DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[CMS–6095–N]

Medicare Program; Updates to the Master List of Items Potentially Subject to Face-to-Face Encounter and Written Order Prior To Delivery and/or Prior Authorization Requirements; Updates to the Required Face-to-Face and Written Order Prior To Delivery List; and Updates to the Required Prior Authorization List

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

ACTION: Updates to the Master List of Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements (the ''Master List'') and updates to the Required Face-to-Face and Written Order Prior to Delivery List and the Required Prior Authorization List.

SUMMARY: This document announces the updated Healthcare Common Procedure Coding System (HCPCS) codes on the Master List. It also announces updates to the HCPCS codes on the Required Face-to-Face and Written Order Prior to Delivery List and the Required Prior Authorization List.

DATES: Implementation of updates to the Master List and the Required Face-to-Face and Written Order Prior to Delivery List are effective on August 12, 2024. Required prior authorization of newly added lumbar-sacral orthoses and lower limb orthoses is effective nationwide on August 12, 2024. Prior authorization of newly added osteogenesis stimulators will be implemented in two phases, with phase 1 including one State per Durable Medical Equipment Medicare Administrative Contractor (DME MAC) jurisdiction on August 12, 2024. The States included in phase 1 are California, Florida, Ohio, and Pennsylvania. Phase 2 will include all remaining U.S. States and territories not included in phase 1, effective on November 12, 2024.

FOR FURTHER INFORMATION CONTACT:

For information related to the Master List or Required Prior Authorization List, contact Susan Billet, (410) 786–1062; Emily Calvert, (410) 786–4277; Justin Carlisle, (410) 786–4265; Stephanie Collins, (410) 786–0959; or Jessica Martindale, (410) 786–1558.

For information related to the Required Face-to-Face Encounter and Written Order Prior to Delivery List, contact Jennifer Phillips, (410) 786–1023; Misty Whitaker, (410) 786–4975; Olufemi Shodeke, (410) 786–1649; or Cristine Egan, (410) 786–8088.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 2019, the Centers for Medicare & Medicaid Services (CMS) 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'' (the November 2019 final rule) (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'').

The Master List serves as a library of items, that have been identified as potential vulnerabilities to the Trust Fund based on criteria outlined in 42 CFR 414.234(b), from which items may be selected to be placed on either the Required Face-to-Face Encounter and Written Orders Prior to Delivery List (the ''F2F/WOPD List'') and/or Required Prior Authorization List under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act. Only those items that are selected and announced via **Federal Register** notice are subject to such regulatory conditions of payment. The November 2019 final rule provided that the **Federal Register** notice would be for a period of no less than 60 days. It also clarified that certain items (that is, power mobility devices) require a face-to-face encounter per statute and would remain on both the Master List and the F2F/WOPD List, indefinitely.

The November 2019 final rule information related to face-to-face encounters, written orders prior to delivery, and 5-element order/prescription for specified DMEPOS items was codified in 42 CFR 410.38. The information in the November 2019 final rule related to the creation and maintenance of the Master List is codified at 42 CFR 414.234. The November 2019 final rule also includes information related to the prior authorization process, as initially outlined in the December 30, 2015 final rule titled ''Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, and Supplies'' (80 FR 81674).

The Master List was last updated in 2022 and currently includes 439 items.

In 2022 and 2023, CMS published the first and second iterations of the Required Face-to-Face Encounter and Written Orders Prior to Delivery List, respectively. There are currently 63 items on the list, including 46 power mobility devices that were included per statute.

The Required Prior Authorization List was last updated in 2022 and currently includes 62 items. All the lists discussed in this notice are available on the *cms.gov* website.

II. Provisions of the Document

This document serves to update three separate lists. First, it provides an update to the Master List. Next, this document updates the items included on the Required Face-to-Face and Written Order Prior to Delivery List. Finally, this document updates items included on the Required Prior Authorization List.

A. Master List

The Master List includes items that appear on the DMEPOS Fee Schedule and meet one of the following criteria, as stated in 42 CFR 414.234(b)(1):

- 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) Medicare Fee-for-Service 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 regulation at § 414.234 (b)(2) and the November 2019 final rule noted previously, the maintenance process of the Master List is described 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 the CERT Medicare Fee-for-Service Supplemental Improper Payment Data report published after 2020, or in an OIG or GAO report published after 2020, and items not meeting the cost thresholds (originally set at $500 for purchases and $50 for rentals and adjusted for inflation) 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 on the Master List are updated when the 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 *http://go.cms.gov/DMEPOSPA.*

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. Specifically, in accordance with 42 CFR 414.234(b)(1)(i) the $500 average purchase fee threshold and the $50 average monthly rental fee threshold is adjusted using the consumer price index for all urban consumers (CPI–U), reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period.

The DMEPOS fee schedule amounts are also updated every year to account for inflation. For CY2021,[1] 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 was 0.6 percent. 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 (referred to as the productivity adjustment) was 0.4 percent. Beginning with the November 18, 2021 release of productivity data, the Bureau of Labor Statistics replaced the term multifactor productivity with total factor productivity stating that this was a change in terminology only and will not affect the data or methodology. Thus, for CY 2021, we applied an update factor of 0.2 percent (reduce the 0.6 percentage increase in the CPI–U by the productivity adjustment of 0.4 percentage point). Applying the 0.2 percent update factor to the CY 2020 average price threshold of $500 results in a CY 2021 adjusted payment threshold of $501 ($500 × 1.002) and an updated rental payment threshold of $50.10 ($50 × 1.002), which we round to $50.

The DME Fee Schedule was updated for CY 2022 [2] and CY 2023,[3] however due to the Covid–19 Public Health Emergency (PHE), the Master List was not updated.

For CY 2022, the CPI–U increase was 5.4 percent and the productivity adjustment was 0.3 percentage points. Thus, for CY 2022, we applied an update factor of 5.1 percent (5.4 percent reduced by 0.3 percentage points).

For CY 2022, the adjusted purchase price threshold was $527 and the adjusted monthly rental fee threshold was $53. We calculated this by applying the 5.1 percent update factor to the CY 2021 average price threshold of $501, resulting in a CY 2022 adjusted payment threshold of $526.55 ($501 × 1.051), and to the CY 2021 average monthly rental fee of $50, resulting in an adjusted payment threshold of $52.55 ($50 × 1.051). Rounded to the nearest whole dollars results in thresholds of $527 and $53.

For CY 2023, the CPI–U increase was 9.1 percent and the productivity adjustment was 0.4 percentage points. Thus, for CY 2023, we applied an update factor of 8.7 percent (9.1 percent reduced by 0.4 percentage points).

For CY 2023 the adjusted purchase price threshold was $573 and the adjusted monthly rental fee threshold of $58. We calculated this by applying the 8.7 percent update factor to the CY 2022 average price threshold of $527, resulting in a CY 2023 adjusted payment threshold of $572.85 ($527 × 1.087), and to the CY 2022 average monthly rental fee of $53, resulting in an adjusted payment threshold of $57.61 ($53 × 1.087). Rounded to the nearest whole dollar, these figures are $573 and $58.

For CY 2024, the CPI–U increase was 3.0 percent and the productivity adjustment was 0.4 percentage points. Thus, for CY 2024, we applied an update factor of 2.6 percent (3.0 percent reduced by 0.4 percentage points).

For CY 2024, the adjusted purchase price threshold is $588 and the adjusted monthly rental fee threshold is $60. We calculated this by applying the 2.6 percent update factor to the CY 2023 average price threshold of $573, resulting in a CY 2024 adjusted payment threshold of $587.89 ($573 × 1.026), and to the CY 2023 average monthly rental fee of $58, resulting in an adjusted payment threshold of $59.51 ($58 ×

[1] *https://www.cms.gov/medicaremedicare-fee-service-paymentdmeposfeescheddmepos-fee-schedule/dme21.*

[2] *https://www.cms.gov/medicaremedicare-fee-service-paymentdmeposfeescheddmepos-fee-schedule/dme22.*

[3] *https://www.cms.gov/medicaremedicare-fee-service-paymentdmeposfeescheddmepos-fee-schedule/dme23.*

1.026). Rounding to the nearest whole dollar, these figures are $588 and $60.

We are adding a total of 76 HCPCS codes (see Table 1) meeting the criteria outlined previously to the Master List. Of these 76 HCPCS codes, 56 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 Medicare Fee-for-Service Supplemental Improper Payment Data report, or both; and 20 are being added for aberrant billing patterns. The codes added due to aberrant billing patterns represent items for which data show suppliers submitted at least 1,000 claims and received at least $1 million in payments during the two 12-month periods from July 2021 to June 2022 and July 2022 to June 2023. There was more than a 30 percent increase in payments for each item from the preceding 12-month period. CMS did not identify explanatory contributing factors for the aberrant billing.

TABLE 1—ADDITIONS TO THE MASTER LIST

HCPCS	Description
A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each.
A4353	Intermittent urinary catheter, with insertion supplies.
A4393	Ostomy pouch, urinary, with extended wear barrier attached, with built-in convexity (1 piece), each.
A4408	Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, with built-in convexity, larger than 4 x 4 inches, each.
A4410	Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each.
A5056	Ostomy pouch, drainable, with extended wear barrier attached, with filter, (1 piece), each.
A5057	Ostomy pouch, drainable, with extended wear barrier attached, with built in convexity, with filter, (1 piece), each.
A6021	Collagen dressing, sterile, size 16 sq. in. or less.
A6023	Collagen dressing, sterile, size more than 48 sq. in.
A6238	Hydrocolloid dressing, wound cover, sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in.
A6251	Specialty absorptive dressing, wound cover, sterile, pad size 16 sq. in. or less, without adhesive border, each dressing.
A6266	Gauze, impregnated, other than water, normal saline, or zinc paste, sterile, any width, per linear yard.
E0482	Cough stimulating device, alternating positive and negative airway pressure.
E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electical stimulation of the tongue muscle, controlled by hardware remote.
E0500	Intermittent Positive Pressure Breathing machine, all types, with built-in nebulizations; manual ot automatic valves; internal or ecternal power source.
E0562	Humidifier, heated, used with positive airway pressure device.
E0618	Apnea monitor, without recording feature.
E0677	Non-pneumatic sequential compression garment, trunk.
E0680	Non-pneumatic compression controller with sequential calibrated gradient pressure.
E0681	Non-pneumatic compression controller without calibrated gradient pressure.
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 foot panel.
E0749	Osteogenesis stimulator, electrical, surgically implanted.
E0782	Infusion pump, implantable, non-programmable (includes all components, *e.g.,* pump, catheter, connectors, etc.).
E0783	Infusion pump system, implantable, programmable (includes all components, *e.g.,* pump, catheter, connectors, etc.).
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement.
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter).
E0984	Manual wheelchair accessory, power add-on to convert manual wheelchair to motorized wheelchair, tiller control.
E1050	Fully-reclining wheelchair, fixed full length arms, swing away detachable elevating leg rests.
E1060	Fully-reclining wheelchair, detachable arms, desk or full length, swing away detachable elevating legrests.
E1070	Fully-reclining wheelchair, detachable arms (desk or full length) swing away detachable footrest.
E1083	Hemi-wheelchair, fixed full length arms, swing away detachable elevating leg rest.
E1084	Hemi-wheelchair, detachable arms desk or full length arms, swing away detachable elevating leg rests.
E1087	High strength lightweight wheelchair, fixed full length arms, swing away detachable elevating leg rests.
E1088	High strength lightweight wheelchair, detachable arms desk or full length, swing away detachable elevating leg rests.
E1092	Wide heavy duty wheelchair, detachable arms (desk or full length), swing away detachable elevating leg rests.
E1093	Wide heavy duty wheelchair, detachable arms desk or full length arms, swing away detachable footrests.
E1100	Semi-reclining wheelchair, fixed full length arms, swing away detachable elevating leg rests.
E1110	Semi-reclining wheelchair, detachable arms (desk or full length) elevating leg rest.
E1150	Wheelchair, detachable arms, desk or full length swing away detachable elevating legrests.
E1160	Wheelchair, fixed full length arms, swing away detachable elevating legrests.
E1170	Amputee wheelchair, fixed full length arms, swing away detachable elevating legrests.
E1171	Amputee wheelchair, fixed full length arms, without footrests or legrest.
E1172	Amputee wheelchair, detachable arms (desk or full length) without footrests or legrest.
E1180	Amputee wheelchair, detachable arms (desk or full length) swing away detachable footrests.
E1190	Amputee wheelchair, detachable arms (desk or full length) swing away detachable elevating legrests.
E1195	Heavy duty wheelchair, fixed full length arms, swing away detachable elevating legrests.
E1200	Amputee wheelchair, fixed full length arms, swing away detachable footrest.
E1221	Wheelchair with fixed arm, footrests.
E1222	Wheelchair with fixed arm, elevating legrests.
E1223	Wheelchair with detachable arms, footrests.
E1224	Wheelchair with detachable arms, elevating legrests.
E1240	Lightweight wheelchair, detachable arms, (desk or full length) swing away detachable, elevating legrest.
E1270	Lightweight wheelchair, fixed full length arms, swing away detachable elevating legrests.
E1280	Heavy duty wheelchair, detachable arms (desk or full length) elevating legrests.
E1295	Heavy duty wheelchair, fixed full length arms, elevating legrest.
E1296	Special wheelchair seat height from floor.
E2341	Power wheelchair accessory, nonstandard seat frame width, 24–27 inches.

TABLE 1—ADDITIONS TO THE MASTER LIST—Continued

HCPCS	Description
E2342	Power wheelchair accessory, nonstandard seat frame depth, 20 or 21 inches.
E2343	Power wheelchair accessory, nonstandard seat frame depth, 22–25 inches.
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access.
E2606	Positioning wheelchair seat cushion, width 22 inches or greater, any depth.
E2631	Wheelchair accessory, addition to mobile arm support, elevating proximal arm.
K0010	Standard—weight frame motorized/power wheelchair.
K0011	Standard—weight frame motorized/power wheelchair with programmable control parameters for speed adjustment, tremor dampening, acceleration control and braking.
K0012	Lightweight portable motorized/power wheelchair.
L0457	TLSO, flexible, provides trunk support, thoracic region, rigid posterior panel and soft anterior apron, extends from the sacrococcygeal junction and terminates just inferior to the scapular spine, restricts gross trunk motion in the sagittal plane, produces intracavitary pressure to reduce load on the intervertebral disks, includes straps and closures, prefabricated, off-the-shelf.
L1681	Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L2006	Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated.
L2280	Addition to lower extremity, molded inner boot.
L3761	Elbow orthosis (EO), with adjustable position locking joint(s), prefabricated, off-the-shelf.
L4000	Replace girdle for spinal orthosis (cervical-thoracic-lumbar-sacral orthosis or shoulder orthosis.
L5615	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control.
L5926	Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type.
L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector.
L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal devices.
L7366	Battery charger, twelve volt, each.

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 has 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. Additionally, items are removed from the list sooner than 10-year timeframe if the purchase or monthly rental amount drops below the payment threshold. There are three (See Table 2) HCPCS codes being removed from the Master List for the CY 2024 update, as they no longer meet the criteria for inclusion.

TABLE 2—DELETIONS FROM THE MASTER LIST

HCPCS	Description
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment.
E0565	Compressor air power source.
L1833	Knee orthosis (KO), adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf.

The full updated Master List is available in the Downloads & Links section of the following CMS website: *http://go.cms.gov/DMEPOSPA*

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

As previously stated, PMDs are included on the F2F/WOPD List per statutory obligation. For the other DMEPOS items, we consider factors such as operational limitations, item utilization, 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.

When selecting these items, we balance our program integrity goals with the needs of beneficiaries to 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 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, and necessary documentation for items on the F2F/WOPD List.

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.

Prior to publication of this **Federal Register** notice, 63 items have been included on the F2F/WOPD List. We have not been notified of any issues related to beneficiary access, and billing trends have been consistent with anticipated volumes.

Based on our regulatory authority at 42 CFR 410.38, this **Federal Register** notice is adding the following 13 additional HCPCS codes to the F2F/WOPD List (See Table 3).

We have selected codes for three hospital beds, two osteogenesis stimulators, six lumbar sacral orthoses, and two knee orthoses. We note that such items were selected based on our analysis of the CERT improper payment information, practitioner encounter information, jurisdictionally identified billing vulnerabilities, policy analysis, and in coordination with the prior authorization program.

We continue to believe additional practitioner oversight of beneficiaries in need of items included on the F2F/WOPD List will help further our program integrity goals of reducing fraud, waste, and abuse. It helps ensure beneficiary receipt of items specific to their medical needs, as the written order/prescription must be communicated to the supplier prior to delivery. For such items, we continue to 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.

TABLE 3—ADDITIONS TO THE F2F/WOPD LIST—NEW NON-STATUTORILY REQUIRED ITEMS

HCPCS	Description
E0290	Hospital bed, fixed height, without side rails, with mattress.
E0301	Hospital bed, heavy duty, extra wide, with weight capacity greater than 350 pounds, but less than or equal to 600 pounds, with any type side rails, without mattress.
E0304	Hospital bed, extra heavy duty, extra wide, with weight capacity greater than 600 pounds, with any type side rails, with mattress.
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive.
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spinal applications.
L0635	Lumbar-sacral orthosis (LSO), sagittal-coronal control, lumbar flexion, rigid posterior frame/panel(s), lateral articulating design to flex the lumbar spine, 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, anterior panel, pendulous abdomen design, prefabricated, includes fitting and adjustment.
L0636	Lumbar-sacral orthosis (LSO), sagittal-coronal control, lumbar flexion, rigid posterior frame/panels, lateral articulating design to flex the lumbar spine, posterior extends from sacrococcygeal junction to T–9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, anterior panel, pendulous abdomen design, custom fabricated.
L0638	Lumbar-sacral orthosis (LSO), sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T–9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, custom fabricated.
L0639	Lumbar-sacral orthosis (LSO), sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T–9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L0640	Lumbar-sacral orthosis (LSO), sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T–9 vertebra, anterior extends from symphysis pubis to xiphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, custom fabricated.
L0651	Lumbar-sacral orthosis (LSO), sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T–9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated, off-the-shelf.
L1845	Knee orthosis (KO), double 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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L1852	Knee orthosis (KO), double 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.

Per the regulatory guidelines established at § 414.234(b), and as previously discussed, items may be removed from the Master List. If items are removed from the Master List, they are no longer eligible for inclusion on the F2F/WOPD List. As such, as of the effective date of this **Federal Register** notice, HCPCS L1833 is removed from the Master List and is likewise removed from the Required F2F/WOPD List.

TABLE 4—DELETIONS FROM THE F2F/WOPD LIST

HCPCS	Description
L1833	Knee orthosis (KO), adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf.

The F2F/WOPD List is available on the following CMS website: F2F/WOPD List.

C. Items Subject to Prior Authorization Requirements

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. As stated in § 414.234(c), we 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. 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.

We are updating the Required Prior Authorization List to include the addition of nine HCPCS codes and removal of one HCPCS code. HCPCS code L1833 is being removed from the Required Prior Authorization List as the item no longer meets the criteria to be maintained on the Master List and is no longer eligible for inclusion. The remaining 61 HCPCS codes currently on the Required Prior Authorization List remain on the List without interruption. To assist stakeholders in preparing for implementation of the prior authorization program, we are providing 90 days' notice.

TABLE 5—DELETIONS FROM THE REQUIRED PRIOR AUTHORIZATION LIST

HCPCS	Description
L1833	Knee orthosis (KO), adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf.

The following three HCPCS codes for osteogenesis stimulators, three HCPCS codes for lumbar-sacral orthoses (LSO), and three HCPCS codes for lower limb orthoses (LLO) are added to the Required Prior Authorization List:

TABLE 6—ADDITIONS TO THE REQUIRED PRIOR AUTHORIZATION LIST

HCPCS	Description
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spinal applications.
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications.
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive.
L0631	Lumbar-sacral orthosis (LSO), 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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L0637	Lumbar-sacral orthosis (LSO), sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T–9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L0639	Lumbar-sacral orthosis (LSO), sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T–9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L1843	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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L1845	Knee orthosis (KO), double 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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L1951	Ankle foot orthosis (AFO), spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, includes fitting and adjustment.

We believe prior authorization of these nine additional HCPCS codes will help further our program integrity goals of reducing fraud, waste, and abuse, while also protecting access to care.

In recent years, osteogenesis stimulators have been a concern due to continually high improper payment rates, having been identified in CMS' CERT Medicare Fee-for-Service Supplemental Improper Payment Data reports (2017–2020) as having improper payment rates ranging from 8.5 to 40.9 percent.

LSOs and LLOs have been identified by the CERT program as two of the top 20 DMEPOS service types with improper payments over the past several years. Since 2020, LLOs have had an improper payment rate ranging from 44 to 66 percent, with projected improper payments ranging between $76 and $187 million. Similarly, LSOs have had an improper payment ranging from 35 to 58 percent, with projected improper payments ranging between $78 and $178 million since 2020. In 2019, the Department of Justice (DOJ) announced 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 DMEPOS companies and licensed medical professionals allegedly participated in health care fraud schemes involving more than $1.2

billion in loss.[4] In 2022, CMS added several LSOs and LLOs to the Required Prior Authorization list (87 FR 2051); however, additional program integrity action in this space is warranted.[5]

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 three newly added LSO and the three newly added LLO codes nationwide, beginning on the date specified in the in the **DATES** section. We will implement prior authorization for the three newly added osteogenesis stimulator codes in two phases beginning on the dates specified in the in the **DATES** section. This phased-in approach will allow us to identify and resolve any unforeseen issues by using a smaller claim volume in phase 1 before implementing phase 2. We selected States for the two phases based on utilization data.

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 of the newly added osteogenesis stimulators: California, Florida, Ohio, and Pennsylvania.

For phase 2, which begins on the date specified in the **DATES** section, prior authorization expands to all remaining States and territories not captured in phase 1.

The prior authorization program for the remaining 61 HCPCS 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 sub regulatory communications, final timelines customized for the DMEPOS item subject to prior authorization and 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 Downloads & Links section of the following CMS website: *http://go.cms.gov/DMEPOSPA.*

III. Collection of Information Requirements

This document provides updates to the Master List, the F2F/WOPD List, and the Required Prior Authorization List.

A total of 76 HCPCS codes (see Table 1) meeting the criteria outlined previously are added to the Master List. Of these 76 HCPCS codes, 56 are added because these items meet the updated payment threshold and are listed in an OIG or GAO report of a national scope, a CERT Medicare Fee-for-Service Supplemental Improper Payment Data report, or both; and 20 are being added for aberrant billing patterns. There are three HCPCS codes (see Table 2) being removed from the Master List for the CY 2024 update, as these no longer meet the criteria for inclusion, as outlined previously.

Thirteen HCPCS are being added to the F2F/WOPD List. Of these 13 codes, three are hospital beds, two are osteogenesis stimulators, six are lumbar sacral orthoses, and two are knee orthoses. This notice removes one knee orthosis code from the F2F/WOPD List.

The updates to the F2F/WOPD List do not constitute information collections requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

This notice removes one HCPCS code from the Required Prior Authorization List, as it no longer meets the requirements for inclusion (see Table 5). A total of nine HCPCS codes (see Table 6) are selected for addition to the Required Prior Authorization List. Of these nine HCPCS codes, three are osteogenesis stimulators, three are LSOs, and three are LLOs. The remaining 61 HCPCS codes currently subject to the DMEPOS prior authorization requirement will continue uninterrupted.

There is an information collection burden associated with this program that is currently approved under OMB control number 0938–1293, which expires August 31, 2025. This package accounts for burdens associated with the addition of items to the Required Prior Authorization Lists and assumes a burden for 2024 of approximately $8.4 million for providers to comply with the required information collection. The burden associated with the additions to the Required Prior Authorization List has been assessed in the PRA package referenced previously and is included in this **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), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), 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 significant effects ($200 million or more in any 1 year). This regulatory

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

[5] Due to the need for certain patients to receive an orthoses item that may otherwise be subject to PA when the 2-day expedited review would delay care and risk the health or life of the beneficiary, we suspended prior authorization requirements for certain codes in these limited circumstances, effective April 13, 2022. This suspension remains in effect. *https://www.federalregister.gov/documents/2022/08/10/2022-17187/medicare-program-suspension-of-required-prior-authorization-for-certain-durable-medical-equipment.*

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 have an estimated net savings of $32.1 million. Gross savings is based upon a 20 percent reduction in the total amount paid for claims in CY 2022. We deducted from the gross savings the anticipated cost for performing the prior authorization reviews to estimate the net savings. Our gross savings estimate of 20 percent is based on previous results from other prior authorization programs, 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 $9.0 million to $47.0 million in any one 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 2024, that threshold is approximately $183 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 Chyana Woodyard who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–10356 Filed 5–10–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 2800, 2860, 2880, and 2920

[BLM_HQ_FRN_MO4500175819]

RIN 1004–AE60

Update of the Communications Uses Program, Cost Recovery Fee Schedules, and Section 512 of FLPMA for Rights-of-Way; Corrections

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule; corrections.

SUMMARY: The Bureau of Land Management (BLM) is correcting a final rule that appeared in the **Federal Register** on April 12, 2024.

DATES: Effective on May 13, 2024.

FOR FURTHER INFORMATION CONTACT: Stephen Fusilier, Branch Chief, Rights-of-Way, telephone: 202–309–3209, email: *sfuslie@blm.gov,* or by mail 1849 C St. NW, Washington, DC 20240, for information regarding the substance of this final rule.

Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. For a summary of the final rule, please see the final rule summary document in docket BLM–2022–0002 on *www.regulations.gov.*

SUPPLEMENTARY INFORMATION: In **Federal Register** Document 2024–06997 appearing on page 25922 in the **Federal Register** of Friday, April 12, 2024, the following corrections are made:

§ 2801.2 [Corrected]

■ 1. On page 25957, in the second column, in amendatory instruction 3.b, in the definition of ''Maintenance,'' redesignate the second paragraph (ii) as paragraph (iii).

§ 2881.5 [Corrected]

■ 2. On page 25972, in the second column, in amendatory instruction 41, in the definition of ''Processing activities,'' redesignate the second paragraph (ii) as paragraph (iii).

This action by the Principal Deputy Assistant Secretary is taken pursuant to an existing delegation of authority.

Steven H. Feldgus,

Principal Deputy Assistant Secretary, Land and Minerals Management.

[FR Doc. 2024–10398 Filed 5–10–24; 8:45 am]

BILLING CODE 4331–29–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 175, 176, 178, and 180

[Docket No. PHMSA–2021–0092 (HM–215Q)]

RIN 2137–AF57

Hazardous Materials: Harmonization with International Standards

Correction

In rule document 2024–06956 beginning on page 25434 in the issue of Wednesday, April 10, 2024, make the following correction:

§ 172.101 [Corrected]

■ On pages 25473 through 25475, in § 172.101, the Hazardous Material Table should appear as follows:

§ 172.101 Hazardous Materials Table [Corrected]