

and Programs Division, at telephone 240-418-6822 or via email to colin.bennett@gsa.gov for clarification of content.

SUPPLEMENTARY INFORMATION:

A. Purpose

Federal leave law (5 U.S.C. 6304(b) and 6305) requires that employees be on defined, time-limited, foreign tours of duty as well as have agency agreements in place for return transportation. The Department of State Standardized Regulations (DSSR) covering living quarters allowance (5 U.S.C. 5923(a)(2) and DSSR 031.12) also require documented tours of duty with an agency commitment for return transportation. At GSA, the overseas tour of duty and permanent change of station commitments and requirements are contained within a single, standard agency form: GSA Form 5040, the "Overseas Employment and Service Agreement". As part of the Federal Travel Regulations (FTR) (41 CFR part 302), when an agency pays for permanent change of station the employee must commit to at least one year of subsequent agency service. This form also contains clauses that serve to create an enforceable service agreement under the FTR.

This form was first developed during 2022 and was published for public comment on February 14, 2023 (88 FR 9521) and then on June 8, 2023 (88 FR 37542). Our agency has subsequently used this form to determine leave benefits and foreign allowance eligibility, advise employees of their rights and responsibilities, and ensure that the human resources and payroll accounting records are accurate before, during and after the permanent change of station.

B. Annual Reporting Burden

Respondents: 25 per year.
Responses per Respondent: 1.
Total Annual Responses: 25.
Hours per Response: 8.
Total Burden Hours: 200.

C. Public Comments

Public comments are currently being solicited to help GSA understand whether any modifications or improvements to GSA Form 5040 are necessary, or would be beneficial, to streamline the leave and allowance eligibility approval process. Interested persons are also invited to send comments regarding: (a) whether this collection of information is necessary, (b) whether it will have practical utility, (c) whether our estimate of the public burden of this collection of information is accurate, and (d) whether or not there

might be ways to minimize the data collection burden through the use of information technology.

Obtaining Copies of Proposals: Please visit the GSA Forms Library at <https://www.gsa.gov/forms-library> to view and/or download a copy of GSA Form 5040. Requesters may obtain a copy of the information collection documents from the GSA, Regulatory Secretariat Division by emailing GSARegSec@gsa.gov. Please cite OMB Control No. 3090-0329, "Overseas Employment Service Agreement (GSA Form 5040)," in all correspondence.

Patrick Dale,

Team Lead, Regulatory Secretariat Division, General Services Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6099-N]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratoria on Enrollment of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Medical Supply Companies

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

ACTION: Notice.

SUMMARY: This notice announces the imposition of a 6-month nationwide moratorium on the Medicare enrollment of DMEPOS supplier medical supply companies.

DATES: The moratorium takes effect February 27, 2026.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786-1302.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Authority To Impose Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively known as the Affordable Care Act), Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance

Program (CHIP). One of these was section 6401(a) of the Affordable Care Act, which added a new section 1866(j)(7) to the Social Security Act (the Act). It provided the Secretary with authority to impose a temporary moratorium on the enrollment of new fee-for-service (FFS) Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines that a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs.

Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the state determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In February 2011, in accordance with the aforementioned authority, CMS published a final rule with comment period titled, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers" (76 FR 5862). This final rule implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(i) and (iv), CMS, or CMS in consultation with the Department of Health and Human Services Office of Inspector General (HHS-OIG) or the Department of Justice (DOJ) or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type or particular geographic areas or both. At § 424.570(a)(1)(ii), CMS stated that it would announce a temporary moratorium in a **Federal Register** notice that includes the rationale for the imposition of the temporary enrollment moratorium. This notice fulfills that requirement.

B. CMS' Previous Temporary Enrollment Moratoria

We first used our moratorium authority to prevent enrollment of new home health agencies, subunits, and branch locations (hereafter collectively referred to as HHAs) in Miami-Dade County, Florida and Cook County,

Illinois, as well as surrounding counties, and Part B ambulance suppliers in Harris County, Texas and surrounding counties, in a notice issued on July 31, 2013 (78 FR 46339). We exercised the moratorium authority again in a notice published on February 4, 2014 (79 FR 6475), when we extended the existing moratoria for an additional 6 months and expanded it to include enrollment of HHAs in Broward County, Florida; Dallas County, Texas; Harris County, Texas; and Wayne County, Michigan and surrounding counties, and enrollment of ground ambulance suppliers in Philadelphia, Pennsylvania and surrounding counties.

We extended these moratoria for an additional 6 months on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), July 28, 2015 (80 FR 44967), and February 2, 2016 (81 FR 5444). On August 3, 2016 (81 FR 51120), we extended the current moratoria for an additional 6 months and expanded them to statewide for the enrollment of new HHAs in Florida, Illinois, Michigan, and Texas, and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas. On August 3, 2016, we announced the lifting of temporary moratoria for all Part B emergency ambulance suppliers. Ultimately, the original 2013 moratorium, after being extended and revised several times,¹ expired on January 30, 2019.

C. Determination of the Need for Moratoria

In determining whether to establish an enrollment moratorium, CMS considers whether a high risk of fraud, waste, or abuse exists. CMS relies on its

¹ On January 9, 2017, CMS issued another notice to extend the temporary moratoria for a period of 6 months (82 FR 2363). On January 9, 2017 (82 FR 2363) and July 28, 2017 (82 FR 35122), CMS again issued a notice to extend the temporary moratoria for a period of 6 months. On September 1, 2017, CMS lifted the statewide temporary moratorium on the enrollment of new Medicare Part B non-emergency ground ambulance suppliers in Texas under the authority of § 424.570(d). This lifting of the moratorium also applied to Medicaid and CHIP in Texas. This decision was a result of the Presidential Disaster Declaration signed on August 25, 2017, for several counties in the State of Texas due to Hurricane Harvey. Upon declaration of the disaster, CMS carefully reviewed the potential impact of continued moratoria in Texas and decided to lift the temporary enrollment moratorium on non-emergency ground ambulance suppliers in Texas in order to aid in the disaster response. CMS published a formal announcement of this decision on November 3, 2017 (82 FR 51274). On January 30, 2018 (83 FR 4147), CMS announced the extension of the temporary moratoria for an additional 6 months. In August 2018, CMS announced the extension of the temporary moratoria for an additional 6 months. CMS allowed the temporary moratoria to expire on January 30, 2019.

and law enforcement's longstanding experience with ongoing and emerging fraud trends and activities gained through civil, criminal, and administrative investigations and prosecutions.

1. Consultation With Law Enforcement

The HHS–OIG over the years has highlighted the issue of DMEPOS supplier fraud, waste, and abuse in numerous reports. In February 2025, for instance, the OIG stated: “For over a decade, OIG has raised concerns about fraudulent practices among DME suppliers and has highlighted billions of dollars in potentially improper Medicare payments made to suppliers.”² We will discuss in more detail the OIG's longstanding concerns about DMEPOS fraud, waste, and abuse in section II. of this notice.

2. Data Analysis

In evaluating the need for the subject moratorium, we also used data analysis that included reviewing both current and historic Medicare enrollment and claims data. We analyzed key metrics pertaining to enrollment volume and trends for the more than 80 types of DMEPOS suppliers in the Medicare FFS program.³ We also analyzed indicators of fraud, waste, and abuse, such as the percentages of DMEPOS suppliers within each type that had a revocation of Medicare billing privileges, payment suspension based on a credible allegation of fraud or reliable indication that an overpayment exists, law enforcement referral, investigation, or benefit integrity unit (BIU) complaint since 2023. The Medicare Data Analysis section of this notice details our Medicare FFS data analysis.

3. Beneficiary Access to Care

Beneficiary access to care in Medicare, Medicaid and CHIP is of critical importance to CMS and our state partners. CMS carefully evaluated access to care for Medicare beneficiaries nationwide. We discuss our findings for Medicare beneficiaries in the Beneficiary Access to Care section later in this notice. We also discuss the issue of Medicaid and CHIP beneficiary access in the Application to Medicaid

² <https://www.oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000908.asp>.

³ These types are listed on the Form CMS–855S (Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB Control No. 0938–1056) (<https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms019480>). DMEPOS suppliers enroll in Medicare via the Form CMS–855S.

and Children's Health Insurance Program (CHIP) section of this notice.

4. When a Temporary Moratorium Does Not Apply

Under § 424.570(a)(1)(iii), a temporary moratorium does not apply to any of the following:

- Changes in practice location (except if the location is changing from a location outside the moratorium area to a location inside the moratorium area).
- Changes in provider or supplier information, such as phone number or address.
- Changes in ownership (except changes in ownership of home health agencies that would require an initial enrollment).

Also, in accordance with § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.

5. Lifting a Temporary Moratorium

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS remains in effect for 6 months. If CMS deems it necessary, the moratorium may be extended in 6-month increments. CMS evaluates whether to extend or lift the moratorium before the end of the initial 6-month period and, if applicable, before the expiration of any subsequent moratorium periods. If the moratorium announced in this notice is extended, CMS will publish a document regarding such extension(s) in the **Federal Register**.

As provided in § 424.570(d), CMS may lift a moratorium at any time if: (1) the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act; (2) circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability; (3) the Secretary has declared a public health emergency; or (4) in the judgment of the Secretary, the moratorium is no longer needed. Once a moratorium is lifted, the provider or supplier types that were unable to enroll because of the moratorium will be assigned to the “high” screening level in accordance with §§ 424.518(c)(3)(iii) and 455.450(e)(2) if such provider or supplier applies for enrollment at any time within 6 months from the date the moratorium was lifted.

II. National DMEPOS Medical Supply Company Moratorium

Under its authority at § 424.570(a)(2)(i) and (a)(2)(iv), CMS is implementing a nationwide temporary moratorium on the Medicare enrollment of medical supply company DMEPOS suppliers nationwide. In this section, we explain the rationale for and scope of this moratorium.

A. Longstanding Program Integrity Problems Within the Overall DMEPOS Supplier Sphere

As we explained at length in the Calendar Year (CY) 2026 Home Health Prospective Payment System (HH PPS) proposed rule⁴ (published in the July 2, 2025, **Federal Register** (90 FR 29108)), DMEPOS fraud, waste, and abuse has been a very serious problem for many years, putting hundreds of millions (even billions) of taxpayer dollars at risk and potentially resulting in patient harm, such as in cases where beneficiaries use unnecessary or substandard items. Indeed, numerous OIG reports since 1998 have outlined payment safeguard issues associated with DMEPOS suppliers as a whole. For example, in 2024 the OIG stated: “Although CMS has a number of safeguards in place to prevent bad actors from billing DMEPOS in Medicare, fraudulent billing for DMEPOS continues to be a major concern. Recent cases demonstrate that DMEPOS continues to be a target of fraudulent billing and that new schemes have developed.”⁵ In fact, the OIG has several pending DMEPOS-focused studies based on concerning trends and the high risk of fraud, waste, and abuse historically associated with this supplier type:

- OEI-02-24-00311: White Paper: Fraud, Waste, and Abuse Related to Durable Medical Equipment in Medicare (Expected FY 2026).⁶

- OEI-03-25-00080: CMS’s Use of Surety Bonds To Protect Medicare Part B From Overpayments to Durable

Medical Equipment Suppliers (expected FY 2026).⁷

- OEI-02-24-00310: Durable Medical Equipment Fraud and Safeguards in Medicare (expected FY 2026).⁸

- SRS-A-25-030: Audits of the Medicare Enrollment Screening Process for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (expected FY 2027).⁹

Considering the wide and ever-changing range of payment safeguard risks associated with DMEPOS suppliers, we have taken and will continue to take measures to address them.

B. Specific Concerns About Medical Supply Companies and Certain Types of Supplies

DMEPOS fraud schemes do not necessarily follow a consistent pattern but can vary widely in their particular facts. Too, DMEPOS fraud, waste, and abuse is not restricted to certain types of items or particular areas of the country but occurs with numerous different product types and in many geographic areas. Both CMS and the OIG have, though, seen particular issues with certain types of DMEPOS suppliers and supplies.

As an illustration, the OIG in May 2024 issued a report titled “Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees” (A-09-21-03019). The report noted that prior OIG reviews identified vulnerabilities associated with orthotic braces, such as: (1) questionable DMEPOS supplier billing practices; (2) improper payments made for braces that were not medically necessary or were not documented; and (3) fraud related to off-the shelf (OTS) braces.¹⁰ The May 2024 report also cited issues related to Medicare’s oversight of OTS braces, including the following:

- Medicare paid for OTS braces that were—

- ++ Ordered by suppliers that did not have treating relationships with beneficiaries; and

- ++ Marketed to beneficiaries by telemarketers using prohibited direct solicitation.

- Payments to suppliers for fraudulently billed OTS braces have cost Medicare millions of dollars.¹¹

Given these issues, the OIG recommended that CMS analyze DMEPOS supplier billing patterns, identify emerging fraud schemes related to OTS braces, and use CMS’s authority to prevent further losses to the Medicare program.¹² Significantly, for purposes of this CMS notice, this included using DMEPOS billing patterns to determine, in part, whether to impose a temporary moratorium on enrolling new DMEPOS suppliers of OTS braces.¹³

Another OIG report cited in the CY 2026 HH PPS proposed rule (90 FR 29108), titled “Medicare Improperly Paid Suppliers for Intermittent Urinary Catheters” (A-09-22-03019), was released in February 2025. Citing the ongoing risk of improper payments, the OIG performed a nationwide audit to determine whether Medicare paid suppliers for catheters consistent with Medicare requirements for catheters furnished to beneficiaries between July 2021 through June 2022.¹⁴ The OIG found that payments for 15 sample items did not comply with Medicare requirements, in some cases because suppliers were non-compliant with requirements for catheter refills, proof of delivery, or a standard written order; this resulted in approximately \$35.1 million in improper payments.¹⁵ Even before this report, though, CMS in early 2023 had identified a concerning rise in urinary catheter billings attributed to a fraud scheme involving 15 DMEPOS companies that had recently changed ownership. CMS’ own investigation of this matter determined that: (1) Medicare beneficiaries did not receive catheters from these DMEPOS companies and were not billed directly; (2) physicians did not order these supplies; and (3) the supplies were not needed.¹⁶ Although CMS took prompt action to address this matter, including stopping payments from being made to these suppliers and revoking the Medicare enrollments of all 15

⁴ “Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies. The CY 2026 HH PPS rule contained a number of DMEPOS related provisions” (90 FR 29199 through 29201).

⁵ <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000867.asp>.

⁶ <https://www.oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000939.asp>.

⁷ <https://oig.hhs.gov/reports/work-plan/browse-work-plan-projects/cmss-use-of-surety-bonds-to-protect-medicare-part-b-from-overpayments-to-durable-medical-equipment-suppliers/>.

⁸ <https://www.oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000867.asp>.

⁹ <https://oig.hhs.gov/reports/work-plan/browse-work-plan-projects/srs-a-25-030/>.

¹⁰ <https://oig.hhs.gov/reports/all/2024/medicare-remains-vulnerable-to-fraud-waste-and-abuse-related-to-off-the-shelf-orthotic-braces-which-may-result-in-improper-payments-and-impact-the-health-of-enrollees/#:~:>

¹¹ *Ibid.* pp. 7–12.

¹² *Ibid.*, p. 13.

¹³ HHS–OIG report A-09-21-03019: “Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees” (page 15) May 2024. <https://oig.hhs.gov/documents/audit/9902/A-09-21-03019.pdf>.

¹⁴ <https://oig.hhs.gov/reports/all/2025/medicare-improperly-paid-suppliers-for-intermittent-urinary-catheters/>.

¹⁵ *Ibid.*

¹⁶ *Ibid.*

suppliers, both the OIG report and our investigation underscored the program integrity issues in the DMEPOS arena.¹⁷

There have also been a considerable number of criminal convictions and other findings over the last several years involving DMEPOS suppliers. We included a non-exhaustive list of such recent cases in the CY 2026 HH PPS proposed rule (90 FR 29199–29201). We restate several here, each of which involved medical supply company specialties:

- A California woman was sentenced in December 2023 to 15 years in prison for billing Medicare for over \$24 million by submitting fraudulent claims for medically unnecessary DME—mostly power wheelchairs (PWC)—and PWC repairs. As the *de facto* owner of two DMEPOS supplier companies (both of which were Medicare-enrolled in the names of her out-of-state relatives), the individual orchestrated a scheme in which she paid marketers for patient referrals and then directed them to take patients to physicians, who prescribed medically unnecessary DMEPOS (including PWCs) that her companies used to submit fraudulent claims to Medicare. Two other defendants were convicted in this case, including one who worked at both DMEPOS companies as a repair technician.¹⁸

- In September 2023, a federal district court entered a judgment against a Virginia DMEPOS supplier for damages and penalties under the False Claims Act for over \$12 million. In its complaint filed in district court, the United States alleged that over a nearly 6-year period, Medicare paid the supplier over \$600,000 for medical braces furnished to Medicare beneficiaries related to DMEPOS prescriptions that the supplier illegally purchased from marketing companies. The DMEPOS supplier paid a fee for each prescription that it purchased and then used these prescriptions (along with personal and medical data provided by the marketing companies) to submit 923 fraudulent Medicare claims.¹⁹

- A California father and son in March 2024 were sentenced to prison for their roles in fraudulently receiving over \$21 million in Medicare payments. The pair, along with others, conspired to commit Medicare fraud by billing for medically unnecessary DME, such as knee, ankle, shoulder, wrist and back

braces. They had established two DMEPOS supplier companies; to find customers, they entered into sham agreements with “marketing” companies that, instead of marketing, provided information about Medicare beneficiaries for \$125 to \$350 each. The packets included, among other things, a signed prescription from a physician (obtained via telemedicine) claiming that the brace was medically necessary for the beneficiary. Yet, in almost all cases, the physician signing the prescription had no previous doctor-patient relationship with the beneficiary. The two men then billed Medicare through their DMEPOS companies for the unnecessary items.²⁰

- A Texas man was sentenced to prison in February 2024 for conspiring to pay health care kickback payments for unnecessary DME, resulting in over \$20 million in claims to—and \$13 million in payments from—the Medicare program. The individual owned and operated two DMEPOS suppliers. Through another entity, the individual secured access to thousands of Medicare beneficiaries’ information by paying, on a weekly basis, kickbacks in exchange for signed physician orders for the braces.²¹

- In August 2023, a Florida man was sentenced to prison for conspiring to defraud the Medicare program. The individual and another person illegally paid kickbacks of over \$565,000 to buy fraudulent DMEPOS orders, including orders purportedly “signed” by physicians who, in fact, never signed or authorized these orders and did not know their names and identities were being used in this manner. They also resold some of the fraudulent orders to other DMEPOS suppliers—receiving more than \$425,000 in proceeds—so that those suppliers, in turn, could fraudulently bill Medicare for DMEPOS items. Furthermore, the two individuals acquired five of their own fraudulent DMEPOS supply companies and themselves used fraudulent DMEPOS orders to file more than \$11 million in fraudulent Medicare claims.²²

- Several DMEPOS suppliers in January 2024 agreed to pay \$2.1 million to resolve allegations that they violated the False Claims Act by submitting false claims for payment to Medicare and other federal health care programs. The

settlement resolved allegations that over a 9-year period, the companies:

- ++ Sold used beds but billed federal health care programs as if they were new beds.

- ++ Sold various hospital beds and pressure support surfaces to beneficiaries of federal health care programs under a miscellaneous code, which sometimes resulted in the federal program paying a higher price.

- ++ Presented claims to the federal government and its contractors that mischaracterized travel time as DMEPOS repair time in order for it to be reimbursable by federal health care programs.²³

- A Florida man was sentenced to 87 months in prison in September 2022 for his role in using a DMEPOS company to commit Medicare and Medicaid fraud. Having established the company, he sought to conceal his role as its true owner who exercised control over the company (and the fraud) by listing a nominee or “straw” owner as the owner on its corporate records and bank account. The individual admitted that he—and not a straw owner—bought lists of Medicare “patients” and then directed a “biller” to submit fraudulent claims to Medicare for DMEPOS that a physician did not prescribe, that were not medically necessary, and that were not being supplied to any Medicare beneficiary or Medicaid recipient. During a 3-month period—and under the individual’s direction—the supplier submitted over \$2.3 million in fraudulent claims to Medicare and Medicaid and was paid over \$1.6 million. The proceeds of the fraud were transferred from the supplier’s account to accounts held in the names of shell companies. Those proceeds were then withdrawn from the shell company accounts by others so they could not be traced to the individual.²⁴

- A South Carolina man was sentenced to 9 years in prison in March 2024 for his role in a nearly \$100 million healthcare fraud scheme. The individual controlled and operated at least 10 DMEPOS companies located throughout the United States. The person and his conspirators used these companies to submit false and fraudulent claims to Medicare for braces that were not medically necessary and/or were obtained through the payment of kickbacks and bribes. Specifically, the companies entered into agreements with an offshore, advertised call center

¹⁷ <https://www.justice.gov/usao-sdca/pr/father-and-son-duo-sentenced-prison-21-million-dollar-medicare-scheme>.

¹⁸ <https://www.justice.gov/usao-cdca/pr/redondo-beach-woman-sentenced-15-years-prison-leading-24-million-scam-billed-medicare>.

¹⁹ <https://www.justice.gov/usao-edva/pr/virginia-medical-equipment-provider-ordered-pay-12-m-medicare-fraud-scheme-civil>.

²⁰ <https://www.justice.gov/usao-sdny/pr/florida-business-owner-sentenced-five-years-prison-defrauding-medicare-more-11-million>.

²¹ <https://www.justice.gov/usao-sc/pr/durable-medical-equipment-companies-pay-millions-false-claims-settlement>.

²² <https://www.justice.gov/usao-sdfl/pr/miami-man-who-used-durable-medical-equipment-company-front-health-care-fraud-sentenced>.

to purchase physicians' orders so the DMEPOS companies could bill Medicare. When a Medicare beneficiary called the applicable 1–800 number, the beneficiary would be screened for eligibility and then convinced that the beneficiary needed a brace and oftentimes upsold on other braces. The call center would then contact a telemedicine company whose physician or nurse practitioner would issue a prescription without regard to the medical necessity. Beneficiaries were prescribed braces without ever being examined by, seeing, or, in some instances, even speaking to a medical professional.²⁵

Elderly diabetics have also been a target for DMEPOS suppliers. For example, a Florida diabetic shoe company and its president agreed in January 2022 to pay over \$5.5 million to settle claims brought under the False Claims Act that it sold custom diabetic shoe inserts that were not actually custom-fabricated in accordance with Medicare standards. The company billed Medicare for the custom version or sold the inserts to other providers who then billed Medicare, which allowed the company to produce and sell more inserts and increase profits by “cutting corners.”²⁶

C. Consultation With Law Enforcement and Moratorium Determination

In light of these concerns, pursuant to our consultations with both the OIG and the Department of Justice under § 424.570(a)(2)(iv) regarding a DMEPOS moratorium, and as outlined in greater detail in the Data Analysis section of this notice, CMS has determined that medical supply companies have significant potential for fraud, waste or abuse. Accordingly, and also given the recent nationwide trends of OIG and DOJ investigating and charging owners of DMEPOS suppliers across the country for fraudulent billing schemes, we believe that a moratorium on the enrollment of medical supply companies into Medicare could assist in stemming this activity.

We recognize that a moratorium under § 424.570 only applies to newly enrolling providers and suppliers, and that currently enrolled medical supply companies under our initiative will be largely unaffected unless they are opening a new location in the moratorium area. (As each DMEPOS supplier location must be separately and

individually enrolled in accordance with § 424.57(b)(1), enrolling a new location is considered an initial enrollment.) Yet preventing medical supply company fraud, waste, and abuse requires a wide-ranging and comprehensive approach involving multiple components, not merely one or two. By blocking the initial enrollments of these very high-risk supplier types, we can help prevent the aforementioned problems from worsening. This, in turn, would complement other means we have in place to address program integrity issues involving enrolled medical supply companies (for example, site visits, requiring surety bonds and annual reaccreditation, etc.)

D. Scope of DMEPOS Medical Supply Company Moratorium

Beginning on the effective date of this notice, no new DMEPOS suppliers of the following seven types (as well as no new practice locations of these seven types) will be enrolled into Medicare unless the supplier's enrollment application was received by the applicable Medicare contractor prior to this notice's effective date; geographically, the moratorium applies to suppliers of these seven types seeking to enroll anywhere in the United States, including all states, territories, and the District of Columbia. Said types are included in the moratorium due to a significant potential for fraud, waste, and abuse. The seven supplier types are as follows:

- Medical supply company.
- Medical supply company with orthotics personnel.
- Medical supply company with pedorthic personnel.
- Medical supply company with prosthetics personnel.
- Medical supply company with prosthetic and orthotic personnel.
- Medical supply company with registered pharmacist.
- Medical supply company with respiratory therapist.

Exclusively for purposes of the moratorium's applicability, a medical supply company is considered a business whose principal function is to furnish DMEPOS supplies (regardless of supply type) directly to another party, such as, but not limited to: (1) beneficiaries with a medical order (for example, via mail order); (2) medical providers and suppliers; or (3) both. As an illustration, a grocery store's, pharmacy's, or inpatient or outpatient medical provider's principal function is typically not the provision of DMEPOS. It is instead, for instance, the selling of food or toiletries, the dispensing of medicines, the direct provision of

medical care (such as a hospital, HHA, physician's office), etc. Hence, the moratorium would generally not apply to these DMEPOS suppliers.

For those previously referenced medical supply types requiring specific personnel (for example, prosthetics personnel), the supplier—again, for moratorium purposes only—has at least one such individual serving in an employment, advisory, contractual, or other role; thus, a “medical supply company with orthotics personnel” would be a medical supply company with at least one orthotic professional in one of the roles noted previously (such as advisory).

We emphasize that CMS will very closely screen all DMEPOS supplier applications submitted during the moratorium to ensure that the supplier is not a medical supply company. This will include, but not be limited to, site visits and online research of the business. We also note that under § 424.530(a)(4) and (f), we have the authority to deny enrollment and impose a reapplication bar of up to 10 years for a provider's or supplier's submission of false or misleading information on (or omission of information from) the enrollment application in order to gain enrollment in the Medicare program. We have similar grounds for revoking a provider's enrollment for the submission of false or misleading information, and under § 424.535(a) we can impose a reenrollment bar of up to 10 years. We thus caution medical supply companies that any attempt to circumvent the moratorium by enrolling as another DMEPOS supplier type could lead to the supplier being: (1) effectively banned from Medicare for many years; and (2) as indicated in § 424.530(a)(4) and on the Form CMS–855S certification statement, subject to referral to the OIG for investigation and possible criminal, civil, or administrative penalties.

Furthermore, we note that under § 424.551, a DMEPOS supplier that undergoes a non-exempt change in majority ownership (CIMO) within 36 months of its initial enrollment (or within 36 months of its most recent CIMO) must enroll in Medicare as a brand new supplier, undergo a survey, and become newly accredited. The supplier's current enrollment is terminated. This means that the supplier's new enrollment is an initial enrollment no less than if the supplier had never enrolled in Medicare before. Hence, our moratorium would prohibit the supplier in this § 424.551 situation from reenrolling in Medicare because, again, it would constitute an initial

²⁵ <https://www.justice.gov/usao-sc/pr/mt-pleasant-man-sentenced-nine-years-federal-prison-role-one-largest-medicare-fraud>.

²⁶ <https://www.justice.gov/usao-sdfl/pr/diabetic-shoe-company-agrees-pay-55-million-resolve-false-claims-act-allegations>.

enrollment; the supplier is “new.” The aforementioned moratorium exemption under § 424.570 for changes of ownership does not apply to such a scenario.

E. Application to Medicaid and CHIP

Section 1866(j)(7) of the Act authorizes imposition of a temporary enrollment moratorium for Medicare, Medicaid or CHIP if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either program. The Secretary is not required to impose a particular moratorium on all three programs. The statutory discretion noted previously affords the Secretary the opportunity to impose a moratorium on any combination of the three programs or one program alone.²⁷

At this time, we believe it is in the best interest of Medicaid and CHIP beneficiaries across the country to allow each state to decide whether some form of a DME moratorium is appropriate for their respective Medicaid and CHIP programs, and the scope of any such moratorium. Each state has greater expertise and experience with their pool of DME provider types—including the requirements for each type of DME provider—than CMS. Nevertheless, CMS encourages each state to, as appropriate, implement a DME provider moratorium tailored to the specifics of their beneficiary population as well as any geographic considerations. Additionally, CMS is offering every state and territory the opportunity to consult with CMS on the prospect of implementing a Medicaid- or CHIP-based (or both) DME moratorium in their jurisdictions.

F. Data Analysis

1. Medicare

Our review of Medicare payment and enrollment data supports the need for a national moratorium on medical supply

²⁷ The aforementioned February 2, 2011, final rule also established new Medicaid regulations at 42 CFR part 455, subpart E, including § 455.470, which implements the moratoria authority under section 1902(kk)(4) of the Act. In a similar vein, that final rule implemented § 457.990, providing that part 455, subpart E applies to CHIP in the same manner as it applies to Medicaid. Under § 455.470(a)(1) through (3), the Secretary may impose a temporary moratorium, in accordance with § 424.570, on the enrollment of new providers or provider types after consulting with any affected State Medicaid agencies. The State Medicaid agency will impose a temporary moratorium on the enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program unless the state later determines that the imposition of a moratorium would adversely affect Medicaid beneficiaries' access to medical assistance and so notifies the Secretary in writing.

companies. As background, CMS data indicates that small DMEPOS suppliers drive overall Medicare DMEPOS payments despite serving roughly the same number of beneficiaries as large suppliers.²⁸ In fact, data from 2023 to 2025 reflects that about 85 percent of DMEPOS supplier payments from 2023 to present went to small DMEPOS suppliers. Further, within the category of small DMEPOS suppliers, ‘medical supply company’ suppliers account for the majority of Medicare FFS payments from 2023 to October 2025. During that same period, medical supply company specialties (medical supply company, medical supply company with orthotics personnel, etc.) had a 17 percent revocation rate, meaning that 17 percent of these suppliers eventually had their Medicare enrollments revoked. This is nearly triple the rate for other DMEPOS supplier types. Yet the higher prevalence of program integrity issues associated with medical supply companies compared to other DMEPOS supplier types is not limited to revocation rates. Medical supply companies also had higher payment suspension, law enforcement referral, and BIU complaint rates from 2023 through late October 2025 than other DMEPOS supplier types. Consider the following:

- The 7 types of medical supply companies listed in section II.D. of this notice were all in the top 20 out of over 80 DMEPOS supplier specialty types when looking at the highest percentage of DMEPOS suppliers of a specific specialty type that were revoked at least once since 2023.
- Five of the 7 types of medical supply companies were in the top 10 when reviewing the highest percentage of DMEPOS suppliers with a payment suspension since 2023.
- Six of the 7 types of medical supply companies were in the top 10 when examining the highest percentages of law enforcement referrals since 2023.
- All 7 types were in the top 15 when looking at the highest percentage of BIU complaints for each DMEPOS supplier type since 2023.

Of the nearly 80,000 DMEPOS suppliers enrolled in Medicare as of October 2025, medical supply companies are one of the largest categories with more than 6,000 enrollments, or 7.5 percent of the national DMEPOS supplier universe. (Though the number varies by year, approximately 600 medical supply

²⁸ Within the context of CMS's data review, large DMEPOS suppliers are those with a tax identification number (TIN) that is associated with 25 or more Medicare FFS enrollments. All other DMEPOS suppliers are small suppliers.

companies enroll in Medicare each year (or 300 over a 6-month period)).

Establishing a moratorium on medical supply companies will simultaneously help address the heart of DMEPOS fraud while still maintaining a large pool of—

- Medical supply companies (that is, over 6,000 that are currently enrolled); and
- Non-medical supply company DMEPOS suppliers (for example, pharmacies) that are either presently enrolled or can newly enroll/open new practice locations.

Explained otherwise, the moratorium will only impact prospective newly enrolling medical supply companies in one of the aforementioned seven categories. As discussed in more detail later in this section, there is already an adequate nationwide quantity of such suppliers. Therefore, we do not foresee shortages or access to care issues arising from the moratorium. In addition, beneficiaries who do not receive supplies directly from a medical supply company (for example, the patient receives supplies from the hospital at which the individual is an inpatient) will not be impacted; again, the ability of a variety of DMEPOS supplier types to continue to open new locations (for example, pharmacies) minimizes any concerns pertaining to limiting beneficiary access-to-care. Moreover, because many DMEPOS items are delivered across state borders via mail orders, we have less concern with a medical supply company/DMEPOS moratorium than other provider or supplier types.

2. Orthotic Brace Codes on the Master List of DMEPOS Items

CMS publishes a “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”).²⁹ The Master List is a library of items that have been identified as potential vulnerabilities to the Trust Funds 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-

²⁹ See the November 18, 2019, final rule titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements” (84 FR 60648) and also 42 CFR 410.38.

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. In general, some of this criteria include that the DMEPOS item has—

- An average purchase fee of \$500 in the DMEPOS fee schedule or a \$50 monthly rental cost, subject to annual adjustments; and
- Been identified as having a high rate of potential fraud or unnecessary utilization in an OIG or Government Accountability Office report that is national in scope and published in 2015 or later—or listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate.

The DMEPOS Master List also includes 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 patterns³⁰ and lack explanatory contributing factors (for example, new technology or coverage policies).

The orthotic braces on the Master List are items that are susceptible to fraud, waste, and abuse based on multiple factors. There are currently 32 braces that fall into the category of prefabricated braces. Nine of those 32 braces also fall into the category of OTS braces, the same class of braces highlighted as a major risk for fraud, waste, and abuse in the OIG’s 2024 report on OTS orthotics fraud, waste, and abuse.³¹ Per CMS billing data from CY 2023 through late October 2025 for the 32 Healthcare Common Procedure Coding System (HCPCS) Level II codes at issue, medical supply companies submitted more than 70 percent of the more than 2.1 million claim lines for the 32 prefabricated orthotic brace codes on the Master List. With respect to the most problematic category of braces—the OTS variety—medical supply companies submitted more than 80

percent of the more than 1.5 million claim lines submitted by DMEPOS suppliers between 2023 and late October 2025. This data regarding the highest risk orthotic braces—namely those on the Master List—complemented our other fact gathering that pointed toward a nationwide medical supply company DMEPOS moratorium.

3. Medicaid and CHIP

As previously discussed, at this time we believe it is in the best interests of Medicaid and CHIP beneficiaries and the states to delegate to each state the decision as to whether a DME moratorium is appropriate for that state. CMS encourages states to, where appropriate, implement a DME provider moratorium tailored to the specifics of their beneficiary population, as well as any geographic considerations. Accordingly, we did not perform a Medicaid and CHIP data analysis as part of this moratorium initiative.

G. Beneficiary Access to Care

With more than 79,000 DMEPOS suppliers of all types currently approved nationwide, CMS data analysis indicates that the current supplier network adequately supports beneficiary needs without compromising access or the quality of care. Indeed, access to care appears strong on state and local levels. Two other considerations indicate that our moratorium will not negatively impact Medicare beneficiary access-to-care. First, only seven medical supply company types of DMEPOS suppliers will be subject to the moratorium. Pharmacies, physicians, hospitals, physical therapists, and other DMEPOS supplier types will remain able to open new practice locations throughout the country. If a need arises in a particular geographic location, a variety of DMEPOS supplier types can potentially fill the gap. Second, many categories of DMEPOS supplies can be shipped via mail order, even across the country. Mail order DMEPOS services are common today and can help alleviate limitations on medical supply companies not being able to open new locations during the moratorium.

Given all the foregoing, we do not believe a nationwide medical supply company moratorium will substantially limit Medicare beneficiary access to care.

III. No Judicial Review of CMS’s Decision To Impose an Enrollment Moratorium

In accordance with section 1866(j)(7)(B) of the Act, there is no

judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. CMS under §§ 424.530(a)(10) and 424.570(c) denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. However, § 424.514(d)(2)(v)(C) states that if the provider or supplier was required to pay an application fee, the fee will be refunded if the application is denied because of the imposition of a moratorium. A provider or supplier that is impacted by a moratorium also may use the existing procedures at 42 CFR part 498 to administratively appeal such denial based on the moratorium; under 42 CFR 498.5(l)(4), though, the scope of any such appeal would be limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Regulatory Impact Statement

A. Statement of Need

This notice is necessary to help reduce the prevalence of Medicare fraud, waste, and abuse among DMEPOS medical supply companies.

B. Overall Impact

We have examined the impacts of this notice as required by E.O. 12866, “Regulatory Planning and Review”; E.O. 13132, “Federalism”; E.O. 13563, “Improving Regulation and Regulatory Review”; E.O. 14192, “Unleashing Prosperity Through Deregulation”; and the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 through 612; section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995; 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; and distributive impacts). Based on our analysis, the Office of Information and Regulatory Affairs (OIRA) has determined that this

³⁰ 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: (A) Double the percent change of all DMEPOS claim payments for items that meet the aforementioned claim and payment criteria, from the preceding 12-month period; or (B) Exceeding a 30 percent increase in payment.

³¹ HHS–OIG report A–09–21–03019: “Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees” May 2024. A–09–21–03019.pdf.

notice is not significant pursuant to section 3(f)(1) of Executive Order 12866. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget. In accordance with Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this notice does not meet the criteria for a major rule as defined in 5 U.S.C. 804(2).

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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 RFA provisions at 5 U.S.C. 604. 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 and has fewer than 100 beds. This notice is primarily applicable to DMEPOS suppliers, not rural hospitals. Therefore, the Secretary has certified that this notice will not have a significant economic impact on the operations of small rural hospitals.

We expect savings to the Medicare program from the reduction in the number of newly enrolling medical supply companies. However, we do not have data upon which to base an estimate of the amount of savings.

C. Regulatory Flexibility Analysis (RFA)

1. Small Business Impact

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organization, and small governmental jurisdictions. Most entities and most other providers and suppliers are small entities, either by nonprofit status or by having revenues less than \$37.5 million to \$41 million in any 1 year. Individuals and states are not included in the definition of a small entity. For several reasons, we do not believe that our DMEPOS moratorium will have a significant economic impact on a substantial number of small businesses.

First, in 2025 there were 79,360 approved DMEPOS supplier Medicare enrollments, representing an 8.3 percent decrease since 2023. This reflects a consolidating but mature market. The consolidation of the DMEPOS marketplace reflects a certain level of saturation, whereby the number of currently enrolled DMEPOS suppliers can meet the demand for items/supplies from the Medicare beneficiary

population. As of October 2025, over 6,000 of the nearly 80,000 approved DMEPOS suppliers are medical supply companies. We believe that most small medical supply companies in this sector are already enrolled. Hence, the moratorium would not directly harm their ongoing operations. All currently enrolled medical supply companies could continue billing Medicare and operating normally. Once the medical supply company moratorium is in effect, we anticipate that small businesses hoping to establish themselves as medical supply companies will be able to pivot to other sectors.

Second, even though some small businesses hoping to enroll in Medicare as medical supply companies will be impacted, many other small businesses can still enroll as a different type of DMEPOS supplier; for example, over 30 percent of all retail pharmacies in the United States are believed to be independent community pharmacies. While not necessarily purely equivalent to small businesses, independent pharmacies stand as a sound proxy for the concept of a small business in the pharmacy space. Moreover, the number of potentially impacted medical supply companies is miniscule—very far from substantial—when compared to the well over 2 million Medicare providers and suppliers, many of which are small businesses.

Third, even though some small businesses will be impacted by the moratorium, the risk to the Medicare Trust Funds and Medicare beneficiaries by nefarious medical supply companies, small or large, is too great to warrant refraining from this moratorium. The negative effect on some small businesses that seek to enter the program as a medical supply company is outweighed by the benefit of protecting the Trust Funds, beneficiaries, and the taxpayers from substantial fraud, waste, and abuse.

2. Alternatives Considered

There are three principal alternatives we considered in preparing this notice. First, we considered forgoing a moratorium entirely. Yet the ongoing, serious problem of DMEPOS fraud, waste, and abuse requires measures beyond those that CMS currently utilizes; indeed, while these measures have certainly been helpful, the issue of DMEPOS program integrity remains. Second, we contemplated a moratorium on all DMEPOS supplier types. We chose not to because this could unnecessarily impact certain DMEPOS supplier types that are not typically among the highest risk sub-types. Third,

we considered limiting the moratorium to certain states. We believe, though, that the problems the moratorium seeks to address are nationwide rather than restricted to particular geographic areas.

D. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA of 1995 UMRA 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 \$187 million. This notice will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than \$187 million in any one year.

E. State and Local Costs

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

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.

[FR Doc. 2026-03971 Filed 2-25-26; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of