DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 414

[CMS–6097–N]

RIN 0938–ZB98

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 and Written Order Prior to Delivery List; and Updates to 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, the Required Face-to-Face and Written Order Prior to Delivery List, and the Required Prior Authorization List are effective on April 13, 2026.

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; Olufemi Shodeke, (410) 786–1649; or Cristine Egan, (410) 786–8088.

For information related to the Master List or Required Prior Authorization List, contact Emily Calvert, (410) 786–4277; Justin Carlisle, (410) 786–4265; Stephanie Collins, (410) 786–0959; (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 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 5-element order/prescription 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, and Supplies'' (80 FR 81674).

The Master List was last updated on May 13, 2024 (89 FR 41324) and currently includes 512 items. The Master list is available on the CMS website at: *http://go.cms.gov/DMEPOSPA.*

In 2024, CMS published the most recent iteration of the Required Face-to-Face Encounter and Written Order Prior to Delivery List. There are currently 75 items on the list, including 46 PMDs that were included per statute. This list is also available on the CMS website *http://go.cms/gov/DMEPOSF2F.*

The Required Prior Authorization List was last updated in 2024 and currently includes 67 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)(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 website at: *http://go.cms.gov/DMEPOSPA.*

This document provides the annual update to 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 (MFP) 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 the statutory sections 1834(a)(14), 1834(h)(4) and 1842(s)(1)(B) of the Act, certain DMEPOS fee schedule amounts are updated for calendar year (CY) 2025,[1] by the percentage increase in the CPI–U for the 12-month period ending June 30, 2024, 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 (MFP) (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. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act, was referred to by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of this change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned previously, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historically published TFP data. For CY 2025, the productivity adjustment is 0.6 percent and the CPI–U percentage increase is 3.0 percent. Thus, the 3.0 percentage increase in the CPI–U is reduced by the 0.6 percentage increase in the TFP resulting in a net increase of 2.4 percent for the update factor for CY 2025.

For CY 2025, the adjusted purchase price threshold is $602, and the adjusted monthly rental fee threshold is $61. We calculated this by applying the 2.4 percent update factor to the CY 2024 average price threshold of $588, resulting in a CY 2025 adjusted payment threshold of $602.11 ($588 × 1.024), and to the CY 2024 average monthly rental fee of $60, resulting in an adjusted payment threshold of $61.44 ($60 × 1.024). Rounding to the nearest whole dollar, these figures are $602 and $61.

We are also adding a total of 18 HCPCS codes (see Table 1) meeting the criteria outlined previously to the Master List. Of these 18 HCPCS codes, 8 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 10 are being added for aberrant billing patterns. The codes added due to aberrant billing patterns represents items for which data show suppliers submitted at least 1,000 claims and received at least $1 million in payments during the 12-month periods from July 2023 to June 2024. 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.

[1] *https://www.cms.gov/medicaremedicare-fee-service-paymentdmeposfeescheddmepos-fee-schedule/dme25.*

TABLE 1—ADDITIONS TO THE MASTER LIST

HCPCS	Description
A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service.
A6214	Foam dressing, wound cover, sterile, pad size more than 48 square inch., with any size adhesive border, each dressing.
A6233	Gauze, impregnated, hydrogel, for direct wound contact, sterile, pad size more than 48 square inch, each dressing.
A6583	Gradient compression wrap with adjustable straps, below knee, 30–50 mmhg, each.
A6593	Accessory for gradient compression garment or wrap with adjustable straps, not-otherwise specified.
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment.
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions.
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device.
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less.
E0743	External lower extremity nerve stimulator for restless legs syndrome, each.
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories.
E1399	Durable medical equipment, miscellaneous.
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver.
E2377	Power wheelchair accessory, expandable controller, including all related electronics and mounting hardware, upgrade provided at initial issue.
L1499	Spinal orthosis, not otherwise specified.
L2999	Lower extremity orthoses, not otherwise specified.
L5783	Addition to lower extremity, user adjustable, mechanical, residual limb volume management system.
L5841	Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control.

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 no HCPCS codes being removed from the Master List for the CY 2025 update.

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

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

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.

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, 75 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 eight additional HCPCS codes to the F2F/WOPD List (See Table 2). We have selected eight codes related to oxygen and its delivery systems. We note that such items were selected based on practitioner encounter information, jurisdictionally identified billing vulnerabilities, policy analysis, and our analysis of the CERT improper payment information. Oxygen Supplies/Equipment have been identified by CMS' Comprehensive Rate Testing (CERT) program as one of the top 20 DMEPOS service types with improper payments over the past several years. In 2024, oxygen supplies/equipment had an improper payment rate of 11.3% with a projected improper payment of approximately $81 million.

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

HCPCS	Description
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing.
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing.
E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge.
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing.
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing.
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate.
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each.
E1392	Portable oxygen concentrator, rental.

The F2F/WOPD List is available on the following 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 seven HCPCS codes (See Table 3). To assist stakeholders in preparing for implementation of the prior authorization program, we are providing 90 days' notice.

The following five HCPCS codes for orthoses and two HCPCS codes for pneumatic compression devices are added to the Required Prior Authorization List:

TABLE 3—ADDITIONS TO THE REQUIRED PRIOR AUTHORIZATION LIST

HCPCS	Description
L0651	Lumbar-sacral orthosis, 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.
L1844	Knee orthosis, 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, custom fabricated.
L1846	Knee orthosis, 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, custom fabricated.
L1852	Knee orthosis, 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.
L1932	Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment.
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure.
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure.

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

Orthoses have been identified by the CERT program as one of the top 20 DMEPOS service types with improper payments over the past several years. Orthoses have had an improper payment rate ranging from 35.2–57.5 percent, with projected improper payments ranging between $91 to $178 million. 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.[2] Similarly, in 2022, the DOJ convicted the owners and operators of four orthotic brace suppliers in Texas and Arkansas for a $6.5 million illegal kickback scheme, including violations of the federal Anti-Kickback Statute.[3] Also, the OIG released a report May 2024 stating that Medicare remains vulnerable to fraud, waste and abuse related to off-the-shelf orthotic braces

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

[3] *https://www.justice.gov/archives/opa/pr/orthotic-brace-suppliers-convicted-65-million-health-care-fraud-scheme.*

and recommended that CMS strengthen its oversight of Medicare billing for these braces by determining whether to conduct additional prepayment or postpayment reviews.[4] In response to the OIG's findings and recommendation, in 2022 and 2024, CMS added several lumbar-sacral orthoses and lower limb orthoses to the Required Prior Authorization list (87 FR 2051); however, additional program integrity action in this space is warranted.

In recent years, pneumatic compression devices 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 (2021 to 2024) as having improper payment rates ranging from 61.5 to 78.9 percent with projected improper payments ranging from $29,605,954 to $41,580,669. In particular, there has been a significant increase in improper payments due to medical necessity. In 2020, the error rate due to medical necessity was zero percent; however, in 2024, it was 37.1 percent, demonstrating that additional program integrity action is warranted.

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 five newly added orthoses and the two pneumatic compression devices nationwide, beginning on the date specified in the **DATES** section.

The prior authorization program for the remaining 67 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 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 18 HCPCS codes (see Table 1) meeting the criteria outlined previously are added to the Master List. Of these 18 HCPCS codes, 8 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 10 are being added for aberrant billing patterns. There are no HCPCS codes being removed from the Master List for the CY 2025 update.

Eight HCPCS codes (see Table 2) are being added to the F2F/WOPD List. The selected HCPCS codes are all related to oxygen and its delivery systems. 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 seven HCPCS codes (see Table 3) are selected for addition to the Required Prior Authorization List. Of these seven HCPCS codes, five are orthoses items, and two are pneumatic compression device items. The remaining 67 HCPCS codes currently subject to the DMEPOS prior authorization requirement, will continue uninterrupted.

There is an 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 $8.4 million for providers to comply with the prior authorization requirement.[5] 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; 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

[4] *https://oig.hhs.gov/reports/recommendations/tracker/?view-mode=report-grouped&search=A-09-21-03019&hhs-agency=all#results.*

[5] The annual burden of $8.4 million is associated with the PRA package approved in 2022. This PRA package is in the renewal process and has an updated annual burden of $4.8 million.

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 $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 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 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 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 2025, that threshold is approximately $187 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 Evell J. Barco Holland who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–00487 Filed 1–12–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 260108–0025; RTID 0648–XF259]

Atlantic Surfclam and Ocean Quahog Fisheries; 2026 Fishing Quotas for Atlantic Surfclams and Ocean Quahogs; and Suspension of Atlantic Surfclam Minimum Size Limit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS announces that the quotas for the Atlantic surfclam and ocean quahog fisheries for 2026 will remain status quo. NMFS also suspends the minimum size limit for Atlantic surfclams for the 2026 fishing year. Regulations for these fisheries require NMFS to notify the public of the allowable harvest levels for Atlantic surfclams and ocean quahogs from the Exclusive Economic Zone even if the previous year's quota specifications remain unchanged. The 2026 quotas were previously announced as projected values. This action confirms the final quotas are unchanged from those projections. This action continues to provide sustainable fishing opportunities to these fisheries.

DATES: Effective January 13, 2026, through December 31, 2026. Applicable beginning January 1, 2026.

FOR FURTHER INFORMATION CONTACT: Douglas Potts, Fishery Policy Analyst, 978–281–9341.

SUPPLEMENTARY INFORMATION: The Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP) requires that NMFS issue a notice in the **Federal Register** of the upcoming year's quota, even if the quota remains unchanged from the previous year. At its June 2025 meeting, the Mid-Atlantic Fishery Management Council (Council) recommended no change to the quota specifications for Atlantic surfclams and ocean quahogs for the 2026 fishing year. We are announcing 2026 quota levels of 3.4 million bushels (bu) (181 million Liters (L)) for Atlantic surfclams, 5.36 million bu (285 million L) for ocean quahogs, and 100,000 Maine bu (3.52 million L) for Maine ocean quahogs. These quotas were published as projected 2026 limits in the **Federal Register** on May 13, 2021 (86 FR 26186). This rule establishes these quotas as unchanged from 2021 and final.

In addition, the regulations at 50 CFR 648.75(b)(3) allow the Regional Administrator to annually suspend the minimum size limit for Atlantic surfclams unless discard, catch, and biological sampling data indicate that 30 percent or more of the Atlantic surfclams have a shell length less than 4.75 inches (121 millimeters (mm)) and the overall reduced size is not attributable to harvest from beds where growth of the individual clams has been reduced because of density-dependent factors. The default minimum size limit is intended to prevent the fishery from harvesting too many small clams such that it could harm the overall population. The size limit is unnecessary if small clams are not a significant portion of overall catch. At its June 2025 meeting, the Council reviewed recent developments in the fishery and recommended the Regional Administrator once again suspend the minimum size limit for Atlantic surfclams for the 2026 fishing year. Commercial surfclam data for 2025 indicated that 10.5 percent of the overall