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DMEPOS

Hot Button Legal Issues Facing DME Suppliers Over the Next 12 Months

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Introduction

Introduction

- The DME industry has been in existence since the 1970s.
- For many years, Capitol Hill and CMS did not focus on the DME industry.
- This began to change in the late 1990s.
- In an effort to control costs, there is an emphasis on patients receiving as much health care as possible in their homes.
- This emphasis became more important during the pandemic; and the DME industry has shone brightly during the pandemic.
- Success depends on identifying the key issues DME suppliers can expect to face over the next 12 months and being prepared to respond to these issues.
- This webinar addresses those key issues.

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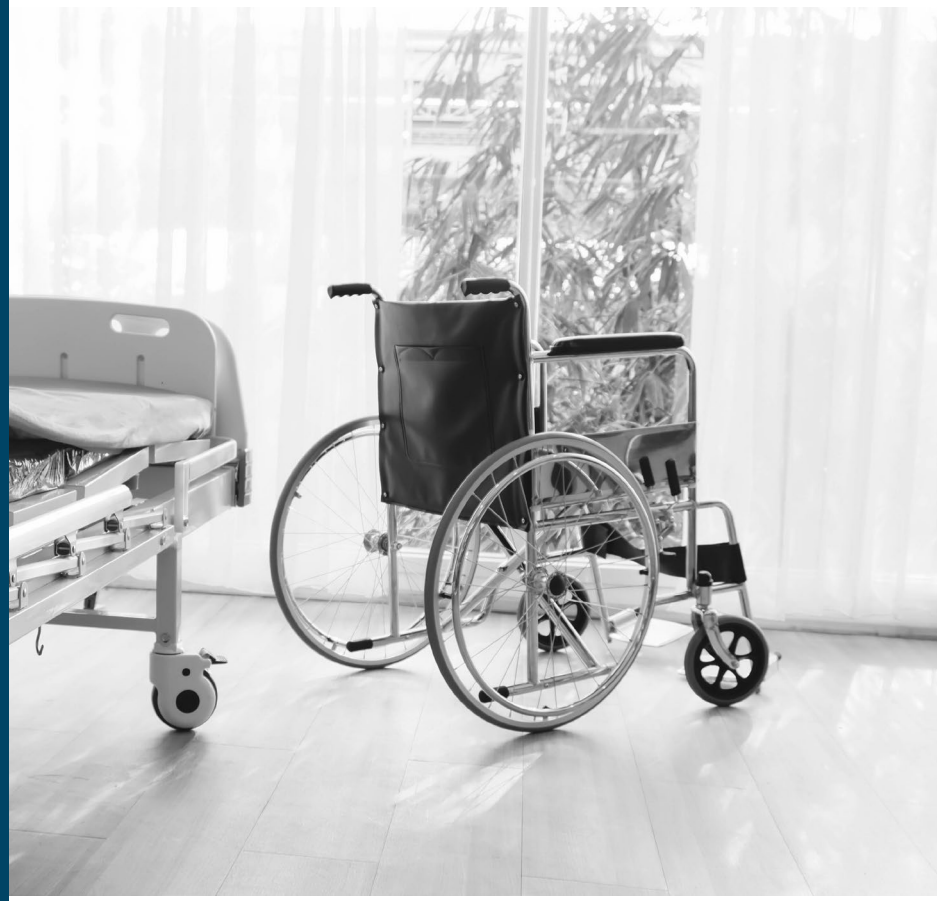
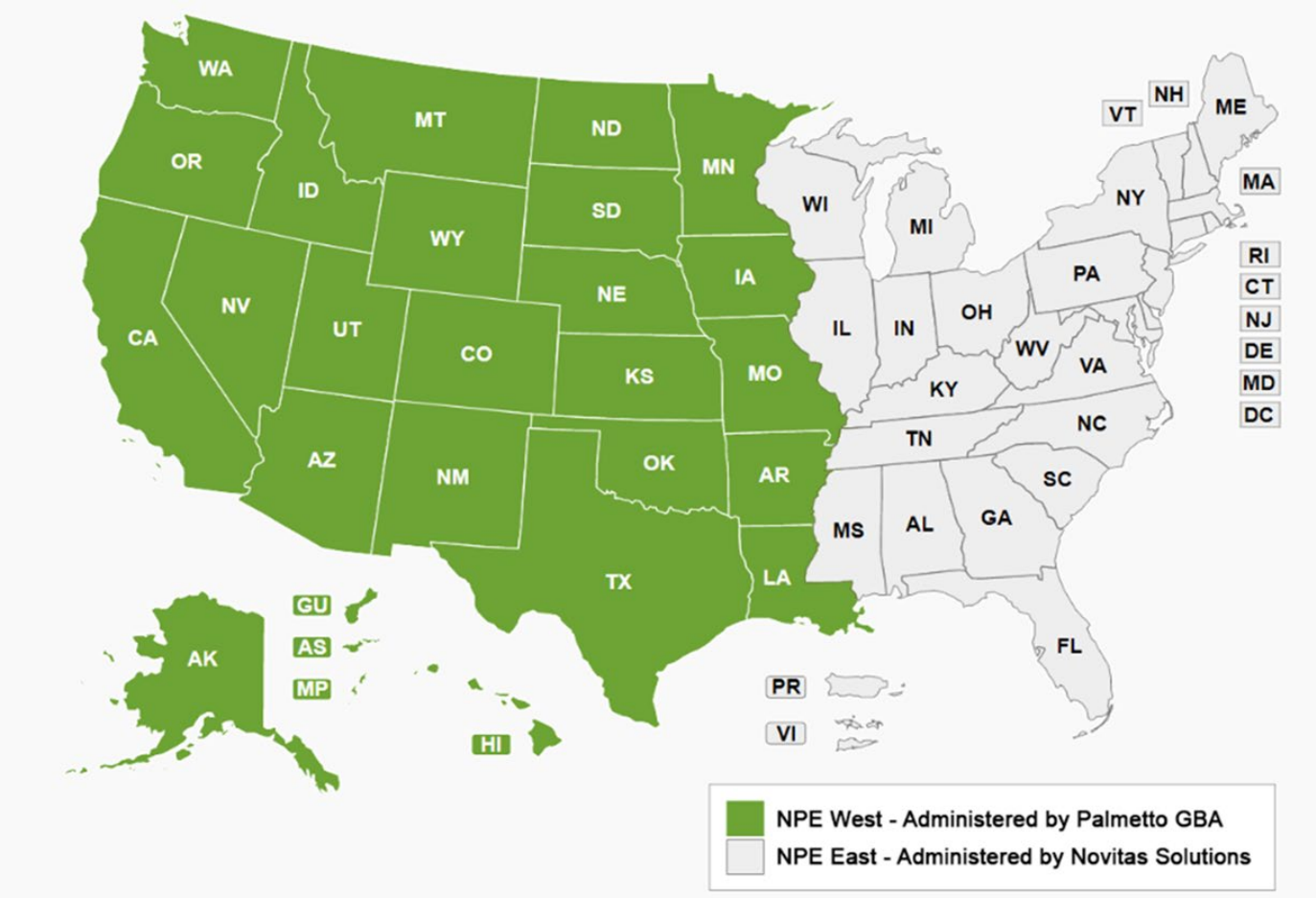
Provider Enrollment Changes



Provider Enrollment Changes

- From one contractor to five
  - ONE
    - National Supplier Clearinghouse (NSC)
  - FIVE
    - NPE East
    - NPE West
    - Palmetto GBA
    - Deloitte Consulting
    - C-HIT

NPE Contractors



Provider Enrollment Appeals & Rebuttals Contractor (PEARC)

- Effective October 9, 2023
- PEARC
  - Chags Health Information Technology, LLC (C-HIT)
- Responsible for processing all provider enrollment related appeals including:
  - Corrective Action Plan
  - Reconsideration
  - Rebuttals

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Telehealth

Introduction

- In the years leading up to the pandemic, health care delivery had been shifting towards telehealth.
- Pre-pandemic — the shift towards telehealth had been led by commercial insurers, not by Medicare.
- But then, COVID changed everything.
- Beginning in March 2020, the health care delivery system went into triage mode.

Introduction

- The focus was to keep as many patients as possible out of the hospitals so as to free up hospital beds for the sickest.
- Out of necessity, technology had to be relied upon and third-party payors (“TPPs”), including Medicare, had to accept the reality of relying on telehealth.
- And, so, this is the point where the law had to scramble to keep up with the unfolding events on the ground.
- COVID accomplished in months what would normally have taken years to accomplish if the pandemic had never occurred.

Medicare, DME and Telehealth

- Pre-pandemic— in order for Medicare to recognize a physician's order for DME, resulting from a telehealth encounter, several limiting elements had to be met:
  - The beneficiary had to reside in a rural area.
  - The beneficiary had to leave his residence and drive to an "originating site" (e.g., critical access hospital).
  - Once inside the originating site, the beneficiary was required to have both a visual and audio telehealth encounter with the physician.
- When the pandemic hit, Medicare determined that the telehealth restrictions needed to be relaxed during the pandemic.

Medicare Policy Changes

- Policy Changes
  - Since early March 2020, CMS has issued a number of waivers, regulations, and rules pertaining to telehealth. In doing so, CMS:
    - expanded the health care workforce by removing barriers to providing care;
    - removed regulatory barriers with the goal of ensuring that hospitals could handle a surge of COVID patients; and
    - removed regulatory barriers with the goal of ensuring that patients had access to care while remaining at home.

Medicare Policy Changes

- Coronavirus Preparedness and Response Supplemental Appropriations Act (March 6, 2020)
  - Pursuant to this Act, Congress authorized HHS to waive certain Medicare telehealth requirements. The Act expanded coverage to:
    - patients outside of rural areas;
    - patients in their homes; and
    - new (not just established) patients.

Medicare Policy Changes

- Coronavirus Preparedness and Response Supplemental Appropriations Act (March 27, 2020)
  - This Act allows HHS to waive statutory coverage requirements for telehealth. The Act further increased funding for e.g., remote care technologies. The Act was effective through the end of the Public Health Emergency ("PHE") which ended on May 11, 2023.
  - Waivers for telehealth have been extended through end of 2024.
  - Without congressional action, things will go back to the way they were prior to the PHE.

Medicare Policy Changes

- Medicare Telehealth Changes
  - Patients can receive telehealth and other technology-based services wherever the patients are located.
  - Telehealth services can be provided to new or established patients.
  - Certain evaluation and management (“E & M”) services, behavioral health visits, and educational services can be provided via audio only.
  - Other services must be furnished with audio and video technology, but IT and location requirements have been relaxed.

Medicare Policy Changes

- CMS has expanded the types of practitioners who may provide telehealth services. Telehealth can now be billed by all provider types who are eligible to bill Medicare for their professional services.
- CMS can add new CPT codes to the list of services that can be provided via telehealth on a sub-regulatory basis which will result in quicker addition of CPT codes to the list of codes that may be provided by telehealth.
- Clinicians can provide:
  - remote evaluation of patients and
  - virtual check-in services to both new and established patients.

Medicare Policy Changes

- Medicare payment for telephone E & M codes are equivalent to payment for office and/or outpatient visits with established patients.
- Clinicians can provide remote patient monitoring services to both new and established patients and these services can be provided to patients with only one disease.
- To the extent that an NCD or LCD would require a face-to-face visit for evaluations and assessments, clinicians do not have to meet those requirements for the duration of the PHE. This, however, does not apply to power mobility devices.

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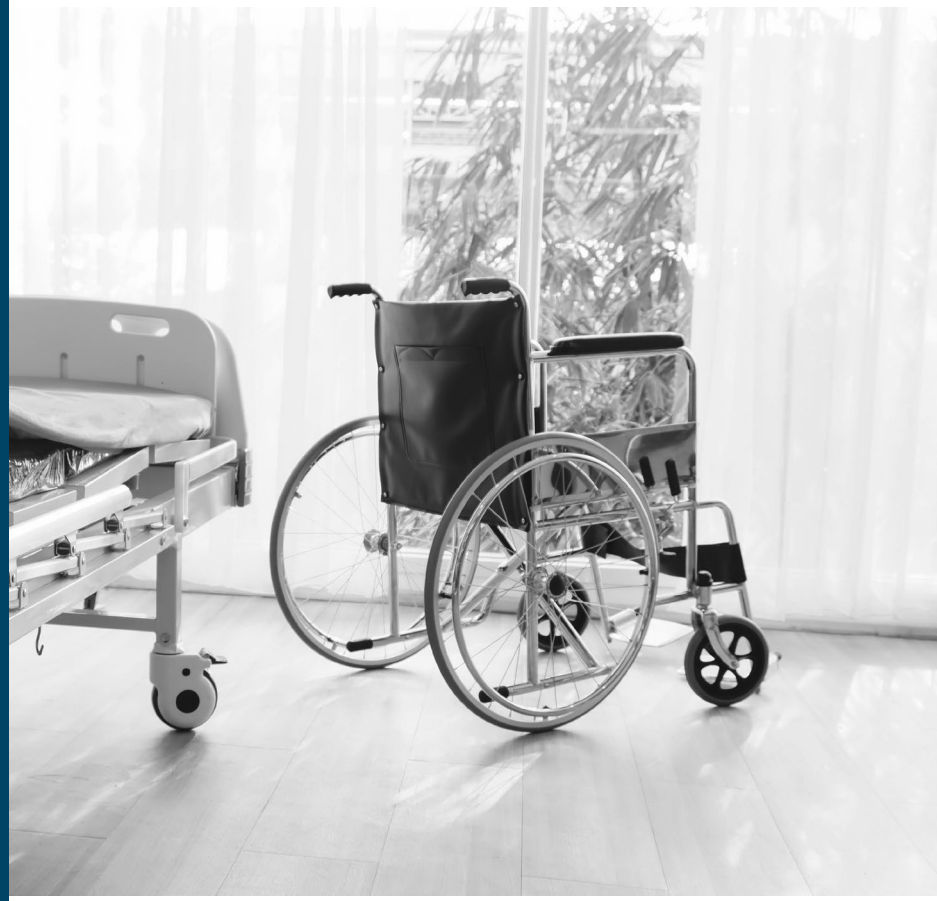
Remote Physiologic Monitoring



Remote Physiologic Monitoring

- Historically, physicians, hospitals, therapists, third-party payors (“TPPs”), and other stakeholders have been reactionary when it comes to providing health care to patients. This type of reactionary health care is inefficient and expensive.
- And so, TPPs, governmental agencies, and other health care stakeholders are pushing health care into a proactive/preventative model.
- A mechanism to accomplish this is Remote Physiologic Monitoring (“RPM”). A relatively new phenomenon, RPM is designed to allow physicians to monitor their patients to determine if they meet certain metrics on a daily basis. If patients fail to meet the metrics, RPM is designed for the physician to intervene in order to proactively solve the problem … thereby alleviating the need for a trip to the hospital.

Remote Physiologic Monitoring

- A DME supplier may desire to offer RPM equipment and services to physicians … so that the physicians can efficiently offer RPM to their patients.
- In exchange for these services, the physicians will compensate the DME supplier; and the physicians will be responsible for submitting their own claims for RPM services.
- Physicians must meet all requirements to bill the RPM codes:
  - as outlined by the CPT Codebook and
  - as required by TPPs.

Remote Physiologic Monitoring

- In entering the RPM space, DME suppliers need to be cautious.
- Software companies, pharmacies, DME suppliers, and others are aggressively marketing RPM to physicians. Because an increasing number of physicians are providing RPM, Medicare is witnessing a spike in RPM claims.
- This is resulting in governmental agency review of RPM arrangements.
- The key question is whether the physician is providing legitimate RPM or whether the physician (with the assistance of others) is “gaming the system” to receive another source of revenue.

Remote Physiologic Monitoring

- At the end of the day, the physician must have operational responsibilities and financial risk in providing RPM.
- The DME supplier (or software company) cannot provide RPM services to the physician on a turnkey basis.
- The physician must have sufficient “skin in the game” to justify his submission of claims for RPM.

Remote Physiologic Monitoring

- In order to avoid potential kickback problems:
  - The physician should onboard his patients into the RPM program as opposed to the DME supplier/software company onboarding the patients on behalf of the physician.
  - The physician must pay a fair market value (“FMV”) purchase price to the DME supplier/software company for the monitoring equipment.
  - The physician must pay FMV compensation to the DME supplier/software company for its services.

Remote Physiologic Monitoring

- Generally, the RPM codes are billed for physiologic monitoring.
- The CPT code book and CMS guidance provide examples of data that can be collected such as weight, blood pressure, and pulse oximetry.
- The monitoring device must meet the definition of “medical device” outlined in the Federal Food, Drug, and Cosmetic Act.

Remote Physiologic Monitoring

- Metrics such as weight, blood pressure, and pulse oximetry are not strictly required in order to bill under 99454; however, the data must be:
  - uploaded digitally (i.e., automatically) and
  - reliable and valid physiologic data that allows the practitioner to develop and manage a plan of treatment.
- The data collected must be more than information to confirm compliance with a plan of care.

Remote Physiologic Monitoring

- Per the CPT Codebook, at least 16 days of data each 30 days must be collected and transmitted to meet the requirements of 99453 and 99454.
- If the monitoring is less than 16 days, the requirements are not met.
- For 99454, the data must be digitally recorded and uploaded for the practitioner's review.
- No in-person or telephone communication is required for 99454.

Remote Physiologic Monitoring

- In order to bill 99457, clinical staff, the practitioner, or other qualified health care professional must have live, interactive communication with the patient for at least 20 minutes in a 30-day period.
- There is no definitive guidance whether this activity can be outsourced by a patient's physician.
- The physician should review TPP billing requirements to ensure that the physician meets the requirements to bill for RPM.
- The person speaking with the patient must be a physician, clinical staff, or other qualified health care professional.
- An "other qualified health care professional" includes nurses, PAs, and speech/occupational therapists.

Remote Physiologic Monitoring

- CPT Code 99458 is billed for additional 20 minutes of live, interactive communication within a 30-day period.
  - For example, if a physician spends 40 minutes during a 30-day period on live, interactive communication pertaining to remote physiologic monitoring management, then the physician can bill 99457 for the first 20 minutes and 99458 for the subsequent 20 minutes.
  - There does not appear to be a limit on the number of times 99458 can be billed in a month if all requirements are met.

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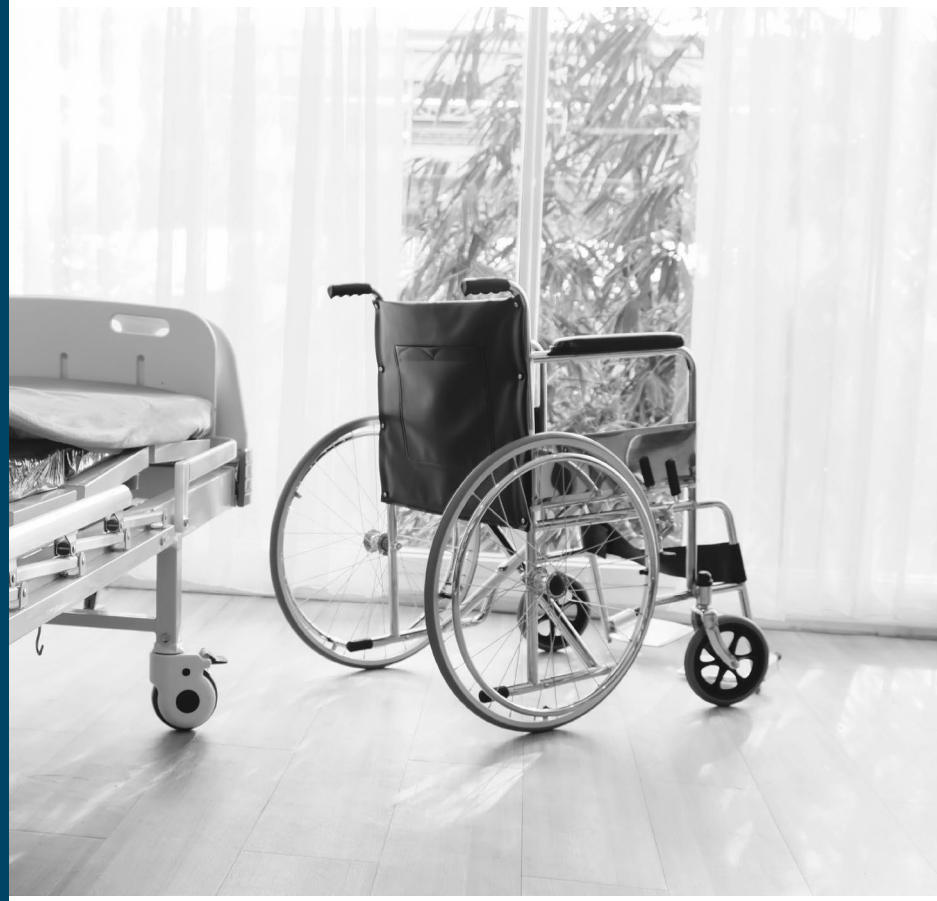
Written Order Prior to Delivery



Products Added to Face-to-Face Encounter and WOPD List

- On January 13, 2022, CMS published the HCPCS codes that will be added to the list of products that require a face-to-face encounter and written order prior to delivery (“WOPD”) as well as the HCPCS codes added to the list of products that require prior authorization.
- On January 17, 2023, 10 additional orthoses were added to the list.
- On May 13, 2024, a third notice was published and added 13 additional codes (3 hospital beds, 2 osteogenesis stimulators, 6 lumbar sacral orthoses and 2 knee orthoses).

Products Added to Face-to-Face Encounter and WOPD List

- For dates of service 08/12/2024 and later, the List of Required Face-to-Face Encounter and Written Order Prior to Delivery List can be found at the following link:

  chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.cms.gov/files/document/required-face-face-encounter-and-written-order-prior-delivery-list.pdf

Products Added to Face-to-Face Encounter and WOPD List

- For items on the Face-to-Face Encounter and WOPD List, the completed Standard Written Order ("SWO") must be communicated to the supplier prior to delivery.
- The SWO requires:
  - Beneficiary name or Medicare Beneficiary Identifier (MBI) Number
  - Description of the item
  - Quantity, if applicable
  - Treating practitioner name or National Provider Identifier (NPI)
  - Date of the order
  - Treating practitioner signature

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Non-Invasive Positive Pressure Ventilation

NIV NCA for Chronic Respiratory Failure Due to COPD

- On 9/11/24, CMS published "NCA: Noninvasive Positive Pressure Ventilation" in the *Home for the Treatment of Chronic Respiratory Failure* consequent to COPD.
- CMS is opening the NIV NCD, revising the coverage policy for chronic respiratory failure due to COPD.
- Primary focus is on when and how BiPAP machines and NIVs can be used in the home.
- Comments were due to CMS by October 11
  - CMS to publish proposed NCA – Feb. 9, 2025, with 30-day comment period
  - CMS to publish final NCD – June 9, 2025

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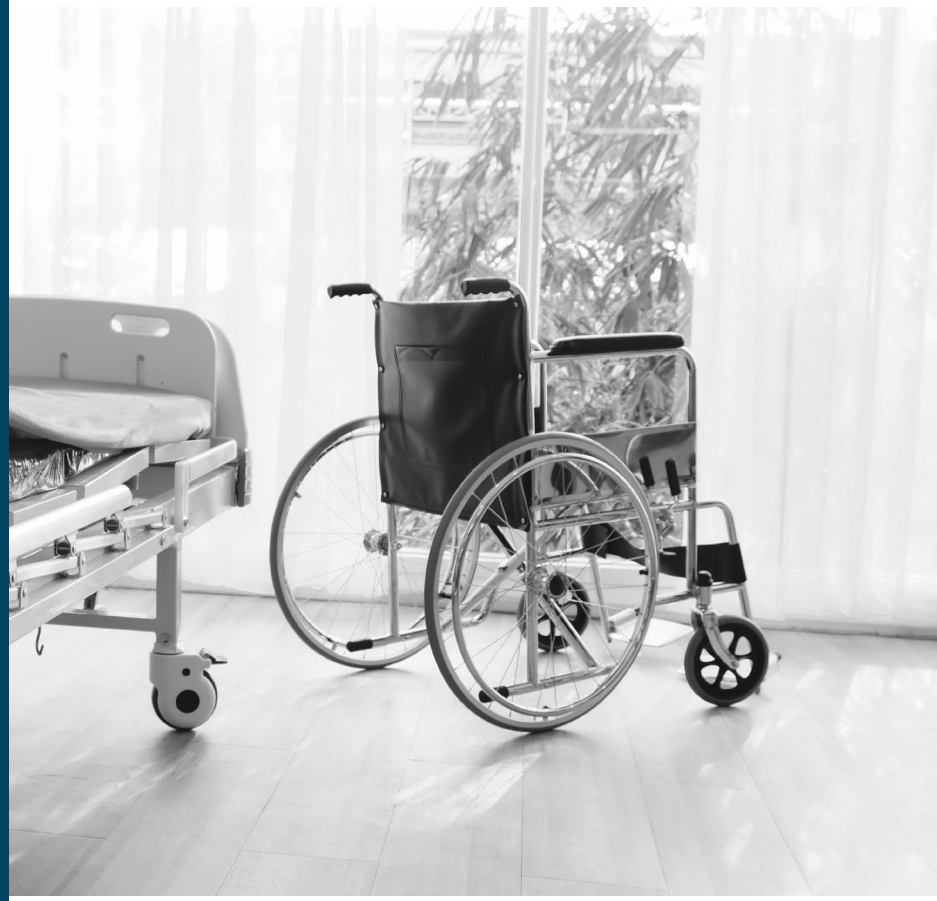
Continuous Glucose Monitors



OIG CGM Report

- Medicare Payments Compared to the Prices Available to Consumers and Suppliers for Continuous Glucose Monitors and Sensors.
  - We will compare Medicare payments to suppliers' acquisition costs and prices otherwise available to consumers for selected continuous glucose monitors (CGMs) and their sensors to determine if there are potential cost savings for Medicare and enrollees. In 2022, Medicare Part B allowed more than $1.1 billion in payments for CGMs and sensors. If we find that Medicare payments for CGMs greatly exceed their acquisition costs, then CMS has authority to adjust payment rates for CGMs and sensors through two methods: CMS can adjust the fee schedule prices using its inherent reasonableness authority, or it can introduce an item into the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program.

OIG CGM Report

- OIG reviewing whether the Medicare payment for CGMs are significantly higher than supplier acquisition costs and whether the payment can be adjusted using inherent reasonableness or adding it to CBP.
  - Expected to be issued in FY2025.
  - Recommendation may include inclusion in competitive bidding

Provision of CGM

- Changes to LCD were effective April 16, 2023
- expanded coverage for continuous glucose monitors (CGM) and for services provided on or after April 16. CGM services are now covered for all patients with diabetes who are treated with insulin or who have hypoglycemia and meet at least one of the following specifications:
  - Two or more level 2 hypoglycemic events (glucose <54 mg/dL) that persist despite multiple modifications to the treatment or medication plan,
  - One level 3 hypoglycemic event (glucose <54 mg/dL) characterized by altered mental and/or physical state requiring third-party assistance for treatment.

Provision of CGM

- This coverage change includes type 1, type 2, and gestational diabetes.
- CMS also removed the coverage requirement that the beneficiary's insulin treatment regimen needs frequent adjustments based on blood glucose monitor or CGM testing results.
- An in-person or Medicare-approved telehealth visit with the prescribing physician is required within six months of starting CGM

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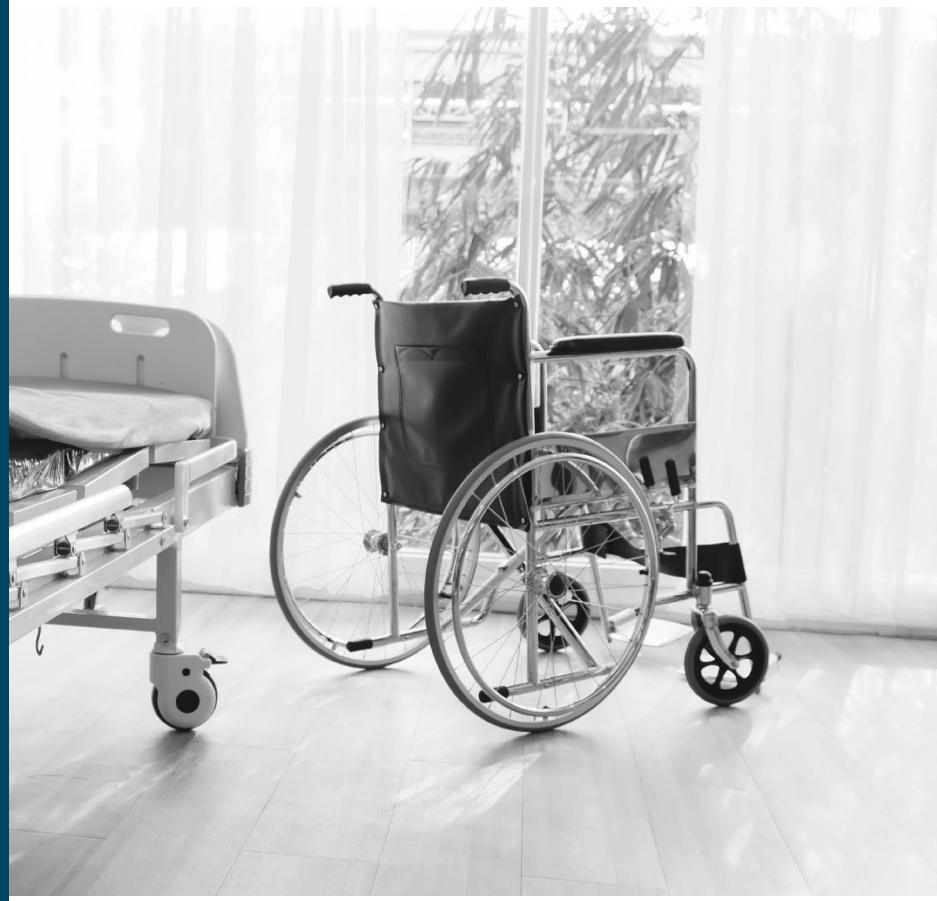
Competitive Bidding



Future of Competitive Bidding

- All DMEPOS Competitive Bidding Program (CBP) Round 2021 contracts for off-the-shelf (OTS) back and knee braces expired on December 31, 2023.
- Starting January 1, 2024, we are in a temporary gap period for the DMEPOS CBP.
- CMS will start bidding for the next round of the DMEPOS CBP after it:
  - Completes the formal public notice and comment rulemaking process
  - Implements necessary DMEPOS CBP changes to:
    - Establish sustainable prices
    - Save money for Medicare patients and taxpayers
    - Help limit fraud, waste, and abuse in the Medicare Program
    - Ensure patient access to quality items and services

Future of Competitive Bidding

- During the temporary gap period, Medicare-enrolled DMEPOS suppliers may furnish DMEPOS items and services to patients.
- Here are the payment rules:
  - Adjusted fees in former competitive bidding areas (CBAs) are based on 100% of the single payment amount for the CBA increased by the projected percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) from January 2023 - January 2024
  - Adjusted fees in non-CBAs are based on fully adjusted rates per the applicable methodology under 42 CFR 414.210(g)

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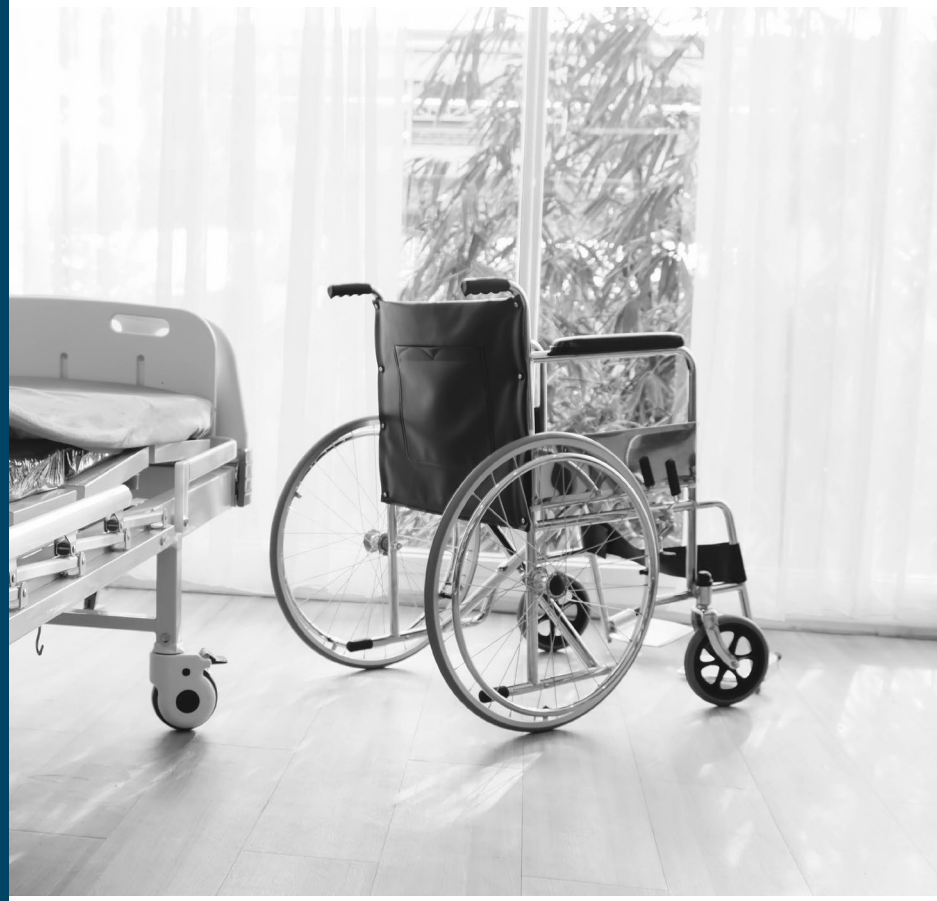
Questions?



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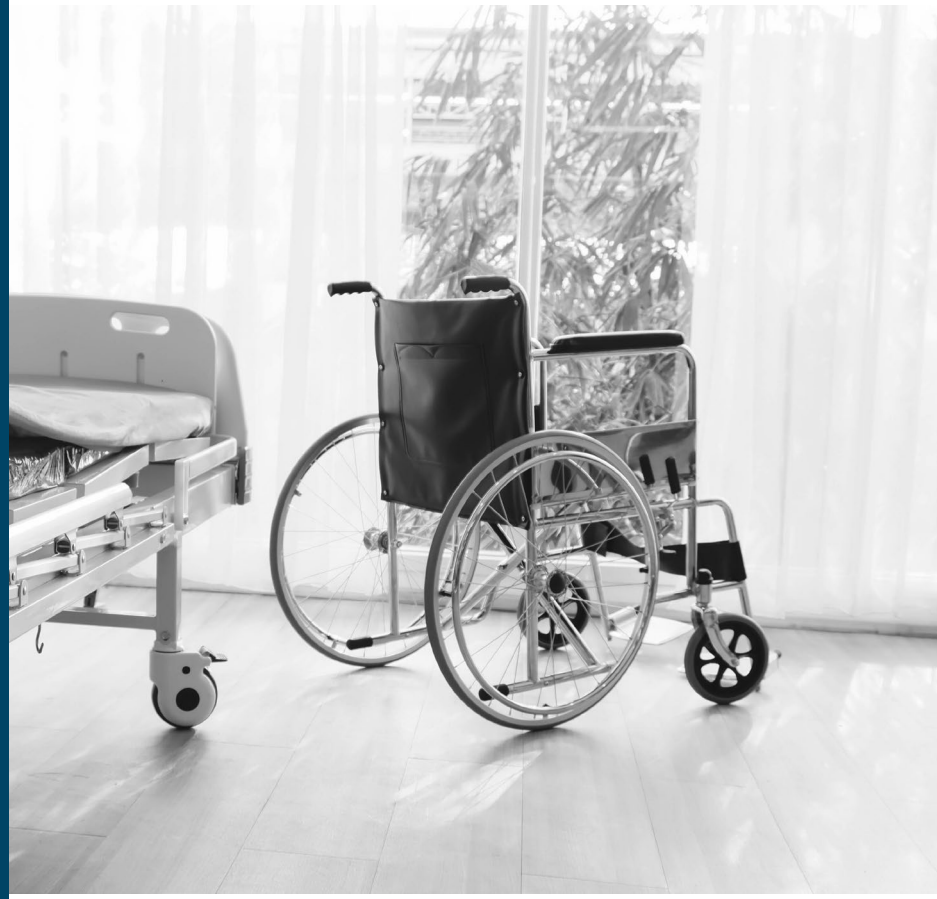

Thank you

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