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

**[CMS-1738-P]**

**Summary of Proposed Rule**

On November 4, 2020, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule that addresses certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) policy issues and Healthcare Common Procedure Coding System (HCPCS) issues (85 *FR* 70358-70414). Specifically, it establishes methodologies for adjusting the Medicare DMEPOS fee schedule using information from the Medicare DMEPOS competitive bidding program. These rates would apply for items furnished on or after April 1, 2021, or the date immediately following the duration of the public health emergency (PHE) period for COVID-19. It also establishes application submission and evaluation processes and other procedures related to the HCPCS Level II code application and procedures for making benefit category and payment determination for new items and services. In addition, it 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. It also expands the scope of the Medicare Part B benefit for DME by revising its interpretation of the "appropriate for use in the home" requirement in the definition of DME for certain drugs or biologicals infused in the home setting using an external infusion pump.

**The 60-day comment period ends at close of business on January 4, 2021.**

**Table of Contents**





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## I. Executive Summary

1. DMEPOS Fee Schedule Adjustments

CMS proposes to establish revised DMEPOS fee schedule adjustment methodologies for items and services furnished in non-competitive bidding areas (CBAs) on or after April 1, 2021 or the date immediately following the duration of the PHE for COVID-19, whichever is later. It proposes three different fee schedule adjustment methodologies for items and services that have been included in more than ten competitive bidding programs furnished in non-CBAs. CMS proposes that it will:

- Continue to pay the 50/50 blended rates in non-contiguous non-CBAs (such as areas in Hawaii and Alaska) as its fee schedule adjustment methodology (no longer a transition).
- Continue to pay the 50/50 blended rates in rural contiguous areas as its fee schedule adjustment methodology (no longer a transition).
- Establish fee schedule amounts equal to 100 percent of the adjusted payment amount in all other non-rural non-CBAs within the contiguous United States.

Payment methodologies for former CBAs—areas that were formerly CBAs prior to the gap in the competitive bidding program (CBP)—would remain the same. For items and services furnished in no more than 10 competitive bidding areas, CMS proposes to continue using its established methodology–110 percent of the average single payment amounts (SPAs). Under its proposals and its alternatives examined, CMS would continue to pay suppliers significantly higher rates for furnishing items and services in rural and non-contiguous areas as compared to other areas based on stakeholder input indicating higher costs in these areas, greater travel distance, and other factors. CMS will likely have several different fee schedule adjustment methodologies in effect, depending on where an item or service is furnished, and whether CMS has awarded Round 2021 CBP contracts for that item or service. It recently announced that it will only award Round 2021 CBP contracts to bidders in the Off-the-shelf (OTS) back braces and OTS knee braces product categories.

2. Finalize and Address Comments from the May 11, 2018 Interim Final Rule

CMS indicates in this rule its intention to finalize and address comments from 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. HCPCS Level II Code Application Process

This proposed rule proposes application procedures and evaluation processes for external HCPCS Level II code applications. Most of these proposals are codifying in regulation current processes CMS has established in sub-regulatory guidance.


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*Coding cycles for code applications*: CMS proposes specific coding cycles for drug or biological products, and non-drug, non-biological items and services including timeframes for application submission and final decisions; and additional procedures and exceptions to these proposed processes. With respect to timeframes, CMS proposes to follow a bi-annual coding cycle for consideration of code applications for new DME items and services and for all non-drug, non-biological items and services. It proposes to continue to have quarterly coding cycles for drug or biological products.

*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. CMS proposes, for example, to use the following criteria to evaluate a HCPCS application to add a non-drug, non-biological code:

- The item or service is not appropriate for inclusion in or already coded in a different HIPAA standard medical data code data set, such as CPT®, ICD, or CDT®;
- The item or service is primarily medical in nature;
- If applicable, the item has the appropriate marketing authorization from the Food and Drug Administration (FDA), or is exempt from premarket notification requirements; and
- There is a claims processing need on the part of Medicare to identify the item or service in the HCPCS Level II code set

If these criteria are not met CMS can also evaluate whether the subject of the code application meets two other criteria:

- Performs significantly different clinical function compared to other items or services described in the HCPCS Level II code set
- Results in a significant therapeutic distinction compared to the use of other similar items or services described in the HCPCS Level II code set

4. Benefit Category and Payment Determinations

This proposed rule would also 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. The purpose of the procedure would be to determine whether the product for which a HCPCS code has been requested meets the appropriate Medicare definition to determine how payment for the item of service would be made, and to obtain public consultation on this determination.

5. Classification and Payment for CGMs under Medicare Part B

In addition, CMS puts forth proposals on how to classify and pay for continuous glucose monitors (CGM) under Medicare Part B. 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


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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). Based on an administrative ruling (CMS-1682-R) published on January 12, 2017, CMS classified that only "therapeutic CGMs" (or nonadjunctive CGMs) met the definition of DME as these items were approved by FDA for use in place of a blood glucose monitor for making diabetes treatment decision. CGMs that did not replace a blood glucose monitor for making diabetes treatment decisions (referred to as adjunctive) were not considered DME. CMS is now proposing to classify all CGM systems (adjunctive and non-adjunctive) as DME, effective April 1, 2021. It now believes that adjunctive CGMs are primarily and customarily used to serve a medical purpose as this type of CGMs can provide information about potential changes in glucose levels while a beneficiary is sleeping and is not using a blood glucose monitor.

CMS proposes to continue to pay fee schedule amounts established in its 2017 administrative ruling updated based on the annual update factors for CGM receiver/monitors. The same DMEPOS fee schedule amount would be paid for nonadjunctive and adjunctive CGM receiver/monitors (durable component). Proposed fee schedule amounts for CGM receivers would range from $208.76 to $245.59 (for class II) and $231.77 to $272.63 (for class III); to be updated by the 2021 update factor. CMS proposes to separate payment for CGM supplies and accessories into three separate categories of supplies and accessories to account for variation in the type of supplies needed for different devices and use of a blood glucose monitor.

- Nonadjunctive CGM system monthly supplies: $222.77 (for class II) and $259.20 (for class III); to be updated by 2021 update factor.
- Adjunctive CGM system monthly supplies: $175.62 (for class II) and $198.77 (for class III); to be updated by the 2021 update factor. Nets out blood glucose monitor and supplies.
- Manual non-adjunctive CGM system monthly supplies: $46.86 (for class II) and $52.01(class III devices); to be updated by the 2021 update factor. These are more limited systems – supplies pay for disposable batteries and sensors.

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. There is only one 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.[1] CMS notes that Medicare would be responsible for a smaller portion of the total costs of administration if this proposal is finalized. Beneficiaries would be responsible for a larger portion of the total costs in the home setting,

[1] Patisiran is a medication for the treatment of polyneuropathy in patients with hereditary transthyretin-mediated amyloidosis, a fatal rare disease estimated to affect 50,000 people worldwide.


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since there is no cap on the beneficiary cost-sharing for DME as there is in the hospital outpatient setting.

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

CMS proposes to revise the definition of "item" under the CBP in its regulations 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.

## II. DMEPOS Fee Schedule Adjustments

### A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary to establish and implement the Competitive Bidding Program (CBP) in Competitive Bidding Areas (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The CBP, phased in over several years, utilizes bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services.[2] These items include, for example, hospital beds and related accessories, oxygen supplies and equipment, and wheelchairs, scooter, and related accessories. The programs are collectively referred to as the "Medicare DMEPOS Competitive Bidding Program."

CMS refers to areas in which the CBP has been implemented as competitive bidding areas (CBAs). Currently, there are no CBAs due to a gap period in the DMEPOS CBP; CMS uses the term "former CBAs" to refer to the areas that were formerly CBAs prior to the gap. Starting January 1, 2021, there will be CBAs for two product categories (OTS back braces and OTS knee braces product categories) in Round 2021 of the CBP. CMS refers to areas in which the CBP is not or has not been implemented as non-competitive bidding areas (non-CBAs). Non-CBAs include rural areas, non-rural areas, and non-contiguous areas. A rural area is 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.[3] Non-contiguous areas refer to areas outside the contiguous U.S. – that is, areas such as Alaska, Guam, and Hawaii (81 FR 77936).

For competitively bid items and services furnished in a CBA, the single payment amounts (SPAs) based on the bidding process replace the Medicare allowed amounts. 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. These adjustments

[2] The 2007 DMEPOS competitive bidding final rule (Medicare Program; Competitive Acquisition for Certain DMEPOS and Other Issues published in the April 10, 2007 Federal Register (72 FR 17992)), established CBPs for certain Medicare Part B covered items of DMEPOS throughout the United States.
[3] As defined in 42 CFR 414.202


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continue to be made as additional covered items are phased in under the CBP or information is updated as new CBP contracts are awarded. Similar approach can be used by the Secretary 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 §414.210(g)(8), the adjusted fee schedule amounts are revised each time a SPA for an item or service is updated following one or more new DMEPOS CBP competitions and as other items are added to the DMEPOS CBP. The fee schedule amounts that are adjusted using SPAs are not subject to the annual DMEPOS covered item update and are only updated when SPAs from the DMEPOS CBP are updated or, in accordance with §414.210(g)(10), when there are temporary gaps in the DMEPOS CBP. Updates to the SPAs may occur as contracts are recompeted. In 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 (CPI-U).

CMS also discussed DMEPOS changes made to the CBP from the 21st Century Cures Ac, the 2018 Interim Final Rule, and the Coronavirus Aid, Relief, and Economic Security Act (or CARES Act) in detail. Key changes are highlighted below.

The 21st Century Cures Act extended the transition period for the phase-in of fee schedule adjustments and required the Secretary to take into account certain factors when making any fee schedule adjustments, including stakeholder input, the highest bid by a winning supplier in a CBA, and other factors such as average travel distance with respect to non-CBAs and CBAs.

In the 2019 Interim Final Rule (83 FR 21918), CMS resumed the transitional, blended fee schedule amounts in rural and non-contiguous areas, noting stakeholder concerns and the need to preserve beneficiary access. CMS also finalized changes to the bidding and pricing methodologies under the DMEPOS CBP for future competitions including the Round 2021 CBP. CMS finalized lead item pricing for all product categories under the DMEPOS CBP, which uses 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). It also finalized change to the bidding methodology by using maximum (instead of median) winning bids for lead items in each product category.

The CARES Act continued the 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. The CARES Act also 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. Payment rates for these items in areas other than rural and non-contiguous non-CBAs is 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount.


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**B. Current Issues**

1. Section 16008 of the Cures Act Analysis

Section 16008 of the Cures Act mandates that CMS solicit and take into account a number of factors in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. This includes (1) stakeholder input it has 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. CMS also discusses its analysis of the Cures Act factors and the effect it believes increased payment levels have had in rural and non-contiguous non-CBAs, and the effect fully adjusted fees have had in non-rural contiguous non-CBAs. It also provides its analysis of other metrics it believes are important in measuring the impacts of its payment policies.

CMS presents a summary of its general findings developed in accordance with section 16008 of the Cures Act. CMS' conclusions are discussed below.

a. Stakeholder Input

Stakeholders, mostly suppliers, stated that the fully adjusted fee schedule amounts are not sufficient to cover supplier costs for furnishing items and services in non-CBAs. Stakeholders expressed concerns about the average travel distance, higher costs, and lower average volumes, in rural areas. They believe that this could cause or has caused beneficiary access issues and could potentially cause adverse health outcomes if beneficiaries go without items.

CMS states that it has been closely monitoring beneficiary health outcomes and access to DMEPOS items. It has seen 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. During this time, suppliers accepted assignment (Medicare payment in full) for almost all items and services (99.79 percent in 2017 and 99.81 percent in 2018). It also notes that beneficiary inquiries and complaints, related to DMEPOS items and services have steadily declined since 2016 and have not increased.

b. Highest Winning Bid

CMS has found no pattern indicating that maximum bids are higher for areas with lower volume than for areas with higher volume. CMS refer readers to the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34360 through 34367).

c. Travel Distance Analysis

From its analysis presented in the 2019 ESRD PPS DMEPOS proposed rule (83 FR 34367 through 34371), CMS notes that the average distance traveled in CBAs is generally greater than in most non-CBAs. However, when looking at certain non-CBA rural areas such as far and


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remote areas (FAR), Outside Core Based Statistical Area (OCBSAs), and super rural areas, suppliers generally must travel farther distances to beneficiaries located in these areas than beneficiaries located in CBAs and other non-CBAs.

CMS notes that is has updated some of the travel distance data with data from 2018 and partial 2019 data spanning January through November 2019 and found similar results. CMS has not found evidence that fully adjusted fee schedule amounts are too low and have an adverse impact on beneficiary access. CMS states that it believes it should, however, err on the side of caution and thus may incentivize suppliers to furnish items and services to all rural areas.

d. Costs

Costs, on average, are higher in CBAs than they are in the non-CBAs, for most of the cost data that CMS examined. For certain cost data, CMS also found that Alaska and Hawaii—both non-contiguous areas—tended to have higher costs than many contiguous areas of the United States. CMS believes these findings support a payment methodology that considers such increased costs in non-contiguous areas.

e. Volume

Overall, suppliers in CBAs have significantly more volume than suppliers in non-CBA MSAs, micro areas, or OCBSAs, based on claims data CMS examined and its analysis. CMS found that total services per supplier continued to increase in 2018 and 2019 in all non-CBAs, while assignment rates are 99 percent or higher.

f. Number of Suppliers

The number of suppliers billing Medicare FFS for items subject to fee schedule adjustments in all non-CBAs declined from June 2018 through the end of 2019. CMS notes 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. CMS states, however, that it is 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.

CMS also examined certain product categories more closely, including oxygen and oxygen equipment, as this lack of access to these items could result in serious health implications. It concludes from its analysis that access to oxygen and oxygen equipment is not in jeopardy. CMS recognizes, however, that non-CBAs can have far less volume and fewer billing suppliers than CBAs and states that it should err 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, CMS also has been monitoring other metrics it believes are important in measuring the impacts of its payment policies. This includes examining


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trends in assignments rates, mortality rates, hospitalization rates, ER visit rates, SNF admission rates, physician visit rates, monthly days in hospital, and monthly days in SNF. Most of these metrics are based on analysis of claims data. In its review of these data, it concludes that it does not believe that it payment rates had a discernible impact on any trends that were already occurring before it paid the higher fees, and it does not see any appreciable differences between the areas in which it paid the higher 50/50 blended rates in rural and noncontiguous non-CBAs and the areas in which it paid the fully adjusted fees in nonrural/contiguous non-CBAs. In addition, assignments rates are still high in all non-CBAs—over 99 percent—, which means over 99 percent of suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME.

## C. Provisions of the Proposed Regulations

1. Proposed Fee Schedule Adjustment Methodologies

CMS proposes 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, whichever is later. A separate fee schedule methodology applies for items and services furnished in (1) non-contiguous non-CBAs; (2) non-CBAs within the contiguous United States that are defined as rural areas at §414.202; and (3) 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, CMS proposes to continue using the methodology in §414.210(g)(3) to adjust the fee schedule amounts for these items and services furnished on or after April 1, 2021.[4] The rest of the discussion in this section relates to adjusting fee schedule amounts for DMEPOS items and services included in more than ten competitive bidding programs.

a. Adjustment of fee schedule amounts in non-contiguous non-CBAs

CMS proposes to continue paying the 50/50 blended rates in non-contiguous non-CBAs. As proposed, this 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). This proposed adjustment would apply for items and services furnished on or after April 1, 2021, or the date immediately following the PHE. Fifty percent of the adjusted rate would be based on rate from competitive bidding and the other fifty percent would be based on the unadjusted fee schedule amount prior to competitive bidding trended forward by the annual update factors. Specifically, CMS calculates the rate as follows: 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[5] and 50 percent of the unadjusted fee schedule amount for the area, which is the fee schedule amount in

[4] Calculated as 110 percent of the unweighted average of the single payment amounts

[5] CMS explained its rationale for a methodology that incorporates 110 percent of the national average price in its CY 2015 ESRD PPS DMEPOS final rule.


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effect on December 31, 2015, increased for each subsequent year beginning in 2016 by the annual update factors.[6]

b. Adjustment of fee schedule amounts in non-CBAs within the contiguous United States (rural contiguous areas)

CMS also proposes to continue paying the 50/50 blended rates in rural contiguous areas. This would also no longer be a transition rule under §414.210(g)(9), but instead be the fee schedule adjustment methodology for items and services furnished in these areas under §414.210(g)(2). This proposed adjustment would apply for items and services furnished on or after April 1, 2021, or the date immediately following the public health emergency. This 50/50 blend is calculated the same as the 50/50 blended rates in non-contiguous non-CBAs detailed above.

c. Adjustment of fee schedule amounts in in all other non-rural non-CBAs within the contiguous United States

CMS proposes that the fee schedule amounts in all other non-rural non-CBAs within the contiguous U.S. equal 100 percent of the adjusted payment amounts established under §414.210(g)(1)(iv). In other words, one hundred percent of the adjusted rate is based on competitive bidding. This proposed adjustment would apply for items and services furnished on or after April 1, 2021, or the date immediately following the PHE.

CMS states that the purpose of the 50/50 blend in rural and non-contiguous CBAs 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. It also believes that this proposal considers stakeholder feedback as well as information from its previous and updated analysis of the Cures Act factors.

CMS also proposes to add paragraph §414.210(g)(9)(vi) to indicate that the transition rules described in this section are no longer applicable on or after April 1, 2021, or the date immediately following the duration of the emergency period. After that date, the adjusted fee schedule amount for a given area is equal to the amount established under paragraph §414.210(g).

2. Results from Round 2021 CBP and Implications

CMS' proposed fee schedule adjustment methodologies rely on SPAs generated by the CBP. CMS announced on October 27, 2020 that it will only award Round 2021 CBP contracts to bidders in OTS Back Braces and OTS Knee Braces product categories (only 2 of the 15 product categories). CMS explained in its announcement that it is not awarding competitive bidding contracts for any of the 13 product categories for Round 2021 that were previously competed

[6] These annual update factors are 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.


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because the payment amounts did not achieve expected savings.[7] As a result, CMS will not have any new SPAs for those items and services in these 13 product categories: commode chairs, continuous positive airway (CPAP) devices, enteral nutrition, hospital beds, nebulizers, negative pressure wound therapy pumps, non-invasive ventilators, oxygen and oxygen equipment, patient lifts and seat lifts, standard manual wheelchairs, standard power mobility devices, support services (Groups 1 and 2), transcutaneous electrical nerve stimulation (TENS) devices, and walkers.

CMS states that it is "seriously considering" whether to simply extend the application of the current fee schedule adjustment transition rules for all of the items and services in the product categories where no CBP contracts are in effect – the 13 products categories described above. In this scenario, CMS would apply the fee schedule adjustment transition rules at §414.210(g)(9) for non-CBAs and apply fee schedule adjustment rules at §414.210(g)(10) for CBAs and former CBAs (CBAs where no CBP contracts are in effect). These would apply until a future round of the CBP. In this situation, the proposed fee schedule adjustments would only apply to the OTS back braces and OTS knee braces furnished in non-CBAs on or after April 1, 2021.

We created the table below to describe how the provisions would likely apply based on our understanding of the regulatory text and the preamble. CMS does not highlight in the text the practical implications of how its proposed and alternative regulatory language affects how the rates are adjusted during the 3-year contract period of the Round 2021 CBP. Commenters should seek clarification on these issues.

The fee schedule adjustments described below apply to items and services furnished in more than ten competitive bidding programs. Of particular note, under its proposal and based on our understanding, SPAs for products categories other than OTC back brace and knee braces in former CBAs would no longer be annually adjusted by the CPI-U; it is not clear whether the SPAs in these areas would resort to the amounts for these products that that were in effect the last day before the CBP contract period of performance ended. Under one of its alternative proposals discussed, CMS would apply §414.210(g)(10) to these former CBAs and these amounts would be adjusted each year based on the CPI-U. In addition, under an alternative discussed, payment rates for these items in areas other than rural and non-contiguous non-CBAs would be 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount instead of 100 percent of the adjusted amount. Application of transition rules compared to existing regulatory text appears to have little practical effect in how these rates are determined or adjusted on an annual basis for the other non-CBAs.

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


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## Comparison of Fee Schedule Adjustments Based on Competitive Bidding for Proposed and Alternative Discussed

| | **Proposed: Fee schedule adjustments for OTS back brace and knee braces** | **Proposed: Fee schedule adjustments for all other product categories (no CBP contracts are in effect)** | **Alternative with transition rules: Fee schedule adjustments for all other product categories (no CBP contracts are in effect)** |
|---|---|---|---|
| CBAs | Based on contract awarded single payment amounts (SPAs)<br><br>Rates stay the same over 3-year contract period: Jan. 1, 2021- Dec. 31, 2023 | N/A | N/A |
| Former CBAs | N/A | Based on SPA from last CBP – amounts would stay the same over the 3-year contract period.<br><br>(reg. text is not clear) | Based on SPA from last CBP – amounts would be adjusted each year based on CPI-U; §414.210(g)(10) |
| Non-CBAs | | | |
| Non-contiguous non-CBAs (areas in Hawaii, Alaska, and U.S. territories) | 50/50 blend of adjusted (based on CBP) and unadjusted (fee schedule prior to CBP); §414.210(g)(2)<br><br>Rates stay the same over 3-year contract period | 50/50 blend of adjusted (based on CBP) and unadjusted (prior to CBP); §414.210(g)(2)<br><br>CPI-U annual adjustment at §414.210(g)(4) | 50/50 blend of adjusted (based on CBP) and unadjusted (fee schedule prior to CBP); §414.210(g)(9)(iii)<br><br>CPI-U annual adjustment §414.210(g)(4) |
| Non-CBAs within the contiguous United States (rural contiguous areas) | 50/50 blend of adjusted (based on CBP) and unadjusted (fee schedule prior to CBP); §414.210(g)(2)<br><br>Rates stay the same over 3-year contract period | 50/50 blend of adjusted (based on CBP) and unadjusted (prior to CBP); §414.210(g)(2)<br><br>CPI-U annual adjustment at §414.210(g)(4) | 50/50 blend of adjusted (based on CBP) and unadjusted (fee schedule prior to CBP); §414.210(g)(9)(iii);<br><br>CPI-U annual adjustment at §414.210(g)(4) |
| All other non-rural non-CBAs | 100% of the adjusted payment amount; §414.210(g)(1)(iv)<br><br>Rates stay the same over 3-year contract period | 100% of the adjusted payment amount; §414.210(g)(1)(iv)<br><br>CPI-U annual adjustment at §414.210(g)(4) | 75/25 blend of the adjusted payment amount (based on CBP) and unadjusted (fee schedule prior to CBP)<br><br>§414.210(g)(9)(v)<br>CPI-U annual adjustment at §414.210(g)(4) |

Source: HPA analysis of regulatory text and proposals.


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3. Alternatives Considered but Not Proposed

CMS states that it is considering, but is not proposing, three alternatives to its proposals for which it is seeking comment.

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

CMS states that it is considering 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, it 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, CMS is considering paying fully adjusted fee schedule rates in all areas except super rural areas or non-contiguous areas and pay 120 percent of the fully adjusted rates in super rural areas or non-contiguous areas. 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.

Consistent with the ambulance fee schedule rural adjustment factor at §414.610(c)(5)(ii), CMS 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. CMS states that this approach would address prior stakeholder concerns that indicated differentials in the cost of providing these items in these low population density areas.

Under this alternative, CMS would also replace §414.210(g)(2) with a new rule that adjusts the DMEPOS 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

CMS states that it also considered proposing an alternative fee schedule adjustment methodology that would establish an additional transition period to allow it to determine the impact of the new SPAs and monitor the impact of adjusted fee schedule amounts. Under this alternative, CMS considered adjusting the fee schedule amounts for items and services furnished in rural areas and noncontiguous 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, 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.


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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

The third alternative address a possible payment methodology for certain products categories that CMS states were essentially removed from Round 2021 of the CBP. Under this alternative, CMS 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. This alternative is also described in more detail above as an option that CMS stated that it is "seriously considering".

**CMS seeks comments on its alternative methodologies and its proposed methodologies. It states that it is interested in receiving comments on whether there are benefit or downsides to its proposals that it did not consider or discuss in this proposed rule. It also seeks specific comments on whether to extend:**

- the transition rules at §414.210(g)(9) and fee schedule adjustment rules at §414.210(g)(10) for these items and services that have essentially been removed from Round 2021 of the CBP;
- 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; and
- the rules at §414.210(g)(10), until such product categories are competitively bid again in a future round of the CBP.

## III. 2018 Interim Final Rule Related to Items and Services Furnished in Rural Areas and Exclusion of Infusion Drugs from the DMEPOS CBP

On May 11, 2018 CMS 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" (referred to as the "2018 Interim Final Rule"). CMS solicited comments on the 2018 Interim Final Rule, but because it has not yet responded to the comments received it is signaling its intent to do so in the final rule.

This interim rule discussed among other issues exclusion of infusion drugs from items subject to the DMEPOS CBP and issues related to the transitional, blended fee schedule amounts in rural and noncontiguous areas and other non-CBAs. CMS also explained in this rule that it would use the extended transition period to further analyze its findings on DMEPOS fee schedule amounts in these areas 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


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furnished on or after January 1, 2019 are necessary (83 FR 21918 through 21919). CMS states that it intends to respond to the comments it received on these issues in the final rule.

## IV. HCPCS Level II Code Application Process

### A. Background

The HCPCS is a standardized coding system used to identify specific items and services submitted to Medicare, Medicaid, and other health insurance programs.[8] The HPCPS is divided into two principal components: Level I is comprised of Current Procedure Terminology (CPT codes)[9] and Level II is comprised of items, services, supplies, and equipment that are not identified by CPT codes. Except for codes on dental procedures[10], CMS maintains HCPCS Level II codes and is responsible for making decisions about additions, revisions, and discontinuation of these codes. There are almost 8,000 HCPCS Level II codes and approximately 150 code applications have been submitted to CMS annually. The procedures used by the public to submit code applications and by CMS to evaluate code requests have been primarily included in guidance released on the CMS website at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required the Secretary to establish procedures for coding and payment determinations for new DME that permits public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD-9-CM (which has been replaced with ICD-10-CM). Beginning in 2002, CMS established annual public meetings for making coding determinations for new DME (66 FR 58743 through 58745) which was expanded in 2005 to include all new public requests for revisions to the HCPCS Level II codes (70 FR 15340).

Beginning in January 2020, CMS revised the procedures for updating HCPCS Level II coding.[11] Applications for HCPCS Level II codes for DMEPOS and other non-drug, non-biological items and services are submitted and reviewed no less frequently than biannually and applications for HCPCS Level II for drugs and biological products are submitted and reviewed no less frequently than quarterly. To accommodate reviewing code applications for drug and biological products on a quarterly basis, CMS stopped including these applications at public meetings. Applicants can resubmit a code application for a drug or biological product in a subsequent quarterly coding

[8]The Health Insurance Portability and Accountability Act of 1996 (HIPAA), required the Secretary to adopt standards for codes sets for electronic transactions. In 2000, HHS adopted HCPCS Level I CPT codes and HCPCS Level II as the standard code set used by all payers for electronic transactions, including health care claims transactions (65 FR 50312).

[9] CPT is a coding system used primarily to identify medical services and procedures furnished by physicians and other health care professionals. The American Medical Association (AMA) makes decisions about CPT codes. More information can be found at www.ama-assn.org/about.cpt-editorial-panel/cpt-code-process.

[10] The Code on Dental Procedures and Nomenclature (CDT code) are a separate medical code set that are considered HCPCS Level II codes but are maintained separately by the American Dental Association. More information can be found at https://www.ada.org/en/publications/cdt.

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


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cycle. Consistent with implementing more frequent HCPCS coding cycles, CMS releases coding decisions quarterly on its website.[12] Table 4 (reproduced below) displays the 2020 schedule for HCPCS Level II coding cycles.

**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 Change Effective Date |
|---|---|---|---|---|---|---|
| DMEPOS and Other Non-Drug, Non-Biological Items and Services | Bi-annual 1 | 1/06/2020 | May 2020 | June 1 and June 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/ Biological Products | Q1 | 1/06/2020 | N/A | N/A | April 2020 | 7/01/2020 |
| Drugs/ Biological Products | Q2 | 4/06/2020 | N/A | N/A | July 2020 | 10/01/2020 |
| Drugs/ Biological Products | Q3 | 6/29/2020 | N/A | N/A | October 2020 | 1/01/2021 |
| Drugs/ Biological Products | Q4 | 9/21/2020 | N/A | N/A | January 2021 or earlier | 4/01/2121 |

## B. Proposals for HCPCS Level II Coding Procedures

CMS proposes to codify certain policies and procedures regarding the submission and evaluation of HCPCS Level II code applications for products paid separately as drugs or biologicals, and non-drug, non-biological items and services, as defined in the proposed rule.[13] CMS proposes codifying the more frequent coding cycles as implemented January 1, 2020, including timeframes for application submission and final decisions, and to update associated policies and processes.

For purposes of this propose rule, the term "products paid separately as drugs or biological" 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 defined in section 1861(t) of the Act. These products are generally in 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; (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 in statute or regulations.[14]

[12] Available at https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets.
[13] The proposals in this proposed rule do not apply to other items and services described in procedural codes for oral health and dentistry that begin with the letter "D" and maintained by the American Dental Association.
[14] Examples of other categories of products for which there is another Part B benefit category includes drugs or immunosuppressive drugs (section 1861(s)(2)(J) of the Act) and pneumococcal pneumonia, influenza, and hepatitis B vaccines (section 1861(s)(10) of the Act).


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For purposes of this proposed rule, the term "non-drug, non-biological items and services" are those that Medicare (and potentially by other payers, such as private insurers) generally pays separately and that are described in the following list. CMS notes that the statutory citations and definitions are not intended to be strict definitions of the items and services in these categories (which are consistent with the categories on the HCPCS Level II code application) but are intended to describe the types of services subject to the HCPCS Level II code application process.

- Medical and surgical supplies, such as splints and casts as described in section 1861(s)(5) of the Act and therapeutic shoes 1861(s)(12) of the Act.
- Dialysis supplies and equipment as described in section 1861(2)(F) of the Act.[15]
- Ostomy and urological supplies as described in section 1861(s)(8) of the Act.
- Surgical dressings as described in section 1861(s)(5) of the Act.
- Prosthetics (artificial legs, arms, and eyes) as described in section 1861(s)(9) of the Act and prosthetic devices as described in section 1862(s)(8) of the Act.
- Orthotics (leg, arm, back, and neck braces) as described in section 1861(s)(9) of the Act.
- Enteral/parental nutrition as described in section 1842(s)(2) of the Act.
- DME (and related accessories and supplies other than drugs) such as oxygen and oxygen equipment, wheelchairs, infusion pumps and nebulizers as described in sections 1861(s)(6) and 1861(n) of the Act.
- Vision items and services, such as prosthetic lenses, as 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.

1. Proposed HCPCS Level II Coding Cycles and Related Policies

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

CMS proposes to continue the coding cycle for Level II code applications for non-drug, non-biological items and services no less frequently than bi-annually. This proposal includes: (1) posting a deadline for submitting code applications in or around January or June each year on the CMS website or in another manner; (2) issuing preliminary recommendations which may include questions or requests for additional information on code applications; (3) holding public meetings to obtain input on code applications and preliminary recommendations; and (4) issuing final coding decisions on the CMS website or in another manner within approximately 6 months of the code application deadline. Consistent with the current practices, coding changes become effectively approximately 3 months after issuance of the final coding decisions. CMS proposes to add new §414.(8)(b), (c), (d), and (e) to codify these procedures.

[15] Renal dialysis services defined under §413.171 are paid under the ESRD PPS. Transitional drug add-on payment adjustment (TDAPA) and the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) require separate coding for certain items and services.


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CMS considered proposing coding cycles of no less frequently that quarterly for non-drug, non-biological items and services but believes quarterly coding cycles would not provide sufficient time to evaluate the applications, hold public meetings, and issue final coding decisions. CMS notes all these activities require more than 3 months to complete. Based on its experience, applications for these items and services are more complex or require more research and review than code applications for drugs or biological products. As many of these items and services may not be regulated by the FDA, these applications require independent research by CMS to determine whether the item or service has functional or clinical differences compared to other similar items and services already described by a HCPCS Level II code.

Consistent with its current process, CMS proposes at §414.(8)(e)(3) that if a non-drug, non-biological item or service raise complex or significant issues and CMS needs additional time to evaluate the application, it may delay issuing a preliminary recommendation and delay the final coding decision. CMS may also delay issuing the final coding decision after issuing a preliminary recommendation. CMS notes these circumstances would include, but are not limited to, situations where the code application involves a significant policy consideration, involves a significant claims processing consideration, or requires in-depth clinical or other research. CMS proposes that when it determines it needs additional time to make a preliminary recommendation or it needs additional time to make a final coding decision, it will continue its 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. CMS will issue these determination at the same time it issues preliminary recommendations and final coding decisions for other items and services included in that coding cycle. When CMS continues to evaluate the application in the next coding cycle it could be delayed into additional subsequent cycles.

*b. Coding Cycles for Drug or Biological Products*

CMS proposes to continue the coding cycle for Level II code applications for drug or biological products no less frequently than quarterly. This proposal includes: (1) posting a deadline for submitting code applications which would occur in or around January, April, June, or September each year on the CMS website or in another manner; (2) issuing final coding decisions on the CMS website or in another manner, within approximately 3 months of the code application deadline. Consistent with the current practices, coding changes would become effectively approximately 3 months after issuance of the final coding decisions. CMS proposes to codify these procedures at proposed §414.(8)(b), (c)(2) and (e).

CMS believes that quarterly cycles are appropriate for most drug or biological applications because its experience is that these applications are more straightforward and take less time to assess than many of the applications for non-drug, non-biological items and services. Consistent with its current process, CMS proposes that when more detailed information may be required, it may delay the final coding decision to a subsequent coding cycle.

Except for code applications that are resubmitted for reevaluation and code applications where a decision is delayed, CMS proposes it would continue not to hold public meetings or issue preliminary recommendations for drug or biological product code applications. CMS believes it is not feasible to include public meetings within the quarterly cycle. In addition, there is no


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statutory requirement for public consultation on drug or biological product coding determinations. As discussed below (section *d*), CMS proposes to add drug or biological product applications to a bi-annual public meeting agenda if an applicant is dissatisfied with a prior coding decision and submits an application for reevaluation.

CMS considered proposing coding cycles of no less frequently that bi-annually for applications for drug and biological products which would align with the proposed cycle for non-drug, non-biological items and services. CMS acknowledges the value in providing an opportunity for public input but it believes that expediting coding decisions for drugs or biological products and the quarterly incorporation of such products in the claims processing system facilitates patient access to new products and outweighs the benefit of including these applications in the public meeting process. **CMS seeks comments on whether it would be preferable to adopt coding cycles of no less frequently than bi-annually for drug or biological product code applications, which would enable CMS to issue preliminary recommendations and solicit public input at public meetings on all products for a given coding cycle**.

Consistent with its current process, CMS proposes at §414.(8)(e)(3) that if a drug or biological product raise complex or significant issues and CMS needs additional time to evaluate the application, it may delay issuing a final coding decision by one or more coding cycles. When CMS determines it needs additional time to make a final coding decision, CMS will continue its 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. CMS will issue these determination at the same time it issues final coding decisions for other drug and biological products included in that coding cycle. When CMS continues to evaluate the application in the next coding cycle, the determination could be delayed into additional subsequent cycles.

CMS also proposes when it delays a final coding decision it may add the drug or biological product application to the public meeting agenda to obtain input and public discussion of the application. Before the public meeting, CMS would issue a preliminary recommendation. CMS notes that 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. If the final decision is delayed, but not placed on a public meeting agenda it will remain on the quarterly cycle schedule. **CMS seeks comments on whether there are other circumstances under which CMS may decide to include a drug or biological product application in a public meeting.**

CMS considered alternatives to soliciting public information in a public meeting, including a web-based public input process with a 15-day period for public comment. CMS notes that a 15-day period is approximately the same amount of time it currently provides for public input on preliminary recommendations issued on non-drug, non-biological code applications. CMS did not propose this because it does not believe there is sufficient time to include a web-based public input process in a quarterly cycle schedule. **CMS seeks comments on whether there may be specific circumstances in which a web-based public input process may be useful for only a limited number of applications in the quarterly coding cycle**.


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

CMS proposes to codify the existing requirement that an application must be timely and complete at new §414.9(a). An application that is not timely and complete and declined by CMS may be submitted by the applicant in a subsequent coding cycle. An application is timely if it is submitted by the applicable code application submission deadline specified by CMS for each coding cycle which is posted on the CMS website or in another manner. An application would be complete if it includes, by the applicable code application submission deadline, the required information and documentation and meets all the administrative elements, including application questions. Consistent with current practice, CMS proposes that for an application to be complete the applicant must provide FDA documentation of the item's 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.

CMS believes that providing a code application deadline extension for biosimilar products to accommodate the submission of required FDA determination past the application deadline will increase the access to biosimilar biological products. For biosimilar products, CMS proposes to establish a 10-business day extension past the code application deadline for submitting a complete application, including FDA marketing documentation. 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. CMS believes a 10-business day extension would be adequate and still allow a final coding decision in the quarterly cycle. **CMA seeks comments on the impact of product launch delay for biosimilar products once they are approved by the FDA and whether a 10-business day deadline extension is necessary**.

CMS does not believe an application deadline extension to accommodate later submission of required FDA documentation would be feasible for all drug or biological applications due to limited resources and the compressed review timeframe under the quarterly cycle. **CMS seeks comments on other potential circumstances that could warrant a deadline extension (for example a deadline extension for particular drugs or drug classes) and the appropriate length of those extensions.**

CMS also proposes to be considered complete, applications for non-drug, non-biological items or services that are not subject to marketing authorization under the Federal Food Drug & Cosmetic (FD&C) Act or the Public Health Services Act (PHSA) 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 application submission deadline specified by CMS. CMS considers availability in the U.S. market as some measure of assurance that the item is available for prescription or use and is ready to receive a HCPCS Level II code. CMS notes that it believes that manufacturers of items subject to FDA marketing authorization intend to market the product and it does not require evidence that the items in available in the U.S. market for use and purchase at the time of the relevant code application deadline.


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CMS did consider 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 application attachment. Given the shorter coding cycles, CMS believes it would be difficult to follow-up with numerous applicants within a cycle for missing information and thus proposed that all information must be submitted by the deadline to be considered complete. **CMS seeks comments on whether it should allow certain supplemental information to be submitted after the application deadline and in what circumstances, including requirements or timeframes, this should be allowed**. CMS notes it will continue its practice of allowing 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.

*d. Proposed Application Resubmission and Reevaluation*

CMS currently allows any applicant dissatisfied with the final coding decision to resubmit an application for a previously considered item or service in a subsequent coding cycle for reevaluation.[16] CMS notes that many resubmitted applications do not contain new information or specify a clear reason for reevaluation of the previously submitted information and review of these applications requires considerable time and resources. CMS proposes to continue to allow resubmission of applications but proposes certain limitations and additional policies for reevaluation of coding decisions.

CMS proposes that an applicant dissatisfied with a final coding decision on an initial code application may resubmit their application for reevaluation no more than two times (§414.9(b)(1)). Any application resubmitted for reevaluation must be timely and complete and must include the following: (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 disagreeing with the prior final coding decision(s).

In addition, CMS proposes for the first resubmission it would strongly encourage, but not require, the submission of new information with the application. For the second resubmission and reevaluation, CMS proposes at new §414.9(b)(2), that in addition to the information and documentation required to be submitted for all resubmissions under proposed §414.9(b)(1), the application must also include the following: (1) significant new information, defined as information that was not previously submitted to CMS with respect to the application that directly related 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 coding decision(s) and supports the request for a different coding decision. CMS states that significant new information could be a newly published relevant clinical study that supports a claim of significant therapeutic distinction made but unsupported in an initial application or additional information that supports a claim that the product performs a significantly different clinical function not captured in the current code set. If significant new information is not submitted with the second resubmission, or

[16] Related information is available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS


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if the applicant does not provide the required information for either resubmission, CMS would decline to reevaluate the application. CMS notes that for an application to be considered for reevaluation if 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. An application for an item or service for a new indication not included in the original application would not be considered a resubmission.

To obtain addition input, CMS also proposes to include all applications for reevaluation on an agenda for a bi-annual public meeting and to issue a preliminary recommendation ((§414.9(b)(3)). For resubmissions of code applications for drug or biological products, 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 the public meeting falls within the quarterly cycle the application was resubmitted, in order to prepare the preliminary recommendation for the public meeting, CMS would delay the discussion to the next public meeting. CMS states this time frame is necessary because it needs approximately 1 month to prepare the preliminary recommendation. In addition, consistent with the review of initial applications, the preliminary recommendations and final decisions for applications that are resubmitted for reevaluation made be delayed to subsequent coding cycles.

2. Proposed Evaluation of HCPCS Level II Code Applications

CMS proposes at §414.10 the processes it would use to evaluate HCPCS Level II code applications to add a code, revise an existing code, or discontinue an existing code. Evaluation of a code application would be based on information and supporting material, any comments received through the public meeting process, any information obtained from and evaluations conducted by federal employees or CMS contractors, and any additional research or information independently obtained that may support or refute the claims made by or the evidence provided by the applicant (§414.10(c)). An evaluation my result in a coding decision that accommodates the request in whole, in part, or with modification and CMS may also deny the coding request. A final coding decision will be publicly available on the HCPCS website.

CMS believes a major goal of an effective code set is to balance the need to identify and differentiate items and services and to have a manageable system for the efficient submission and processing of claims. A code category is generally intended to describe the item or service that is general and not manufacturer specific. CMS states that the term "claims processing need" refers to evaluating HCPCS applications in a manner that sufficiently identifies and differentiates items and services but produce a manageable system and set of codes for the efficient submission and processing of items and services in accordance with the Medicare statute and regulations that are specific to the items and services for which a code is being requested. CMS notes that a claims processing need may be based on a Medicare program integrity need to identify a specific item or service. **CMS seeks comments on the term "claims processing need" including how it is used to evaluate HCPCS Level II code applications**.


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*a. Proposed Evaluation Process for Applications to Add A Code*

CMS proposes at §414.10 the processes that it would use to evaluate HCPCS code applications to add a code, revise an existing code, or discontinue an existing code.

i. Proposed Evaluation Process for Non-Drug, Non-Biological Applications to Add A Code

*(a) Proposed Threshold Factor for Evaluating Non-Drug, Non-Biological Applications*

Consistent with current practice, CMS believes 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 Medicare has a claims processing need to identify the item or service in the code set.

CMS proposes at §414.10(d)(1)(i)-(iv) that it would first determine, as a threshold matter, if the item or service is appropriate for inclusion in the HCPCS Level II code set by assessing whether:

i. The item or service is not appropriate for inclusion in or already coded in a different HIPPA standard medical data code set, such as CPT, ICD, or CDT;
ii. The item of 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.

When determining whether an item of service is appropriate for inclusion in the HCPCS Level II code set, CMS takes into account the type of item or service, the setting it is used, by whom it is used, and how it is used. For example, procedures performed during an inpatient stay are identified by ICD-10-PCS codes and procedures performed by physicians in a physician office are typically described by CPT codes. CMS also considers whether an item or service is part of a comprehensive code and is included as part of a bundled payment. If CMS determines the subject item of service is appropriated coded in another code set, it will redirect the applicant to the other code set.

The HCPCS Level II code set is a standard medical data code set for healthcare equipment and supplies. CMS states to meet this requirement an item or service should be considered "primarily medical in nature", which means 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. Even if an item or service could be used in a healthcare setting, if the primary or customary use is not for a medical purpose, it would not be considered primarily medical in nature. CMS provides several examples of items that it would not consider primarily medical in nature including air conditioners, drinking straws, and wearable clothing.

CMS also proposes to assess whether or not the subject of the code application has the appropriate FDA marketing authorization or is exempt from premarket notification requirements. Applicants must explain the basis for any claimed exemptions from premarket notification requirements, with specific citations to the regulations under 21 CFR parts 862 through 892 as appropriate.


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CMS will also continue to assess whether there is a Medicare claims processing need for a HCPCS Level II code. CMS will continue to use information obtained from and evaluations conducted by federal employees comprising a team known as the CMS HCPCS Workgroup. The HCPCS Workgroup is composed of federal government employees representing the major components of CMS, as well as employees from other pertinent Federal agencies, including the Department of Veteran Affairs and the Defense Health Agency.

Consistent with current practice, if all the above proposed threshold factors are met, CMS will further evaluate the coding request (as discussed below in section ii). CMS also proposes that if one or more of the proposed factors under §414.10(d)(1)(i)-(iii) are not met but there is a Medicare claims processing need (§414.10(d)(iv)), it would evaluate the coding request. CMS provides examples of when Medicare may need to separately identify a non-covered, previously non-coded item or service that has been frequently miscoded and resulted in inappropriate payment. For example, CMS created HCPCS code A4467 (Belt, strap, sleeve, garment, or covering, any type) to identify items that were not considered primarily medical in nature but had been coded with other existing HCPCS Level II codes.

*(b) Proposed Process for Further Evaluating Non-Drug, Non-Biological Applications*
If CMS decides the subject item or service is appropriate for inclusion in the HCPCS Level II code set, it then evaluates the coding request to assess the functional and clinical differences of the subject item or service compared to existing codes. CMS generally makes this assessment based on categories of similar items or services performing the same or similar function for a patient. The information submitted in the code application facilitates this evaluation. CMS can determine to create a new code, revise a code descriptor of an existing code, or take no action because an existing code adequately describes the item or service.

CMS proposes at §414.10(d)(4) to assess if 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; 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.

CMS proposes at §414.10(d)(5) that if it determines that the item of service that is the subject of the code application meets either of the two factors proposed at §414.10(d)(4) and there is a claims processing need to separately identify the item or service with a new code to facilitate Medicare payment, then CMS will create a new code.

*(i) Significantly Different Clinical Function*. CMS proposes an item or service performs 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. CMS notes clinical function refers to what the item or service does for a patient, including the intended purpose of the item of service in the delivery of care. For example, the clinical function of positive airway pressure is respiratory ventilation and the clinical function of an electrode is to conduct electricity.


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CMS discusses how most items and services are developed in an iterative fashion such that the new items or services retain similar features or functionalities as those performed by prior versions and they may not be significantly different from those already described by the code set. As part of this evaluation, CMS examines it 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 item or service that it cannot be categorized in an existing code category. CMS states a new code may be warranted for an item or service with a first-of-kind clinical function. If there is also a Medicare claims processing need to identify the particular item or service, then CMS will create a new code. For example, CMS created HCPCS code Q0480 (Driver for use with pneumatic ventricular assist device, replacement only) which was a first-of-kind clinical item not previously captured by an existing code and which had a Medicare claims processing need.

*(ii) Significant Therapeutic Distinction*. CMS proposes an item of service results in a significant therapeutic distinction when the use of the item or service results in a significantly improved or a significantly different medical benefit when compared with other items or services currently described in the HCPCS Level II code set.

Under current guidance, a significant therapeutic distinction exists when the subject item or service results in an improved medical benefit (e.g. a significantly improved medical outcome) when compared to existing items of services in the code set. CMS reviews requests for a code based on significant therapeutic distinction on a case-by-case basis, taking into consideration the information provided by the applicant.

As discussed below, CMS proposes expanding the opportunities for identifying a significant therapeutic distinction.

- CMS proposes at §414.10(d)(4)(ii)(A) a framework that is based on the general criteria currently used for determining substantial clinical improvement in the Inpatient Prospective Payment System (IPPS) New Technology Add-on Payment (NTAP).[17] CMS would determine the item or service confers a significantly improved or significantly different medical benefit when it finds any of the following:
    - The item or service offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment.
    - The item or service offers the ability to diagnose a medical condition in a patient population where the medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population and that the earlier diagnosis affects the management of the patient.
    - A demonstration of one of the following outcomes: a reduction in at least one clinically significant adverse event, including mortality; a decreased rate in at least one subsequent diagnostic or therapeutic intervention; a decrease number of hospitalizations or physician visits; a more rapid resolution of the disease process treatment such as reduced recovery time; am improvement in an activity of daily living; an improved quality of life; or a demonstrated greater medication adherence or compliance.

[17] 42 CFR 412.87(b)(1)


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

- CMS proposes it may consider instances where the item or service may substantially improve or substantially change the medical benefit realized by a specific subpopulation of patients with the medical condition (§414.10(d)(4)(ii)(B)). For example, certain prosthetics or orthotics might provide a differential benefit for strong or frail patients.

- CMS proposes that when making the determination of significant therapeutic distinction it will make this determination independent of the prevalence of the medical condition treated or diagnosed among Medicare beneficiaries (§414.10(d)(4)(ii)(C)).

- CMS proposes to give substantial weight for determining significant therapeutic distinction for items designated as breakthrough under the FDA Breakthrough Device Program (§414.10(d)(4)(ii)(D)).

**CMS seeks comments about the following issues related to the above proposals**:

- Whether there are certain factors within the framework based on the IPPS NTAP that should be modified or eliminated for evaluating a HCPCS Level II code application.
- Under what circumstances should diagnosing a medical condition be considered a factor for determining substantial therapeutic distinction. CMS notes that diagnostic tests and lab tests are generally not coded in the HCPCS Level II code set and these services are typically administered in a physician's office and a HCPCS Level II code is not needed for Medicare claims adjudication.

An application must contain sufficient information and supporting documentation to support a claim of significant therapeutic distinction. CMS states applicants should provide the best available information to support their claim, including copies of all articles that support the claim as well as any unfavorable articles with appropriate rebuttal or explanation. Published or unpublished information from sources within the U.S. or elsewhere may be submitted. CMS is not proposing to require specific types of evidence but notes greater weight will be given to more methodologically rigorous and scientifically reliable evidence. CMS provides examples of unsubstantiated therapeutic distinction, including supporting information that does not include the actual product that is the subject of the code application.

ii. Proposed Evaluation Process for Drug or Biological Product Applications to Add A Code

The Medicare Part B claims payment system utilizes HCPCS Level II codes to pay for claims for drugs or biological products that are separately paid under Medicare.

*(a) Proposed Threshold Factor for Evaluating Drug or Biological Applications*

Consistent with current practice, CMS believes it is important to first consider whether the drug or biological product that is the subject of the application is appropriate for inclusion in the HCPCS Level II code set and whether Medicare has a claims processing need to identify the drug or biological product in the code set. CMS discusses the payment provisions for drugs or


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biological products under Medicare Part B as described in sections 1842(o) and1847(A) of the Act. Section 1847A of the Act and CMS' corresponding regulations and program instructions have created a claims processing need for using HCPCS Level II codes to report Part B drug or biological products where either CPT codes do not exist or are insufficiently precise to be used for Medicare claims processing.

CMS proposes at §414.10(e)(1) that it would first determine, as a threshold matter, if the drug or biological product is appropriate for inclusion in the HCPCS Level II code set by assessing whether:

i. The product is not appropriate for inclusion in or already coded in a different HIPPA standard medical data code set, such as CPT;
ii. The item of service is primarily medical in nature;
iii. If applicable, the item 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.

*(b) Proposed Process for Further Evaluating Drug or Biological Product Applications*

If CMS decides the subject drug or biological product is appropriate for inclusion in the HCPCS Level II code set, then it determines the appropriate coding action for the application. CMS can create a new code, revise a code descriptor of an existing code, or take no action because an existing code adequately describes the product. In making this determination, CMS considers applicable Medicare Part B statutory and regulatory payment requirements, program instructions, and information. Specifically, CMS proposes at §414.10(e)(2) to include the following information when making a determination: Sections 1842(o) and 1847A of the Act; 42 CFR part 414 Subparts J and K; program instructions implementing section 1847A of the Act; and information from the code application and other applicable sources such as FDA, drug compendia, the manufacturer and scientific literature.

CMS also proposes to evaluate each application to determine if the product is separately payable under Medicare Part B and whether the product is a single source or multiple source drug, biological, or biosimilar biological product (§414.10(e)(3)).

CMS describes a framework for its decision-making process on code applications for drug and biological products. To determine whether the product is separately payable under Medicare Part B, CMS will use the following:

- The active ingredient(s) and drug name(s) of the product and other potentially similar drug or biological products in existing HCPCS Level II codes.
- The product's labeling and description, including whether there are differences between the product and previously coded products; whether the product includes any additional ingredients when compared to previously coded products; and the indications for the product use.
- Prescribing information, setting-of-use and other information found in FDA-required prescription drug labeling. This information helps CMS understand where the product is used and whether the product is separately payable under Medicare Part B. For example, a product furnished exclusively in an inpatient hospital and paid exclusively under Part A does not need a HCPCS Level II code.


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Where the information is insufficient for CMS to determine if the product is separable payable under Medicare Part B, CMS will use the additional information discussed below to assist in making this determination.

As part of this framework. to determine whether the product if a single source or multiple source drug, biological product or biological product, CMS will use the following:

- FDA approval, including the date of approval and how FDA regulates the product (e.g. approved as a drug, biologic, or biosimilar biological product);
- Therapeutic equivalence ratings as provided in section 1847a(c)(6)(C), if applicable;
- Date of first sale in the U.S.;
- 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; and
- Packaging and labeling that indicates how the drug is supplied, including the How Supplied/Storage and Handling Section in prescribing information.

CMS notes that is the subject product 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. A revision of an existing code may be made, however, to include a new trade name in the descriptor, to better distinguish between other similar codes.

In addition, to further clarify the similarities and differences between the subject product and products described in existing codes, CMS will use the following:

- 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 such as pharmacokinetics, contraindications, warnings, drug interactions, and adverse reactions); and
- Billing information such as third-party payers that pay for the product; any codes that are used to bill third-party payers; and any existing policies for reporting the product to third-party payers.

CMS notes this information will also help it determine whether a new code is needed for Medicare claims processing.

CMS proposes to continue, when appropriate to use code descriptors with drug amounts that correspond to quantities of a product that are smaller than the product's package size or usual adult dose (§414.10(e)(5)). CMS notes that many older HCPCS Level II codes, particularly those effective before ASP-based payments, have code descriptors reflecting quantities that correspond to available package amounts. Many newer HCPCS Level II codes have code descriptors reflecting quantities that are less than the smallest available package size. CMS proposes to continue to use smaller quantities in the code descriptors for drug or biological products, as appropriate, to facilitate more accurate billing particularly for products dosed on the patient's weight, age, or other factors. CMS notes that improvements in billing accuracy by using smaller


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quantities in descriptors will also facilitate the accurate tracking of payments for discarded drugs[18] and when the discarded drug policy does not apply, minimize out of pocket costs for drugs that are not administered.

*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 any existing code if the applicant believes the existing HCPCS Level II code does not adequately describe the subject of the application and that a modification to the long descriptor language would provide a better description. CMS will consider whether this is a Medicare claims processing need for the requested revision.

CMS proposes its evaluation of an application would be based on information contained in the code application and supporting material, any comments received through the public process, any information obtained from and evaluations conducted by federal employees or CMS contractors, or any additional research or information that CMS independently obtains ((§414.10(c)). CMS may change the code based in whole, in part, or with modifications; or may deny the coding change request.

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

An application to discontinue an existing code may be submitted when the applicant believes an existing HCPCS Level II code is duplicative of another code or has become obsolete. In order to avoid premature removal of a code, CMS will continue its current process which first determines that the product described by the code is no longer marketed, and there does not appear to be an intent to market. This includes determining that the stock has been depleted and there is no expectation of the stock being refilled. CMS also considers the possibility of the same or similar product reappearing on the market at a later date by the same or a different manufacturer before discontinuing an existing code.

Consistent with other code evaluations, CMS proposes its evaluation of an application would be based on information contained in the code application and supporting material, any comments received through the public process, any information obtained from and evaluations conducted by federal employees or CMS contractors, or any additional research or information that CMS independently obtains ((§414.10(c)). CMS proposes to discontinue an existing code when it finds the code is duplicative or has become obsolete and it has no further expectation that the same or similar item or service will be marketed at a later date ((§414.10(g)).

[18] Information about payment for discarded drugs is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.


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## V. Benefit Category and Payment Determinations for DMEPOS

### A. Background

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. CMS makes 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. It reviews in this section how it makes BCDs and the statutory and regulatory definitions it uses.

To increase transparency and structure around the process for obtaining public consultation on benefit category and payment determinations for these items and services, CMS believes it would be beneficial to set forth in its 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.

### B. Provisions of the Proposed Regulation

CMS proposes to set forth in regulations BCD and payment determination procedures that permit public consultation at public meetings for new DME items and services as well as surgical dressings, splints, casts, and other devices; prosthetic devices; leg, arm, back, and neck braces (orthotics), and artificial legs, arms, and eyes (prosthetics); or therapeutic shoes and inserts. The payment rules for these items and services are located in 42 CFR part 414, subparts C and D, so it proposes to include these procedures under both subparts C and D. CMS also proposes 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 one of the above items.

This proposal generally reflects the procedures that have been used by CMS since 2005, however, CMS proposes 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. CMS also proposes 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), intraocular lenses (IOLs) inserted in a physician's office, or splints, casts, and other devices used for reduction of fractures and dislocations.

For the purpose of these proposed procedures and §414.114, CMS proposes 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. CMS proposes that the procedures for making BCDs and payment


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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.

CMS puts forth the following proposed procedures under new §414.240 for determining whether new items and services meet the Medicare definition of items and services subject to the payment rules at 42 CFR part 414 subpart D.

First, at the start of a HCPCS coding cycle, CMS would perform 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. CMS states that 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 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 would make a preliminary payment determination for the item or service. 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, CMS would post preliminary benefit category determinations and payment determinations on CMS.gov approximately 2 weeks prior to a public meeting described under §414.8(d). 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.

Fourth, 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 would establish the benefit category determinations and payment determinations for items and services through program instructions.

CMS states 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


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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.

**CMS seeks public comment on its 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.** It also notes that its proposed approach does not affect or change its existing process for developing National Coverage Determinations (NCDs) and it can continue to develop NCDs both in response to external requests and internally-generated reviews. It further notes that it is 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

### A. General Background

This section provides a historical review of how the DME benefit has evolved to provide context for classification and payment of CGMs. In brief, 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 3 years;
- 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 DME.

### B. Background on Continuous Glucose Monitors

Based on an administrative ruling (CMS-1682-R) published on January 12, 2017, CMS classified that only "therapeutic CGMs" (or nonadjunctive CGMs) met the definition of DME as these items for approved by FDA for use in place of a blood glucose monitor for making diabetes treatment decisions. These devices have been approved by FDA for use in making diabetic treatment decisions without verifying the CGM readings with readings from a blood glucose monitor. CMS classified CGMs as "adjunctive" or "non-therapeutic" if glucose levels and trends provided by the CGM must be verified by use of a blood glucose monitor. This administrative ruling also established fee schedule amounts for therapeutic CGMs – the receiver/monitor and its associated supplies. Adjunctive or non-therapeutic CGMs are not currently classified as DME.

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


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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.

**C. Current Issues**

In this proposed rule, CMS revisits 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. CMS determines all CGMs (adjunctive and non-adjunctive) would be considered DME and covered by CMS.

1. Requirements of DME Definition

a. Ability to Withstand Repeated Use

As discussed in CMS-1682-R, CMS indicates that 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. It is the component that performs the primary medical function of self-monitoring of glucose levels—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. CMS notes that the receiver for all CGM systems (both adjunctive and nonadjunctive) 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, CMS believes 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 (at least 3 years) in order to meet the definition of DME. CMS believes that the CGM receiver (the durable component of a multicomponent equipment) does meet the 3-year minimum lifetime requirement. CMS cites evidence from reliability analysis from one manufacturer, that predicted a lifetime of greater than 3 years for the CGM system receiver. Therefore, CMS believes 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

CMS proposes to change its determination with regard to whether adjunctive CGMs are primarily and customarily used to serve a medical purpose. It notes that its determination that devices like these are not primarily and customarily used to serve a medical purpose has been rejected by several U.S. district courts.


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CMS now believes 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.[19] 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 now proposes 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.

CMS notes that Medicare does not cover or provide payment for smartphones under the DME benefit. 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. A beneficiary can use a smartphone or other non-DME device to display their glucose readings in conjunction with the covered DME item but cannot use it exclusively.

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.

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


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

a. Fee Schedule Amounts for CGM Receivers/Monitors

CMS proposes 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. The same DMEPOS fee schedule amount would be paid for nonadjunctive and adjunctive CGM receiver/monitors. Proposed fee schedule amounts for CGM receivers would range from $208.76 to $245.59 (for class II) and $231.77 to $272.63 (for class III); to be updated by the 2021 update factor.

CMS indicates its belief that CGM receivers/monitors must be classified as routinely purchased since they are a technological refinement of glucose monitors routinely purchased from July 1986 through June 1987. It states that 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. CMS rationale is that CGM receivers/monitors are comparable to blood glucose monitors and thus the average reasonable charge data for blood glucose monitors from 1986 and 1987 can be used to establish the fee schedule amounts for them in accordance with its regulations at 42 CFR 414.238(b). It does 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.

b. Fee Schedule Amounts for CGM Supplies and Accessories

In brief, CMS proposes to separate payment for CGM supplies and accessories into three separate categories of supplies and accessories to account for variation in the type of supplies needed for the three types of CGMs on the market. In brief, the rates are as follows:

- Nonadjunctive CGM system monthly supplies: $222.77 (for class II) and $259.20 (for class III); to be updated by 2021 update factor.
- Adjunctive CGM system monthly supplies: $175.62 (for class II) and $198.77 (for class III); to be updated by the 2021 update factor. Nets out blood glucose monitor and supplies.
- Manual non-adjunctive CGM system monthly supplies: $46.86 (for class II) and $52.01(class III devices); to be updated by the 2021 update factor. More limited systems – supplies pay for disposable batteries and sensors.

As part of its rationale, CMS states that it does not believe that CGM 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. In contrast to its use of 1986/1987 average reasonable charges to establish fee schedule amounts for the receiver, it does not believe that the


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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.[20]

For this reason, CMS proposes to separate payment for CGM supplies and accessories into three separate categories of supplies and accessories with different fee schedule amounts for each category.

1. Non-adjunctive CGM system

CMS notes that the current fee schedule amounts for supplies and accessories for CGM systems apply to all types of class II or class III CGMs, respectively, but were initially established its administrative ruling (CMS-1682-R) 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). CMS proposes to continue using these fee schedule amounts for supplies and accessories for class II and class II non-adjunctive CGMs adjusted for the fee schedule update factors effective April 1, 2021. The 2021 fee schedule monthly supply amount for non-adjunctive CGM systems would be the 2020 rates of $222.77 (for class II) and $259.20 (for class III) updated by 2021 update factor.

2. Adjunctive CGM system

CMS proposes 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. CMS states that 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. CMS wants to avoid a situation where the beneficiary and program would pay twice for glucose monitoring supplies.

CMS calculates that the monthly cost of the blood glucose monitor and supplies that would be needed for beneficiaries with adjunctive CGM systems would be $34.35. This calculation is based on current Medicare coverage and payment for 135 test strips and lancets per month for insulin-treated beneficiaries using blood glucose monitors. It also includes a monthly supply of batteries, calibration solution and a lancet device plus a monthly allowance for the blood glucose monitor (assumes a 5-year lifetime).

CMS subtracts out the $34.35 monthly cost of the blood glucose monitor and supplies from the monthly cost of the supplies and accessories for class II and class II devices. CMS indicates that based on supplier invoices and other prices, it calculated a 2020 monthly price for supplies and accessories used with class II or class III adjunctive CGMs of $209.97 and $233.12 respectively

[20] For certain supply items, CMS used its gap-filling methodology to determine payment for these supplies. Under its gap-filling approach, CMS deflates the prices obtained from verifiable sources, such as commercial prices based on invoices, to the fee schedule base period (1986 or 1987), and then applies the covered item update factors (as specified in statute) to establish the current fee schedule amounts. The covered item update factors vary in certain years for class II and class III devices.


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(includes monthly cost of blood glucose monitor and supplies). CMS does not provide details on how it derived these numbers, and these amounts are lower than the monthly supply allowance provided for non-adjunctive CGM systems even before netting out the monthly allowance for blood glucose monitor and supplies.[21] Subtracting out the monthly cost of the blood glucose monitor and supplies from the monthly cost of supplies and accessories for class II and class III adjunctive devices results in the following:

- Class II adjunctive CGMs equals a net price of $175.62 ($209.97-$34.35=$175.62)
- Class III adjunctive CGMs equals a net price of $198.77 ($233.12-$34.35=$198.77)

Thus, CMS proposes 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.

3. Manual non-adjunctive CGM system

CMS proposes 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 manual non-adjunctive CGM systems. Rates would be updated by the 2021 update factor. This 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. CMS refers to this as a manual, non-adjunctive CGM system. This system only uses disposable batteries and sensors, and CMS indicates that it calculated these rates based on supplier prices for the supplies and accessories for this category of CGMs. It did not provide any additional details on these items and how the totals were calculated.

## 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. In light of the new benefit, CMS proposes 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. The drug 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.

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." In practice, CMS has interpreted this requirement as limiting coverable DME

[21] It is likely that CMS used lower invoice prices for certain supply items in applying its gap-filling methodology, such as sensors, when determining rates for adjunctive CGM systems.


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items to those items which can be used by a patient or caregiver in the home without the assistance of a healthcare professional. CMS proposes to interpret this requirement to be met for an external infusion pump if: (1) the 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.

CMS proposes 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.

**CMS welcome comments on these issues and in particular—**

- On its 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 its 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 increased access and choice for beneficiaries in need of home infusion drugs as an important component of moving towards increased value-based care; and

- On its 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; CMS welcomes input on alternative standards or factors DME MACs could use when making this determination.

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

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. CMS proposes to make


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conforming changes to its regulations at §414.402. It proposes 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. CMS is implementing the changes to the fee schedule amounts for these items through program instructions

## IX. Regulatory Impact Statement

CMS provides a detailed discussion of impacts by major provisions in the proposed rule, which are summarized below. It determined that its proposed regulations are not economically significant as defined as having an impact of $100 million or more in any 1-year.[22] We highlight areas where certain provisions had an impact on Medicare savings, impacted Medicare providers or suppliers, or Medicare beneficiaries.

### A. Detailed Discussion of Impacts by Major Provision

1. DMEPOS Fee Schedule Adjustments

CMS' Office of the Actuary determined that the proposed regulations would neither increase nor decrease spending from what is assumed in the FY 2021 President's Budget. CMS does seek comment, however, on its three alternatives to its proposal that would have fiscal impacts.

| Alternative Proposal | Impact on Medicare Savings |
|---|---|
| Pay full adjusted fee schedule rates in all areas except super rural areas or non-contiguous areas; pay 120 percent of the fully adjusted rates in super rural areas and non-contiguous areas | Estimates $2.4 billion in Medicare saving and $0.2 billion in Medicaid savings over 5 years. |
| Adjust fee schedule amounts for items and services furnished in non-CBAs between 2021 and 2023 based on 75/25 blend of adjusted and unadjusted rates and phase-in the full fee schedule adjustments beginning January 1, 2024. | Estimates $1.8 billion in Medicare savings and $0.1 billion in Medicaid savings over 5 years. |

[22] As defined in section 3(f) of Executive Order 12866


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| Alternative Proposal | Impact on Medicare Savings |
|---|---|
| Appy fee schedule adjustment transition rules for items and services furnished in non-CBAs and CBAs or former CBA for items and services "essentially removed" from Round 2021 of the CBP. | Estimates minimal impact as these rates are more in line with what OACT assumed would be spent as a result of Round 2021 of the CBP. |

Note: Each alternative assess savings against the FY 2021 President Budget baseline and assumes that the public health emergency ends by January 2021.

2. 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. Overall, CMS estimates that the fiscal impact of this proposal is a small savings to Medicare in 2021.

The impact on beneficiaries, however, could be more significant. If the beneficiary chooses to receive home infusion rather than infusion in an outpatient setting, 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.[23] 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 is patisiran. In 2019, 128 beneficiaries utilized this drug and total Medicare payments to facilities for furnishing this drug was roughly $26 million. If half of these patients shift settings, CMS estimates a Medicare savings of roughly $3 million in FY 2021 if this proposal is finalized – much of the savings is largely attributable to the differential in cost-sharing between the hospital outpatient setting and the home. For example, it estimates that a beneficiary using patisiran would have cost sharing of more than $70,000 per year in the home setting compared to about $24,000 in the hospital outpatient setting. CMS notes that many beneficiaries may have supplemental coverage, like Medigap insurance, from a third-party payer than mitigate this cost sharing and that infusion of these drugs would continue to be available in an outpatient setting.

**CMS seeks comment on information about other infusion drugs or biologicals that may be covered as supplies under the DME benefit if this proposal is finalized. It also seeks 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.**

3. Other Provisions

CMS determined that there was no determinable fiscal impact or no fiscal impact for the other provisions discussed in this section. Of note, CMS does not anticipate change in CGM utilization based on its proposal to classify all CGMs as DME.

[23] By statute, hospital outpatient cost-sharing is capped at the inpatient deductible, which is currently $1,408.


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**B. Regulatory Flexibility Analysis (RFA)**

CMS concludes that this proposed rule does not impose a significant impact on small entities or DMEPOS suppliers, and thus the RFA does not apply to this rule. CMS is seeking comments to aid in understanding the various industries that supply DMEPOS products. It has identified only two industries: pharmacies/drug stores and home health equipment rentals and within those industries almost all DMEPOS suppliers are small entities as defined for use in an RFA. **Given its uncertainty, CMS seeks comment on additional DMEPOS suppliers not accounted for in this rule.**

CMS does not believe that this proposed rule has a significant impact on a substantial number of small entities; on the operations of a substantial number of small rural hospitals; and no consequential effect on state, local, or tribal governments or on the private sector.

**C. Regulatory Review Cost Estimation**

CMS assesses the cost associated with regulatory review. CMS estimates that the total cost of reviewing this proposed rule is $360,750 ($550 x 650 reviewers). This assumes that reviewers spent 5 hours reviewing the proposed rule at a cost of $111.00 per hour, which uses Bureau of Labor Statistics wage information on medical and health service managers. It also assumes that the total number of reviewers of this proposed rule is 650 or about 2 percent of the 2018 number of DME suppliers. **CMS solicits comments on its assumptions.**


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