) The item or service is primarily medical in nature;

(iii) If applicable, the item has the appropriate marketing authorization from FDA, or is exempt from premarket notification requirements; and

(iv) There is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set.

(2) If paragraphs (d)(1)(i), (ii), or (iii) of this section are not met, but paragraph (d)(1)(iv) of this section is met, a request to add a code is further evaluated under paragraph (d)(4).

(3) If neither paragraph (d)(1) nor (2) of this section is met, CMS does not further evaluate the application under paragraph (d)(4) and does not modify the HCPCS Level II code set.

(4) If paragraph (d)(1) or (d)(2) of this section is met, CMS determines if the item or service that is the subject of the code application --

(i) Performs a significantly different clinical function compared to other items or services described in the HCPCS Level II code set. An item or service is considered to perform a significantly different clinical function if it performs a clinical function that is not performed by any other item or service currently described in the HCPCS Level II code set; or

(ii) Results in a significant therapeutic distinction compared to the use of other similar items or services described in the HCPCS Level II code set. An item or service is considered to show a significant therapeutic distinction when the use of that item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

(A) CMS determines that the use of the item or service confers a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, if it finds any of the following:

(1) The item or service offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(2) The item or service offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the item or service to make a diagnosis affects the management of the patient.

(3) A demonstration of one or more of the following outcomes:

(i) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

(ii) A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

(iii) A decreased number of future hospitalizations or physician visits.

(iv) A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.

(v) An improvement in one or more activities of daily living.

(vi) An improved quality of life.

(vii) A demonstrated greater medication adherence or compliance.

(4) The totality of the information otherwise demonstrates that the use of the item or service results in a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

(B) In determining whether the use of the item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar

items or services described in the HCPCS Level II code set, CMS may consider instances where the use of the item or service may substantially improve or substantially change the medical benefit realized by a specific subpopulation of patients with the medical condition for whom the item or service is used, based on a common characteristic within the subpopulation that impacts the medical benefit of the subject item or service.

(C) In determining whether the use of the item or service results in a significantly improved or significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set, CMS makes this determination without regard to the prevalence among Medicare beneficiaries of the underlying medical condition treated or diagnosed by the item or service that is the subject of the code application.

(D) An item's designation under the FDA Breakthrough Devices Program and marketing authorization for the indication covered by the FDA Breakthrough Devices designation are given substantial weight in determining whether the item meets the significant therapeutic distinction factor at paragraph (d)(4)(ii) of this section.

(E) An application must contain sufficient information and supporting documentation to support a claim of significant therapeutic distinction. The totality of the circumstances is considered when making a determination that the use of an item or service confers a significantly improved or a significantly different medical benefit when compared with the use of other similar items or services described in the HCPCS Level II code set.

(5)(i) If the item or service that is the subject of the code application meets either of the two factors set forth in paragraph (d)(4)(i) or (ii) of this section, and CMS determines there is a claims processing need to separately identify the item or service with a new code to facilitate payment under Medicare, then CMS creates a new code.

(ii) If the conditions in paragraph (d)(5)(i) of this section are not met, CMS does not create a new code.

(6) If CMS finds that revisions to the descriptor of an existing code category are appropriate to account for minor distinctions between the subject item or service and other items or services described by the existing code category and to clarify that the item or service is included in the existing code category, then CMS revises the descriptor rather than add a new code.

(e) *Evaluation of drug or biological applications to add a code.* (1) When evaluating a request to add a code for a drug or biological product, CMS first determines if --

(i) The product is not appropriate for inclusion or already coded in a different HIPAA code set, such as CPT®;

(ii) The product is primarily medical in nature;

(iii) If applicable, the product has the appropriate marketing authorization from FDA;

and

(iv) There is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set

(2) If CMS determines that the factors set forth in paragraph (e)(1) of this section are met, then CMS next determines, for the purpose of claims processing (and payment), whether an existing code adequately describes a product, or whether a revision to the descriptor of an existing code category is appropriate, or whether a new code is necessary. In making the determination in this paragraph, CMS considers applicable Medicare Part B statutory and regulatory payment requirements, program instructions, and information such as the following:

(i) Sections 1842(o) and 1847A of the Act.

(ii) 42 CFR part 414 Subparts J and K.

(iii) Program instructions implementing section 1847A of the Act.

(iv) Information from the code application and other applicable sources such as FDA, drug compendia, the manufacturer, and scientific literature.

(3) When evaluating a request to add a code for a drug or biological product, CMS determines if the product that is the subject of the code application --

(i) Is separately payable under Medicare Part B as a drug or biological product; and

(ii) Is a single source drug, multiple source drug, biological, or biosimilar biological product under section 1847A of the Act, or if other specific payment provisions such as those in sections 1842(o)(1)(A) or (F) of the Act apply.

(4) After reviewing an application to add a code for a drug or biological product, and after considering the factors listed in paragraphs (e)(1) through (3) of this section previously, CMS will then make a determination about whether the appropriate action is to add a code, revise a code, or take no coding action, in response to the application for that product.

(5) CMS may assign code descriptors with drug amounts that correspond to smaller quantities of the product to facilitate more accurate billing.

(f) *Evaluation of non-drug, non-biological and drug or biological applications to revise an existing code.* If CMS determines that the revised descriptor suggested by the applicant would provide a more appropriate description of the category of items or services, CMS revises the descriptor accordingly.

(g) *Evaluation of non-drug, non-biological and drug or biological applications to discontinue an existing code.* If CMS determines that an existing code is duplicative of another

code, or has become obsolete and CMS has no further expectation that the same or similar item or service will be marketed at a later date, CMS discontinues the code.

(h) *Coding decision.* CMS's evaluation of a code application may result in a coding decision that reflects an applicant's coding request in whole, in part, or with modification; or a denial of the coding request. Any coding action taken on an applicant's coding request is set forth in the final coding decision.

5. 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 described under §414.8(d).

(4) After consideration of public consultation provided at a public meeting described under §414.8(d) 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.

6. Section 414.210 is amended by—

a. Revising paragraphs (g)(1)(v) and (g)(2); and

b. Adding paragraph (g)(9)(vi).

The revisions and addition read as follows:

§ 414.210 General payment rules.

*	*	*	*	*
(g)	*	*	*	
(1)	*	*	*	

(v) 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.

(2) Payment adjustments for areas outside the contiguous United States and for items furnished on or after April 1, 2021 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 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, 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 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, 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 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 paragraph (g) of this section.

* * * * *

7. 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 described under §414.8(d).

(4) After consideration of public consultation provided at a public meeting described under §414.8(d) 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.

8. In § 414.402, amend the definition “Item” by revising paragraph (1) introductory text to read as follows:

§ 414.402 Definitions.

* * * * *

Item * * *

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in §414.202, group 3 complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs, and further classified into the following categories:

* * * * *

Dated: July 23, 2020.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: August 19, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2020-24194 Filed: 10/29/2020 4:15 pm; Publication Date: 11/4/2020]