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DMEPOS

# OUT WITH THE OLD AND IN WITH THE NEW

Denise M. Leard, Esq.
Brown & Fortunato

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# INTRODUCTION

# CMS GUIDANCE RULES

- CMS has released multiple documents providing significant new guidance to facilitate the provision of DME during the COVID-19 Public Health Emergency ("PHE")
- https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers
  - IFR – effective March 1, 2020 (published April 6, 2020)
    - https://www.cms.gov/files/document/covid-final-ifc.pdf
  - COVID 19 Frequently Asked Questions on Medicare FFS Billing
    - COVID-19 Frequently Asked Questions (FAQs) on (cms.gov)
  - COVID-19 Provider Burden Relief FAQ
    - https://www.cms.gov/files/document/provider-burden-relief-faqs.pdf

# CMS INTERIM FINAL RULE

- LCD/NCD suspension
  - During the PHE, CMS will not enforce the NCD and LCD clinical indications for coverage for respiratory, home anticoagulation management, and infusion pumps
  - CMS is providing "maximum flexibility" for practitioners to care for their patients

# CMS INTERIM FINAL RULE

- LCD/NCD suspension includes, but not limited to:
  - NCD 240.2 Home Oxygen
  - NCD 240.4 CPAP for OSA
  - LCD L33800 Respiratory Assist Devices
  - NCD 240.5 Intrapulmonary Percussive Ventilator
  - NCD 190.11 Home Prothrombin Time/International Normalized Ration for Monitoring Anticoagulation Management
  - NCD 280.14 Infusion Pumps
  - LCD L33794 External Infusion Pumps
  - LCD L33822 Glucose Monitors
  - LCD L33370 Nebulizers
  - LCD 35434 Oximetry services
  - LCD L33785 High frequency chest wall oscillation

# CMS INTERIM FINAL RULE

- Face-to-Face ("F2F") encounter requirements
  - For the duration of the PHE, CMS is waiving the F2F and in person requirements in the DME LCDs and NCDs
  - The waiver does not apply to the power mobility device F2F requirement since that's required by law/statute; but valid telehealth visits will suffice for these

# CMS INTERIM FINAL RULE

- Allowing additional practitioners to order medical equipment and supplies under the Medicaid Home Health Benefit
  - The IFR expands current regulations to allow additional practitioners within their scope of practice to order Medicaid home health services
  - Includes physician assistants and nurse practitioners
  - CARES Act provides permanent allowance

# ENROLLMENT FLEXIBILITIES

- Enrollment
  - Effective July 6, 2020, CMS resumed all accreditation and reaccreditation activities for DMEPOS suppliers including surveys.
    - Surveys can be onsite, virtual, or combination of both (depending on state reopening guidelines)
  - Effective July 6, 2020, CMS resumed all DMEPOS provider enrollment site visits.
  - Effective July 6, 2002, CMS resumed revalidation activities.

# MEDICAID – ORDER EXPANSION

- DMEPOS services are covered under the home health benefit for Medicaid
- H.R.748 - CARES Act
  - … by a nurse practitioner, clinical nurse specialist, or physician assistant after a date specified by the Secretary in no case later than the date that is 6 months after the date of the enactment of the CARES Act.
- IFR
  - In recognition of the critical need to expand workforce capacity, we are amending 42 CFR §440.70 to allow licensed practitioners practicing within their scope of practice, such as, but not limited to, NPs and PAs, to order Medicaid home health services during the existence of the PHE for the COVID-19 pandemic.

# MEDICAID – BIG DEAL?

- Many states have allowed a licensed practitioner to order within the scope of their practice.
- But 11 STATES ONLY ALLOWED PHYSICIANS:
  - Arkansas, California, Louisiana, Maine, Michigan, Missouri, Mississippi, New Mexico, Pennsylvania, Texas, Washington
    - Some allowed some DMEPOS to be ordered by a PA or particular category

# TELEHEALTH

- Under the PHE, all beneficiaries across the country can receive telehealth and other communications technology-based services wherever they are located.
- Clinicians can provide these services to new or established patients .
- Physicians can waive Medicare copayments for these services.
- Broad range of clinicians can now provide certain services by telephone to their patients.
- To enable services to continue while lowering exposure risk, clinicians can now provide additional services by telehealth, including emergency department visits.

# VIRTUAL SERVICES

- Telehealth visits
  - Interactive audio and video
  - New or established patients
- Virtual check-ins
  - Telephone or video
  - New or established patients
- E-Visits
  - Electronic communication via patient portal
  - New and established patients

# POWER MOBILITY DEVICE EVALUATIONS

- F2F for power mobility device ("PMD") is required by statute
- The statute has always allowed for telehealth visits for PMD F2F under previous limitations
  - Must meet the requirements of 42 CFR §§ 410.78 and 414.65 for purposes of DMEPOS coverage.
- Expanded telehealth provisions now also apply to PMD F2F
- PTs/OTs
  - Legislation originally only made it easer to access to existing telehealth services—it originally did not expand the definition of who can provide telehealth services.
  - Currently, a telehealth-eligible provider does include occupational or physical therapists for some services.

# POWER MOBILITY DEVICE EVALUATIONS

- PT/OT via telehealth has limited coverage by Medicare and is covered by some Medicaid plans and commercial plans
- Ultimately, the responsibility of determining whether telehealth is appropriate is up to the PT/OT;
- Objective measurements cannot be done via telehealth; still required per LCD
- CMS has added PTs/OTs to list of practitioners eligible to do telehealth

# CMS PROVIDER BURDEN RELIEF FAQ

- CMS is still waiving signature requirements on proof of delivery slips in response to the COVID-19 pandemic for Dates of Service within the PHE for the COVID-19 pandemic. Suppliers should document in the medical [patient] record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.
- Signature on Orders:
  - DMEPOS items, except for PMDs, can be provided via a verbal order.
  - A signature is required prior to submitting claims for payment but the order can be signed electronically.
  - PMDs require a signed, written order prior to delivery.

# FACE-TO-FACE REQUIREMENTS

- 1135 Waiver
  - CMS has determined it is appropriate to issue a blanket waiver where Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) is lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable, contractors have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required
  - Limited application in current COVID-19 pandemic
- IFR
  - NCDs and LCDs contain clinical conditions a patient must meet to qualify for coverage of the item or service. Some NCDs and LCDs may also contain requirements for face-to-face, timely evaluations or re-evaluations for a patient to initially qualify for coverage or to qualify for continuing coverage of the item or service.
  - … on an interim basis, we are finalizing that to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements

# PRIOR APPROVAL UPDATE/CHANGES

- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies:
  - CMS Flexibilities to Fight COVID-19.
- Prior Authorization in DMEPOS:
  - CMS is paused the national Medicare Prior Authorization program for certain DMEPOS items.
- This flexibility was discontinued on August 3, 2020.
  - PMD
  - Pressure Reducing Support Surfaces
  - Lower Limb Prosthetics (beginning December 1, 2020)

# AUDITS

- CMS suspended Fee-For Service "FFS" audits from DME MACs, SMRC, and RACs until August 3, 2020.
- DME MACs phased-in audits by starting with post-pay reviews on August 17, 2020.
  - Check DME MAC websites for active audits.
- RAC and SMRC started supplier-specific reviews, but they have not started widespread reviews.
- CERT reviews started again August 11, 2020.

# APPEALS

- CMS is allowing DME MACs, QIC, and Part C IRE:
  - To allow extensions to file an appeal
  - Waive requirements for timeliness for requests for additional information to adjudicate appeals
  - To process an appeal even with incomplete Appointment of Representation forms
  - To process requests for appeal that don't meet the required elements
  - To utilize all flexibilities available in the appeal process as if good cause requirements are satisfied

# RESOURCES

- CMS Interim Final Rule:
  - https://www.cms.gov/files/document/covid-final-ifc.pdf
- DMEPOS: CMS Flexibilities to Fight COVID-19:
  - https://www.cms.gov/files/document/covid-dme.pdf
- COVID-19 Provider Burden Relief FAQ:
  - https://www.cms.gov/files/document/provider-burden-relief-faqs.pdf

# RESOURCES

- See COVID-19 FAQ:
  - www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf (updated regularly, includes home oxygen)
- CMS FAQ:
  - 2019-Novel Coronavirus (COVID-19) Medicare Provider Enrollment Relief
- CMS Medicare Telehealth FAQ (March 17, 2020)
- CMS COVID-19 FAQ for State Medicaid and CHIP Agencies
- OCR FAQ on Telehealth and HIPAA during the COVID-19 nationwide PHE
  - https://www.vgm.com/coronavirus/
- COVID-19 Checklist:
  - https://www.aahomecare.org/uploads/userfiles/files/documents/COVID%2019/COVID-19%20Checklist%203_20.pdf

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# LEGAL ISSUES FOR 2021

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- Historically, health care in the U.S. has been based on FFS. This has proven to be expensive and inefficient.
- Third-party payors, including Medicare, are moving away from the FFS model and towards the value-based care ("VBC") model.
- VBC is premised on providers collaborating to furnish health care for a patient and for remuneration to be based, at least in part, on whether certain metrics are achieved.

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- The challenge is that VBC has run up against the prohibitions and restrictions of the federal physician self-referral statute ("Stark") and the federal anti-kickback statute.
- After receiving input from providers/other interested persons, on November 20, 2020, (i) CMS released a Final Rule relaxing some of the restrictions under Stark and (ii) the OIG released a Final Rule relaxing some of the restrictions under the anti-kickback statute.
- The goal of the Final Rules is to encourage providers to collaborate in the provision of health care without being unduly restricted by Stark and the anti-kickback statute.

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- Modifications to Stark:
  - Three new Value-Based Enterprise exceptions.
  - Execution of documents after arrangement begins.
  - Correction of errors after compensation arrangement ends.
  - Indirect compensation.
  - Limited remuneration to physician.
  - Patient Choice.

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- Modifications to Stark (cont'd):
  - Fair Market Value.
  - Volume or value of referrals/business generated.
  - Commercial reasonableness.
  - Rental of office space and equipment.
  - Group practice.
  - Consistency of Stark and the anti-kickback statute.

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- Modifications to the Anti-Kickback Statute:
  - Three new Value-Based Enterprise safe harbors.
  - New Patient Engagement and Support safe harbor.
  - Modification to Local Transportation safe harbor.
  - Modification to Warranty safe harbor.
  - Modification to Personal Services and Management Contract and Outcomes-Based Payments safe harbor.
  - New ACO Beneficiary Incentive Program safe harbor.

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- Modifications to Stark and the Anti-Kickback Statute:
  - Modification to the Electronic Health Records exception to Stark and the Electronic Health Records safe harbor to the anti-kickback statute.
  - New Cybersecurity Technology exception to Stark and Cybersecurity Technology safe harbor to the anti-kickback statute.

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- Certain components of the Final Rules do not directly apply to DME suppliers for two primary reasons:
  - At present, most DME suppliers are not integrated into the VBC arena; most suppliers are paid on an FFS basis.
  - Several of the changes specifically exclude DME suppliers.
- On the other hand, some of the components of the Final Rule do apply to DME suppliers:
  - Modification to the Personal Services and Management Contracts safe harbor to the anti-kickback statute.
  - Modification to the Stark definition of "commercial reasonableness."

# CHANGES TO STARK AND THE ANTI-KICKBACK STATUTE

- Some of the components of the Final Rule do apply to DME suppliers (cont'd):
  - Clarification to the Stark "volume or value standard and other business generated standard."
  - Clarification to the Stark definition of "fair market value."
  - Ability of the parties to a transaction (that implicates Stark) to sign documents (memorializing the arrangement) within 90 days of the beginning of the arrangement.
  - Modification of the Stark definition of "set in advance."

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# QUESTIONS?

Email us at customerservice@achcu.com

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# THANK YOU

**Denise M. Leard, Esq.**
Brown & Fortunato, P.C.
905 S. Fillmore St., Ste. 400
Amarillo, Texas 79101
dleard@bf-law.com | 806-345-6318