§ 105–9.125 Exhaustion of administrative remedies.

(a) A complainant may file a civil action following the exhaustion of administrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 calendar days elapse after the complainant files the complaint and GSA makes no finding with regard to the complaint; or

(2) GSA issues a finding in favor of the recipient.

(b) If GSA fails to make a finding within 180 days or issues a finding in favor of the recipient, GSA must:

(1) Promptly advise the complainant of this fact;

(2) Advise the complainant of his or her right to bring civil action for injunctive relief; and

(3) Inform the complainant:

(i) That the complainant may bring civil action only in a United States district court for the district in which the recipient is located or transacts business;

(ii) That a complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that the complainant must demand these costs in the complaint;

(iii) That before commencing the action the complainant must give 30 calendar days notice by registered mail to the Secretary, HHS, The Administrator, the Attorney General of the United States, and the recipient;

(iv) That the notice must state the alleged violation of the Act, the relief requested, the court in which the complainant is bringing the action, and whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) That the complainant may not bring an action if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

§ 105.9–126 Alternate funds disbursal.

If GSA withholds Federal financial assistance from a recipient under this part, the Administrator may disburse the assistance to an alternate recipient; any public or nonprofit private organization; or agency or State or political subdivision of the State. The Administrator requires any alternate recipient to demonstrate:

(a) The ability to comply with this part; and

(b) The ability to achieve the goals of the Federal Statutes authorizing the Federal financial assistance.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[CMS–6109–N]

RIN 0938–ZC04

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 Encounter 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''); Updates to the Required Face-to-Face Encounter and Written Order Prior to Delivery List; and Updates to the Required Prior Authorization List.

SUMMARY: This document announces updates to the 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 Encounter and Written Order Prior to Delivery List and the Required Prior Authorization List.

DATES: Implementation of updates to the Master List, the Required Face-to-Face Encounter and Written Order Prior to Delivery List, and the Required Prior Authorization List, excluding upper limb orthoses, are effective October 28, 2026.

Prior authorization requirements for the upper limb orthoses will be implemented in three phases. Phase one includes New York, Michigan, Florida, and California and is effective October 28, 2026. Phase two includes the States in phase one and Pennsylvania, Massachusetts, Ohio, Illinois, Texas, Georgia, Arizona, and Oregon and is effective January 26, 2027. Phase three includes all States and territories not included in phases one and two and is effective April 26, 2027.

FOR FURTHER INFORMATION CONTACT: 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; or Olufemi Shodeke, (410) 786–1649.

For information related to the Master List or Required Prior Authorization List, contact Justin Carlisle, (410) 786–4265; Karen Leban, (410) 786–2476; or Jessica Martindale, (410) 786–1558.

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 Social Security Act (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 (PMDs)) require a face-to-face encounter per statute and would remain on both the Master List and the F2F/WOPD List.

The requirements in the November 2019 final rule related to face-to-face encounters, written orders prior to delivery, and standard written orders for specified DMEPOS items were 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, Orthotics, and Supplies'' (80 FR 81674).

The Master List was last updated via the document published in the January 13, 2026 **Federal Register** (91 FR 1250 through 1252) and currently includes 530 items. The Master List is available on the CMS website at: *http://go.cms.gov/DMEPOSPA.*

The January 2026 **Federal Register** document (91 FR 1252 and 1253) also included the most recent iteration of the Required Face-to-Face Encounter and Written Order Prior to Delivery List. There are currently 83 items on the list, including 46 PMDs that were included per statute. This list is also available on the CMS website at: *http://go.cms.gov/DMEPOSF2F.*

The Required Prior Authorization List was last updated via the January 2026 **Federal Register** document (91 FR 1253 and 1254) and currently includes 74 items. All the lists discussed in this notice are available on the CMS website at: *http://go.cms.gov/DMEPOSPA.*

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 Encounter and Written Order Prior to Delivery List. Finally, this document updates items 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 percentage 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) and in the November 2019 final rule, 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 website at: *http://go.cms.gov/DMEPOSPA.*

This document updates the Master List of DMEPOS Items Potentially Subject 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 as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period.

In accordance with sections 1834(a)(14), 1834(h)(4) and 1842(s)(1)(B) of the Act, we updated certain DMEPOS fee schedule amounts for calendar year (CY) 2026,[1] by the percentage increase in the CPI–U for the 12-month period ending June 30, 2025, adjusted by the change in the economy-wide productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''productivity adjustment''). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is

[1] 2026 DMEPOS Fee Schedule; available at *https://www.cms.gov/medicare/payment/fee-schedules/dmepos/dmepos-fee-schedule/dme26.*

published by BLS as private nonfarm business total factor productivity (TFP), previously referred to as multifactor productivity.[2] Please see *https://www.bls.gov/productivity/* for the BLS historical published TFP data. For CY 2026, the productivity adjustment is estimated to be 0.7 percent and the CPI–U percentage increase is 2.7 percent. Thus, the 2.7 percentage increase in the CPI–U is reduced by a 0.7 percentage point productivity adjustment resulting in a net increase of 2.0 percent for the update factor for CY 2026.

For CY 2026, the adjusted purchase price threshold is $614, and the adjusted monthly rental fee threshold is $62. We calculated this by applying the 2.0 percent update factor to the CY 2025 average price threshold of $602, resulting in a CY 2026 adjusted payment threshold of $614.02 ($602 × 1.02), and to the CY 2025 average monthly rental fee of $61, resulting in an adjusted payment threshold of $62.22 ($61 × 1.02). Rounding to the nearest whole dollar, these figures are $614 and $62.

We are adding a total of 20 HCPCS codes (see Table 1) meeting the criteria outlined previously to the Master List. Of these 20 HCPCS codes, A4239, A6022, A6197, K0831, L0456, L0486, L1833, and L3916 are being added for aberrant billing patterns. These codes represent items for which data shows suppliers submitted at least 1,000 claims and received at least $1 million in payments during the 12 months from July 2024 to June 2025. 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. The remaining 12 codes 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.

TABLE 1—ADDITIONS TO THE MASTER LIST

HCPCS	Description
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM) including all supplies and accessories (1 month supply = 1 unit of service).
A4594	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each.
A6022	Collagen dressing, sterile, size more than 16 square (sq) inches (in) but less than or equal to 48 sq in each.
A6197	Alginate or other fiber gelling dressing, wound cover, sterile, pad size more than 16 square (sq) inches (in) but less than or equal to 48 sq.in., each dressing.
E0658	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and chest.
E0659	Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck, and chest.
E0683	Non-pneumatic, non-sequential, peristaltic wave compression pump.
E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist.
E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, including a microprocessor, all components, and accessories.
E0739	Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors.
E2001	Suction pump, home model, portable or stationary, electric, any type, for use with an external urine and/or fecal management system.
E2298	Complex rehabilitative power wheelchair accessory, power seat elevation system, any type.
K0831	Power wheelchair, group 2 standard, seat elevator, captain's chair, patient weight capacity up to and including 300 pounds.
L0456	Thoracic-lumbar-sacral orthosis, 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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L0486	Thoracic-lumbar-sacral orthosis, triplanar control, two piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or CAD–CAM model, custom fabricated.
L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the-shelf.
L1933	Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf.
L1952	Ankle foot orthosis, spiral, (Institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf.
L3916	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated, off-the-shelf.
L5827	Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping.

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 a 10-year timeframe if the purchase or monthly rental amount drops below the payment threshold. There are no HCPCS codes being removed from the Master List for the CY 2026 update.

The full updated Master List is available on the CMS website at: *http://go.cms.gov/DMEPOSPA.*

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

The F2F/WOPD List includes PMDs that are required by 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

[2] *https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.*

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.

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, 83 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 22 additional HCPCS codes to the F2F/WOPD List (See Table 2).

We have selected three codes for lumbar-sacral orthoses, four codes for lower limb orthoses, two codes for upper limb orthoses, eight wheelchair codes, three codes for home ventilators, one code related to oxygen and its delivery system, and one code for an air-fluidized bed. Lumbar-sacral orthoses, lower limb orthoses, upper limb orthoses, ventilators, oxygen supplies/equipment and hospital bed/accessories were identified by CMS' Comprehensive Error Rate Testing (CERT) program as being within the top 20 DMEPOS service types with improper payments in 2025. Several of these codes were also identified by HHS program integrity experts, including our contractors performing medical review as being vulnerable to fraud.

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.

The proposed items were selected based on the clinical appropriateness of requiring a practitioner encounter within the preceding 6 months, jurisdictionally identified billing vulnerabilities, and data analysis, including our analysis of the CERT improper payment information.

TABLE 2—ADDITIONS TO THE F2F/WOPD LIST—NEW NON-STATUTORILY REQUIRED ITEMS

HCPCS	Description
E0194	Air fluidized bed.
E0466	Home ventilator, any type, used with non-invasive interface, (for example, mask, chest shell).
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.
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions.
E1161	Manual adult size wheelchair, includes tilt in space.
K0002	Standard hemi (low seat) wheelchair.
K0003	Lightweight wheelchair.
K0004	High strength, lightweight wheelchair.
K0005	Ultralightweight wheelchair.
K0006	Heavy duty wheelchair.
K0007	Extra heavy-duty wheelchair.
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing.
K0831	Power wheelchair, group 2 standard, seat elevator, captain's chair, patient weight capacity up to and including 300 pounds.
L0486	Thoracic-lumbar-sacral orthosis, triplanar control, two piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or CAD–CAM model, custom fabricated.
L0456	Thoracic-lumbar-sacral orthosis, 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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L0457	Thoracic-lumbar-sacral orthosis, 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.
L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the-shelf.
L1906	Ankle foot orthosis, multi-ligamentous ankle support, prefabricated, off-the-shelf.
L1933	Ankle foot orthoses, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf.
L1952	Ankle foot orthosis, spiral, (Institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf.
L3761	Elbow orthosis, with adjustable position locking joint(s), prefabricated, off-the-shelf.

TABLE 2—ADDITIONS TO THE F2F/WOPD LIST—NEW NON-STATUTORILY REQUIRED ITEMS—Continued

HCPCS	Description
L3916	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated, off-the-shelf.

The F2F/WOPD List is available on the CMS website at: *http://go.cms.gov/DMEPOSF2F.*

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 eight HCPCS codes (See Table 3). To assist stakeholders in preparing for implementation of the prior authorization program, we are providing at least 90 days' notice as further described as follows.

The following HCPCS codes for a pressure-reducing support surface, manual wheelchair base, knee orthosis, thoracic-lumbar-sacral orthoses, and upper-limb orthoses are being added to the Required Prior Authorization List:

TABLE 3—ADDITIONS TO THE REQUIRED PRIOR AUTHORIZATION LIST

HCPCS	Description
E0194	Air fluidized bed.
K0005	Ultralightweight wheelchair.
L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the-shelf.
L0456	Thoracic-lumbar-sacral orthosis, 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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.
L0457	Thoracic-lumbar-sacral orthosis, 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.
L0486	Thoracic-lumbar-sacral orthosis, triplanar control, two piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or CAD–CAM model, custom fabricated.
L3761	Elbow orthosis, with adjustable position locking joint(s), prefabricated, off-the-shelf.
L3916	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated, off-the-shelf.

We believe prior authorization of these eight additional HCPCS codes will help further our program integrity goals of reducing fraud, waste, and abuse, while also protecting access to care. In addition, recent enforcement actions by the U.S. Department of Justice have continued to demonstrate broader program integrity risks, including fraudulent billing schemes involving medically unnecessary equipment, the submission of claims lacking documentation of medical necessity, and the use of telemarketing arrangements targeting Medicare beneficiaries.[3] Additionally, the CMS Fraud Defense Operations Center has reported over $1.5 billion in payments suspended for DMEPOS items associated with suspected fraudulent billing.[4]

Orthoses have been identified by the CERT program as one of the top DMEPOS service types with improper payments over the past several years. From 2023 to 2025, improper payment rates remained consistently elevated, ranging from approximately 40 percent to 48 percent for upper limb orthoses and 35 percent to 47 percent for lower limb orthoses. The improper payment rate for manual wheelchairs ranged from 22.1 percent to 42 percent over that same time period.[5] [6] [7] Additionally, claims for certain pressure-reducing support surfaces have been denied through medical reviews for not meeting Medicare requirements for payment.

Upon implementation, 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 newly added pressure-reducing support surface, manual wheelchair, knee

[3] DOJ July 2025 Press Release; available at *www.justice.gov/opa/pr/durable-medical-equipment-owner-sentenced-12-years-61-million-medicare-fraud-scheme.*

[4] Fraud Defense Operations Center Fast Facts; available at *https://www.cms.gov/files/document/fdoc-fact-sheet-updated.pdf.*

[5] 2023 CMS Medicare Fee for Service (FFS) Supplemental and Improper Payment Data (CERT); available at *https://www.cms.gov/files/document/2023medicarefee-servicesupplemental improperpaymentdatapdf.pdf.*

[6] 2024 CMS Medicare FFS Supplemental and Improper Payment Data (CERT); available at *https://www.cms.gov/files/document/2024-medicare-fee-service-supplemental-improper-payment-data.pdf.*

[7] 2025 CMS Medicare FFS Supplemental and Improper Payment Data (CERT); available at *https://www.cms.gov/files/document/nov-2025-medicare-ffs-supplemental-improper-payment-data-2025922.pdf.*

orthosis, and thoracic-lumbar-sacral orthoses codes beginning on the date specified in the **DATES** section. We will implement a prior authorization program for the two newly added upper limb orthoses codes (L3761 and L3916) in three phases beginning on the dates specified in the **DATES** section. This phased-in approach will allow us to identify and resolve any unforeseen issues by using smaller claim volumes in phase one and phase two before nationwide implementation occurs in phase three.

In phase one of the implementation, which begins on the date specified in the **DATES** section, we will limit the prior authorization requirement of the upper limb orthoses to four states (one in each DME MAC jurisdiction) as follows: New York, Michigan, Florida, and California.

In phase two, which begins on the date specified in the **DATES** section, the prior authorization requirement of the upper limb orthoses items will expand to Pennsylvania, Massachusetts, Ohio, Illinois, Texas, Georgia, Arizona, and Oregon.

In phase three, which begins on the date specified in the **DATES** section, the prior authorization requirement of the upper limb orthoses items will expand nationally to all remaining states and territories not included in the first two phases.

The prior authorization program for the remaining 74 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 on the CMS website at: *http://go.cms.gov/DMEPOSPA.*

III. Collection of Information Requirements

This document provides updates to the Master List, the Required Face-to-Face and Written Order Prior to Delivery List, and the Required Prior Authorization List.

A total of 20 HCPCS codes (see Table 1) meeting the criteria outlined previously are added to the Master List. Of these 20 HCPCS codes, 12 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 8 are being added for aberrant billing patterns. There are no HCPCS codes being removed from the Master List for the CY 2026 update.

Twenty-two HCPCS codes (see Table 2) are being added to the F2F/WOPD List. These codes include three for lumbar-sacral orthoses, four for lower limb orthoses, two for upper limb orthoses, eight for wheelchairs, three for home ventilators, one related to oxygen delivery, and one for air-fluidized beds. The 83 codes currently subject to the F2F/WOPD requirements will continue to remain on the Required F2F/WOPD List. Therefore, a total of 105 codes will be subject to face-to-face encounter and written order prior to delivery as a condition of payment. 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.*).

A total of eight HCPCS codes (see Table 3) are selected for addition to the Required Prior Authorization List. Of these eight HCPCS codes, one is a pressure reducing support surface, one is a manual wheelchair, and six are orthoses. The remaining 74 HCPCS codes currently subject to the DMEPOS prior authorization requirement will continue uninterrupted.

The information collection burden associated with the DMEPOS prior authorization program is currently approved by OMB under control number 0938–1293 (CMS–10524). The control number accounts for the burden associated with the addition of items to the Required Prior Authorization Lists and assumes an annual burden of approximately $4.8 million for providers to comply with the prior authorization requirement. 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 impacts of this regulatory notice as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); 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 those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; as well as the distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a regulatory notice that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel

legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. This regulatory notice is not significant and does not reach the economic threshold and thus is not considered a major regulatory notice.

Per our analysis, the additional items being added to the prior authorization program have an estimated net savings of $15.8 million after deducting implementation costs from gross savings. Gross savings were estimated by reducing the estimated total amount paid for these items in CY 2025 by a reduction in the items' improper payment rates.

The Regulatory Flexibility Act (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 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 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 notice 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 notice 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 2026, that threshold is approximately $193 million. This regulatory notice 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 notice 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 notice was reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mehmet Oz, 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.

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