particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves safety zones to protect waterway users that would prohibit entry within 250 yards of dredging operations, within Marcus Hook Anchorage and will close only one side of the main navigation channel. It is categorically excluded from further review under paragraph L[60a] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T05–0022, to read as follows:

§ 165.T05–0022 Safety Zones, Delaware River Dredging; Marcus Hook, PA.

(a) *Location.* The following areas are safety zones:

(1) Safety zone one includes all waters within 250 yards of the dredge displaying lights and shapes for vessels restricted in ability to maneuver as described in 33 CFR 83.27, as well as all related dredge equipment, while the dredge is operating in Marcus Hook Range. For enforcement purposes Marcus Hook Range includes all navigable waters of the Delaware River shoreline to shoreline, bound by a line drawn perpendicular to the center line of the channel at the farthest upriver point of the range to a line drawn perpendicular to the center line of the channel at the farthest downriver point of the range.

(2) Safety zone two includes all the waters of Anchorage 7 off Marcus Hook Range, as described in 33 CFR 110.157(a)(8) and depicted on U. S. Nautical Chart 12312.

(b) *Definitions.* As used in this section, *designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to assist with enforcement of the safety zone described in paragraph (a) of this section.

(c) *Regulations.* (1) Entry into or transiting within the safety zone one is prohibited unless vessels obtain permission from the Captain of the Port via VHF–FM channel 16 or 215–271–4807, or make satisfactory passing arrangements via VHF–FM channel 13 or 16 with the operating dredge per this section and the rules of the Road (33 CFR subchapter E). Vessels requesting to transit shall contact the operating dredge via VHF–FM channel 13 or 16 at least 1 hour prior to arrival.

(2) Vessels desiring to anchor in safety zone two, Anchorage 7 off Marcus Hook Range, must obtain permission from the COTP at least 24 hours in advance by calling (215) 271–4807. The COTP will permit, at minimum, one vessel at a time to anchor on a ''first-come, first-served'' basis. Vessels will only be allowed to anchor for a 12 hour period. Vessels that require an examination by the Public Health Service, Customs, or Immigration authorities will be directed to an anchorage for the required inspection by the COTP.

(3) Vessels desiring to anchor in safety zone two, Anchorage 7 off Marcus Hook Range, must be at least 650 feet in length overall.

(4) This section applies to all vessels except those engaged in the following operations: Enforcement of laws, service of aids to navigation, and emergency response.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by federal, state and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement period.* This rule will be enforced from January 6, 2022, through January 31, 2022, unless cancelled earlier by the Captain of the Port.

Dated: January 6, 2022.

Jonathan D. Theel,

Captain, U. S. Coast Guard, Captain of the Port, Delaware Bay.

[FR Doc. 2022–00560 Filed 1–12–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[CMS–6081–N]

Medicare Program; Updates to Lists Related to Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Conditions of Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Updates to and selection of certain codes.

SUMMARY: This document announces the updated Healthcare Common Procedure Coding System (HCPCS) codes on the Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements. It also announces the initial selection of HCPCS codes on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and the updates the HCPCS codes on the Required Prior Authorization List.

DATES: The implementation is effective on April 13, 2022. Prior authorization will be implemented in 3 incremental phases, with the final phase being national implementation. Phase 1 includes 1 state per jurisdiction and is effective April 13, 2022, Phase 2 includes 4 States per jurisdiction and is effective July 12, 2022, and Phase 3 is nationwide and is effective October 10, 2022.

FOR FURTHER INFORMATION CONTACT: Susan Billet, (410) 786–1062.

Emily Calvert, (410) 786–4277.
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SUPPLEMENTARY INFORMATION:

I. Background

Sections 1832, 1834, and 1861 of the Social Security Act (the Act) establishes benefits and the provisions of payment for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items under Part B of the Medicare program.

Section 1834(a)(1)(E)(iv) of the Act provides conditions of coverage specific to Power Mobility Devices (PMDs). Specifically, it provides that payment may not be made for a covered item consisting of a motorized or power wheelchair unless a physician (as defined in section 1861(r)(1) of the Act), physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) (as such non-physician practitioners are defined in section 1861(aa)(5) of the Act) has conducted a face-to-face examination of the individual and written a prescription for the item.

Section 1834(a)(11)(B) of the Act requires a physician, PA, NP, or CNS to have a face-to-face encounter with the beneficiary within the 6-month period prior to the written order for certain DMEPOS items (or other reasonable timeframe as determined by the Secretary of the Department of Health and Human Services (the Secretary)).

Section 1834(a)(15)(A) of the Act authorizes the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items.

In 2006, we issued Final Rule ''Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles'' (71 FR 17021) to implement the requirements for a face-to-face examination and written order prior to delivery for PMDs, in accordance with legislation found in section 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), as codified in amended section 1834(a)(1)(E)(iv) of the Act. This regulation applied to all power mobility devices—including power wheelchairs and power operated vehicles (hereinafter referred to as PMDs). The requirements for PMDs mandated a 7-element order/prescription for payment.

In the November 16, 2012 **Federal Register**, we published final rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013'' (77 FR 68892) requiring face-to-face encounter and written order prior to delivery for specified DMEPOS items, in accordance with the authorizing legislation found section 6407 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and amended section 1834(a)(11)(B) of the Act. The regulation, as codified in 42 CFR 410.38, specified the inclusion criteria for creating a list of DMEPOS items to be subject to face-to-face encounter and written order prior to delivery requirements. It also mandated a 5-element order/prescription for payment of specified DMEPOS items.

In the December 30, 2015 **Federal Register**, we published final rule titled ''Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, and Supplies'' (80 FR 81674), in accordance with section 1834(a)(15) of the Act, we established the Master List of Items Frequently Subject to Unnecessary Utilization. The 2015 Master List included certain DMEPOS items that the Secretary determined, on the basis of prior payment experience, are frequently subject to unnecessary utilization, and created a prior authorization process for these items.

On November 8, 2019, we published a final rule titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements'' (84 FR 60648). The rule became effective January 1, 2020, harmonizing the lists of DMEPOS items created by former rules and establishing one ''Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements'' (the ''Master List''). Items are selected from the Master List for inclusion on the Face-To-Face Encounter and Written Orders Prior to Delivery List and/or Prior Authorization List through the **Federal Register**.

II. Provisions of the Document

This document serves to publish three separate lists. First, it provides an update to the Master List of items from which we can select to include on the Required Face to Face Encounter and Written Order Prior to Delivery List, and/or Required Prior Authorization List. This document also serves to announce the initial selection of items to be included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List. Lastly, it updates the items included on the Required Prior Authorization List.

A. Master List of DMEPOS Items Frequently Subject to Unnecessary Utilization

The Master List includes items that appear on the DMEPOS Fee Schedule and meet the following criteria, as established in 84 FR 60648:

- Have an average purchase fee of $500 or greater that is adjusted annually for inflation, or an average monthly rental fee schedule of $50 or greater that is adjusted annually for inflation, or items identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a recent 12-month period, that are also—

++ Identified in a Government Accountability Office (GAO) or Department of Health and Human Services Office of Inspector General (OIG) report that is national in scope and published in 2015 or later as having a high rate of fraud or unnecessary utilization; or

++ Listed in the 2018 or subsequent year Comprehensive Error Rate Testing (CERT) program's Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data Report as having a high improper payment rate.

- Any items with at least 1,000 claims and $1 million in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies that may require time for providers and suppliers to be educated on billing policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months by the greater of—

++ Double the percent change of all DMEPOS claim payments for items that meet the previous claim and payment

criteria, from the preceding 12-month period; or

++ Exceeding a 30 percent increase in payments for the items from the preceding 12-month period.

• Any items statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

In the November 2019 final rule noted previously, we described the maintenance process of the Master List as follows:

• The Master List will be updated annually, and more frequently as needed (for example, to address emerging billing trends), and to reflect the thresholds specified in the regulations.

• Items on the DMEPOS Fee Schedule that meet the payment threshold criteria set forth in § 414.234(b)(1) are added to the list when the item is also listed in a CERT, OIG, or GAO report published after 2020, and items not meeting the cost (approximately $500 purchase or $50 rental) thresholds may still be added based on findings of aberrant billing patterns.

• Items are removed from the Master List 10 years after the date the item was added, unless the item was identified in an OIG report, GAO report, or having been identified in the CERT Medicare Fee for Service Supplemental Improper Payment Data report as having a high improper payment rate, within the 5-year period preceding the anticipated date of expiration.

• Items are removed from the list sooner than 10 years if the purchase amount drops below the payment threshold.

• Items already on the Master List that are identified on a subsequent OIG, GAO, or CERT report will remain on the list for 10 years from the publication date of the new report.

• Items are updated on the Master List when the Healthcare Common Procedure Coding System (HCPCS) codes representing an item have been discontinued and cross-walked to an equivalent item.

• We will notify the public of any additions and deletions from the Master List by posting a notification in the **Federal Register** and on the CMS Prior Authorization website at *https://www.cms.gov/research-statistics-data-systems/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives*.

This document provides the annual update to the Master List of DMEPOS Items Potentially Subjected to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements stated in the November 2019 final rule (84 FR 60648). As noted previously, we adjust the ''payment threshold'' each year for inflation. Certain DMEPOS fee schedule amounts are updated for 2021 [1] by the percentage increase in the consumer price index for all urban consumers (United States city average) CPI–U for the 12-month period ending June 30, 2020, adjusted by the change in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private non-farm business multi-factor productivity (MFP). The productivity adjustment is 0.4 percent and the CPI–U percentage increase is 0.6 percent. Thus, the 0.6 percentage increase in the CPI–U is reduced by the 0.4 percentage increase in the MFP resulting in a net increase of 0.2 percent for the update factor for CY 2021.

For CY 2021, the 0.2 percent update factor was applied to the CY 2020 average price threshold of $500, resulting in a CY 2021 adjusted payment threshold of $501 ($500 × 1.002). This results in a CY 2021 adjusted purchase price threshold of $501. An update factor of 0.2 percent was applied to the CY 2020 average monthly rental fee of $50, resulting in an adjusted payment threshold of $50.10 ($50 × 1.002). Rounding this figure to the nearest whole dollar amount results in a CY 2021 adjusted monthly rental fee threshold of $50.

A total of 31 HCPCS codes (see Table 1) meeting the criteria outlined previously are added to the Master List. Of these 31 HCPCS codes, 18 are added because these items meet the updated payment threshold and are listed in an OIG or GAO report of a national scope or a CERT DME and DMEPOS Service Specific Report(s) or both, and 13 are added for being identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a recent 12-month period.

TABLE 1—ADDITIONS TO THE MASTER LIST

HCPCS	Description
A4352	Intermittent Urinary Catheter; Coude (Curved) Tip, With Or Without Coating (Teflon, Silicone, Silicone Elastomeric, Or Hydrophilic, Etc.), Each.
A5121	Skin Barrier; Solid, 6 x 6 Or Equivalent, Each.
A6203	Composite Dressing, Sterile, Pad Size 16 Sq. In. Or Less, With Any Size Adhesive Border, Each Dressing.
A6219	Gauze, Non-Impregnated, Sterile, Pad Size 16 Sq. In. Or Less, With Any Size Adhesive Border, Each Dressing.
A6242	Hydrogel Dressing, Wound Cover, Sterile, Pad Size 16 Sq. In. Or Less, Without Adhesive Border, Each Dressing.
A7030	Full Face Mask Used With Positive Airway Pressure Device, Each.
A7031	Face Mask Interface, Replacement For Full Face Mask, Each.
E0467	Home Ventilator, Multi-Function Respiratory Device, Also Performs Any Or All Of The Additional Functions Of Oxygen Concentration, Drug Nebulization, Aspiration, And Cough Stimulation, Includes All Accessories, Components And Supplies For All Functions.
E0565	Compressor, Air Power Source For Equipment Which Is Not Self-Contained Or Cylinder Driven.
E0650	Pneumatic Compressor, Non-Segmental Home Model.
E0651	Pneumatic Compressor, Segmental Home Model Without Calibrated Gradient Pressure.
E0652	Pneumatic Compressor, Segmental Home Model With Calibrated Gradient Pressure.
E0656	Segmental Pneumatic Appliance For Use With Pneumatic Compressor, Trunk.
E0657	Segmental Pneumatic Appliance For Use With Pneumatic Compressor, Chest.
E0670	Segmental Pneumatic Appliance For Use With Pneumatic Compressor, Integrated, 2 Full Legs And Trunk.
E0675	Pneumatic Compression Device, High Pressure, Rapid Inflation/Deflation Cycle, For Arterial Insufficiency (Unilateral Or Bilateral System).
E0740	Non-Implanted Pelvic Floor Electrical Stimulator, Complete System.
E0744	Neuromuscular Stimulator For Scoliosis.
E0745	Neuromuscular Stimulator, Electronic Shock Unit.
E0764	Functional Neuromuscular Stimulation, Transcutaneous Stimulation Of Sequential Muscle Groups Of Ambulation With Computer Control, Used For Walking By Spinal Cord Injured, Entire System, After Completion Of Training Program.
E0766	Electrical Stimulation Device Used For Cancer Treatment, Includes All Accessories, Any Type.
E1226	Wheelchair Accessory, Manual Fully Reclining Back, (Recline Greater Than 80 Degrees), Each.
E2202	Manual Wheelchair Accessory, Nonstandard Seat Frame Width, 24–27 Inches.
E2203	Manual Wheelchair Accessory, Nonstandard Seat Frame Depth, 20 To Less Than 22 Inches.
E2613	Positioning Wheelchair Back Cushion, Posterior, Width Less Than 22 Inches, Any Height, Including Any Type Mounting Hardware.

[1] CY 2021 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule (December 4, 2020): *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10504cp.*

TABLE 1—ADDITIONS TO THE MASTER LIST—Continued

HCPCS	Description
L0830	Halo Procedure, Cervical Halo Incorporated Into Milwaukee Type Orthosis.
L1005	Tension Based Scoliosis Orthosis And Accessory Pads, Includes Fitting And Adjustment.
L1906	Ankle Foot Orthosis, Multiligamentous Ankle Support, Prefabricated, Off-The-Shelf.
L2580	Addition To Lower Extremity, Pelvic Control, Pelvic Sling.
L2624	Addition To Lower Extremity, Pelvic Control, Hip Joint, Adjustable Flexion, Extension, Abduction Control, Each.
L7368	Lithium Ion Battery Charger, Replacement Only.

The following five HCPCS codes (see Table 2) are removed from the Master List because they no longer have a DMEPOS Fee Schedule price of $501 or greater, or an average monthly rental fee schedule of $50 or greater, and are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a recent 12-month period or both.

TABLE 2—DELETIONS FROM THE MASTER LIST

HCPCS	Description
A4253	Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, Per 50 Strips.
A4351	Intermittent Urinary Catheter; Straight Tip, With or Without Coating (Teflon, Silicone, Silicone Elastomer, Or Hydrophilic, Etc.), Each.
E2369	Power Wheelchair Component, Drive Wheel Gear Box, Replacement Only.
E2377	Power Wheelchair Accessory, Expandable Controller, Including All Related Electronics and Mounting Hardware, Upgrade Provided At Initial Issue.
L3761	Elbow Orthosis (Eo), With Adjustable Position Locking Joint(S), Prefabricated, Off-The-Shelf.

The full updated list is available in the download section of the following CMS website: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Prior-Authorization-Process-for-Certain-Durable-Medical-Equipment-Prosthetic-Orthotics-Supplies-Items.*

B. Items Subject to Face-to-Face Encounter and Written Order Prior to Delivery Requirements

In the November 2019 final rule, we stated that since the face-to-face encounter and written orders are statutorily required for PMDs, they would be included on the Master List and the Required Face-to-Face Encounter and Written Order Prior to Delivery List in accordance with our statutory obligation, and would remain there.

The Required Face-to-Face Encounter and Written Order Prior to Delivery List, as specified in § 410.38(c)(8), is comprised of PMDs and those items selected from the Master List (as described in § 414.234(b)) to require a face-to-face encounter and a written order prior to delivery as a condition of payment.

The rule established a process of placing items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, including that they be communicated to the public and effective no less than 60 days after a **Federal Register** document publication and CMS website posting.

We note that following the publication of the November 2019 final rule (84 FR 60648), the serious public health threats posed by the spread of the 2019 Novel Coronavirus (COVID–19) became known, and subsequently the addition of new items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List was placed on hold.

We also note that in an interim final rule with comment period titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' and published on April 6, 2020 (84 FR 19230), we stated that ''to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements would not apply during the PHE for the COVID–19 pandemic.'' This language does not apply to the face-to-face encounter and written order prior to delivery requirements stemming from 42 CFR 410.38 and section 1834 of the Act; therefore, the ongoing direction provided in the April 2020 rule is not affected by this document. The list of DMEPOS items selected and promulgated in this document will require a face-to-face encounter (conducted either via telehealth or in-person), per 42 CFR 410.38, effective after 90 days' notice.

At this time, we believe it appropriate to add a limited list of items that pose a risk to the Medicare Trust Funds, to be subject to additional practitioner oversight via the face-to-face encounter and written order prior to delivery requirements.

To assist stakeholders in preparing for implementation of the Required Face-to-Face Encounter and Written Order Prior to Delivery List, we are publishing the proposed code additions and providing 90 days' notice.

Per statutory requirements, Table 3 lists DMEPOS HCPCS codes for PMDs. Section 1834(a)(1)(E)(iv) of the Act explicitly requires a face-to-face and written order for PMDs; therefore, PMDs require a face-to-face encounter per statute. To reflect this, PMDs will both be placed and will remain on the Required Face-to-Face Encounter and Written Order Prior to Delivery List indefinitely.

Section 1834(a)(11)(B) of the Act authorizes the Secretary to select other DMEPOS HCPCS codes that will require a face-to-face encounter and written order prior to delivery as a condition of payment. In addition to PMDs, this **Federal Register** document announces the addition of seven other DMEPOS HCPCS codes, not required by statute, that are selected from the Master List to be placed on the Required Face-to-Face Encounter and Written Order Prior to Delivery List as listed in Table 4, based on our regulatory authority at 42 CFR 410.38.

TABLE 3—STATUTORILY REQUIRED POWER MOBILITY DEVICES

HCPCS	Description
K0800	Power Operated Vehicle, Group 1 Standard, Patient Weight Capacity Up To And Including 300 Pounds.
K0801	Power Operated Vehicle, Group 1 Heavy Duty, Patient Weight Capacity, 301 To 450 Pounds.
K0802	Power Operated Vehicle, Group 1 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds.
K0806	Power Operated Vehicle, Group 2 Standard, Patient Weight Capacity Up To And Including 300 Pounds.
K0807	Power Operated Vehicle, Group 2 Heavy Duty, Patient Weight Capacity 301 To 450 Pounds.
K0808	Power Operated Vehicle, Group 2 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds.
K0813	Power Wheelchair, Group 1 Standard, Portable, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0814	Power Wheelchair, Group 1 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0815	Power Wheelchair, Group 1 Standard, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0816	Power Wheelchair, Group 1 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0820	Power Wheelchair, Group 2 Standard, Portable, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0821	Power Wheelchair, Group 2 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0822	Power Wheelchair, Group 2 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0823	Power Wheelchair, Group 2 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0824	Power Wheelchair, Group 2 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0825	Power Wheelchair, Group 2 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0826	Power Wheelchair, Group 2 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0827	Power Wheelchair, Group 2 Very Heavy Duty, Captains Chair, Patient Weight Capacity 451 To 600 Pounds.
K0828	Power Wheelchair, Group 2 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.
K0829	Power Wheelchair, Group 2 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More.
K0835	Power Wheelchair, Group 2 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0836	Power Wheelchair, Group 2 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0837	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0838	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0839	Power Wheelchair, Group 2 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0840	Power Wheelchair, Group 2 Extra Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.
K0841	Power Wheelchair, Group 2 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0842	Power Wheelchair, Group 2 Standard, Multiple Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0843	Power Wheelchair, Group 2 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0848	Power Wheelchair, Group 3 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0849	Power Wheelchair, Group 3 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0850	Power Wheelchair, Group 3 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0851	Power Wheelchair, Group 3 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0852	Power Wheelchair, Group 3 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0853	Power Wheelchair, Group 3 Very Heavy Duty, Captains Chair, Patient Weight Capacity, 451 To 600 Pounds.
K0854	Power Wheelchair, Group 3 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.
K0855	Power Wheelchair, Group 3 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More.
K0856	Power Wheelchair, Group 3 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0857	Power Wheelchair, Group 3 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds.
K0858	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0859	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds.
K0860	Power Wheelchair, Group 3 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0861	Power Wheelchair, Group 3 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds.
K0862	Power Wheelchair, Group 3 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds.
K0863	Power Wheelchair, Group 3 Very Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds.
K0864	Power Wheelchair, Group 3 Extra Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More.

TABLE 4—NON-STATUTORILY REQUIRED DMEPOS ITEMS

HCPCS	Description
E0748	Osteogenesis Stimulator, Electrical, Non-Invasive, Spinal Applications.
L0648	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T–9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf.
L0650	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T–9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf.
L1832	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L1833	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated, Off-The Shelf.
L1851	Knee Orthosis (KO), Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf.
L3960	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Airplane Design, Prefabricated, Includes Fitting And Adjustment.

As previously stated, PMDs are included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List per statutory obligation. For the other DMEPOS items, we considered factors such as operational limitations, item utilization, acute needs, pandemic impacts, cost-benefit analysis (for example, comparing the cost of review versus the anticipated amount of improper payment identified), emerging trends (for example, billing patterns, medical review findings), vulnerabilities identified in official agency reports, or other analysis.

In selecting these items, we must balance our program integrity goals with the needs of patients, particularly those in need of medical devices to assist with functional activities and ambulation within their home. In other words, we must ensure the appropriate application and oversight of the face-to-face encounter requirements. In consideration of access issues, we note that the regulation 42 CFR 410.38 allows

for use of telehealth, as defined in 42 CFR 410.78 and 414.65, when appropriate to meet our coverage requirements for beneficiaries.

We also believe transparency and education will aid in compliance with these payment requirements and continued access. As such, we will make information widely available to the public at appropriate literacy levels regarding face-to-face encounter requirements, prior authorization, and necessary documentation for items on Required Face-to-Face Encounter and Written Order Prior to Delivery and Prior Authorization Lists.

We believe additional practitioner oversight of beneficiaries in need of items represented by these HCPCS codes will help further our program integrity goals of reducing fraud, waste, and abuse. It will also help ensure beneficiary receipt of items specific to their medical needs. For items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List (Tables 3 and 4), the written order/prescription must be communicated to the supplier prior to delivery. For such items, we require the treating practitioner to have a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription. If the face-to-face encounter is a telehealth encounter, the requirements of 42 CFR 410.78 and 414.65 must be met for DMEPOS coverage purposes.

Consistent with § 410.38(d), the face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS item(s) is ordered. Upon request by CMS or its review contractors, a supplier must submit additional documentation to support and substantiate the medical necessity for the DMEPOS item or both.

The Required Face-to-Face Encounter and Written Order Prior to Delivery List is available on the following CMS website: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.*

C. Items Subject to Prior Authorization Requirements

The November 8, 2019 final rule (84 FR 60648) maintained the process established in the December 30, 2015 final rule (80 FR 81674) that when items are placed on the Required Prior Authorization List, we would inform the public of those DMEPOS items on the Required Prior Authorization List in the **Federal Register** with no less than 60 days' notice before implementation, and post notification on the CMS website.

The Required Prior Authorization List specified in § 414.234(c)(1) is selected from the Master List (as described in § 414.234(b)), and those selected items require prior authorization as a condition of payment. Additionally, § 414.234 (c)(1)(ii) states that CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region.

The purpose of this document is to inform the public that we are updating the Required Prior Authorization List to include six additional Power Mobility Devices (PMDs) and five additional Orthoses HCPCS codes. To assist stakeholders in preparing for implementation of the prior authorization program, we are providing 90 days' notice.

The following six HCPCS codes for PMDs and five HCPCS codes for Orthoses are added to the Required Prior Authorization List:

TABLE 5—ADDITIONS TO THE REQUIRED PRIOR AUTHORIZATION LIST

HCPCS	Description
K0800	Power operated vehicle, group 1 standard, patient weight capacity up to and including 300 pounds.
K0801	Power Operated Vehicle, Group 1 Heavy Duty, Patient Weight Capacity, 301 To 450 Pounds.
K0802	Power Operated Vehicle, Group 1 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds.
K0806	Power Operated Vehicle, Group 2 Standard, Patient Weight Capacity Up To And Including 300 Pounds.
K0807	Power Operated Vehicle, Group 2 Heavy Duty, Patient Weight Capacity 301 To 450 Pounds.
K0808	Power Operated Vehicle, Group 2 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds.
L0648	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T–9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf.
L0650	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T–9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf.
L1832	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise.
L1833	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated, Off-The Shelf.
L1851	Knee Orthosis (Ko), Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf.

We believe prior authorization of these six additional HCPCS codes for PMDs and five HCPCS codes for Orthoses will help further our program integrity goals of reducing fraud, waste, and abuse, while also protecting access to care. For PMDs, the OIG has previously reported that Medicare has inappropriately paid for items that did not meet certain Medicare requirements.[2] Lower limb orthoses (LLO) and lumbar-sacral orthoses (LSO) have been identified by CMS' Comprehensive Error Rate Testing (CERT) program as two of the top 20 DMEPOS service types with improper payments over the past several years. Since 2016, LLOs have had an improper payment rate above 60 percent, with projected improper payments ranging between $235 and $501 million. Similarly, LSOs have had an improper payment rate above 32 percent, with projected improper payments ranging between $116 and $177 million, since 2016. Additionally, in 2019, the Department of Justice (DOJ) announced

[2] OIG Report A–09–12–02068—Medicare Paid Suppliers For Power Mobility Device Claims That Did Not Meet Federal Requirements For Physicians' Face-To-Face Examinations Of Beneficiaries (January 2015): *https://oig.hhs.gov/oas/reports/region9/91202068.pdf.*

federal indictments and law enforcement actions stemming from fraudulent claims submitted for medically unnecessary back, shoulder, wrist, and knee braces. Administrative actions were taken against 130 DMEPOS companies that were enticing Medicare beneficiaries with offers of low or no-cost orthotic braces. The investigation found that some DME companies and licensed medical professionals allegedly participated in health care fraud schemes involving more than $1.2 billion in loss.[3]

These codes will be subject to the requirements of the prior authorization program for certain DMEPOS items as outlined in § 414.234. We will implement a prior authorization program for the six newly added codes for PMDs nationwide and five newly added codes for Orthoses in 3 phases. This phased-in approach will allow us to identify and resolve any unforeseen issues by using a smaller claim volume in phase one before implementing phases 2 and 3. State selection for the three phases was completed based on utilization data for the items selected.

- For phase 1, which begins on the date specified in the **DATES** section, we selected the State in each DME MAC jurisdiction with the highest utilization: New York, Illinois, Florida, and California.
- For phase 2, which begins on the date specified in the **DATES** section of this document, we selected the next three States with the highest utilization in each DME MAC jurisdiction: Maryland, Pennsylvania, New Jersey, Michigan, Ohio, Kentucky, Texas, North Carolina, Georgia, Missouri, Arizona, and Washington.
- For phase 3, which begins on the date specified in the **DATES** section of this document, prior authorization expands to all remaining States and territories not captured in phases 1 and 2.

The prior authorization program for the 51 codes currently subject to the DMEPOS prior authorization requirement will continue uninterrupted.

Prior to providing an item on the Required Prior Authorization List to the beneficiary and submitting the claim for processing, a requester must submit a prior authorization request. The request must include evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Consistent with § 414.234(d), such evidence must include the written order/prescription, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request.

We will issue specific prior authorization guidance for these additional items in subregulatory communications, including final timelines customized for the DMEPOS item subject to prior authorization, for communicating a provisionally affirmed or non-affirmed decision to the requester. In the December 30, 2015 final rule (80 FR 81674) we stated that this approach to final timelines provides flexibility to develop a process that involves fewer days, as may be appropriate, and allows us to safeguard beneficiary access to care. If at any time we become aware that the prior authorization process is creating barriers to care, we can suspend the program. For example, we will review questions and complaints from consumers and providers that come through regular sources such as 1–800–Medicare.

The updated Required Prior Authorization List is available in the download section of the following CMS website: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Downloads/DMEPOS_PA_Required-Prior-Authorization-List.pdf.*

III. Collection of Information Requirements

This document provides updates to the Master List and announces the selection of HCPCS codes to be placed on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and Required Prior Authorization List.

Additionally, this document announces the continuation of prior authorization for 51 HCPCS codes, and the addition of six HCPCS codes for PMDs and five HCPCS codes for Orthoses on the Required Prior Authorization List. There is an information collection burden associated with this program that is currently approved under OMB control number 0938–1293, which expires March 31, 2022. This package accounts for burdens associated with the addition of items to the Required Prior Authorization Lists and assumes a burden for 2021 of approximately $10 million for providers to comply with the required information collection. We will reassess this burden soon and will seek comment on our assessment in a **Federal Register** notice as required under the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

We have examined the impact of this regulatory document as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). This regulatory document is not significant and does not reach the economic threshold and thus is not considered a major regulatory document. Per our analysis, the additional items being added to the prior authorization program (excluding PMDs)[4] have an estimated net savings of $14.8 million. Gross savings is based upon a 10 percent reduction in the total amount paid for claims in Calendar Year 2019. We deducted from the gross savings the anticipated cost for performing the prior authorization reviews in order to estimate the net savings. Our gross savings estimate of 10 percent is based on previous results from other prior authorization programs,

[3] Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for Over $1.2 Billion in Losses (April 9, 2019): *https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.*

[4] The additional PMD codes that will be added were not included in the data analysis because PMD codes are already part of a successful prior authorization program. Since some PMDs are already subject to prior authorization, other PMDs may demonstrate billing shifts across the policy groups, and as such, savings are more difficult to accurately forecast and may be less identifiable.

including prior authorization of other DMEPOS items.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this regulatory document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this regulatory document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This regulatory document will have no consequential effect on State, local, or tribal governments or on the private sector.

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

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

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: January 10, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–00572 Filed 1–12–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, and 512

Office of the Secretary

45 CFR Part 180

[CMS–1753–CN]

RIN 0938–AU43

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period; correction.

SUMMARY: This document corrects technical errors in the final rule with comment period that appeared in the **Federal Register** on November 16, 2021, titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model.''

DATES:

Effective date: Effective January 13, 2022.

Applicability date: The corrections in this correcting document are applicable beginning January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at (410) 786–4617.

SUPPLEMENTARY INFORMATION:

I. Background

In the final rule with comment period that appeared in the November 16, 2021, **Federal Register** (86 FR 63458) titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model'' (hereinafter referred to as the CY 2022 OPPS/ASC final rule with comment period), there were a number of technical and typographical errors that are identified and corrected in this correcting document. The provisions in this correction document are effective as if they had been included in the document that appeared in the November 16, 2021 **Federal Register**. Accordingly, the corrections are effective January 1, 2022.

II. Summary of Errors

A. Summary of Errors in the Preamble

1. Hospital Outpatient Prospective Payment System (OPPS) Corrections

On page 63463, use of incorrect wage index assignments for community mental health centers (CMHCs) resulted in an inaccurate payment impact estimate. We stated that ''we estimate a 1.1 percent increase in CY 2022 payments to CMHCs relative to their CY 2021 payments.'' We are correcting our estimate of the increase in payments for CMHCs from ''1.1 percent'' to ''1.6 percent''.

On page 63490, we noted that one commenter, a hospital association, supported CMS's proposal to continue to unpackage Omidria in the ASC setting. However, there were several commenters, including several hospital associations, that expressed broad support for CMS's proposal to unpackage and pay separately for non-opioid pain management drugs that function as surgical supplies, including the drug Omidria. We are correcting the text to acknowledge the additional commenters.

On page 63497, the table number for the table included on this page was inadvertently omitted from the table's title. Therefore, we are adding the number ''4'' to the table's title.

On page 63543 and 63544, we listed the incorrect APC assignment for CPT codes 66989 and 66991. We are correcting the APC assignment for these codes from APC 1526 to APC 1563.

On page 63548, second column, under section ''6. Calculus Aspiration With Lithotripsy Procedure (APC 5376)'' of the APC-Specific section, we are correcting the long descriptor for