

The Ups and Downs of DME

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Can it be true?

- CMS and its contractors have indicated a more “provider-friendly” approach to DMEPOS claims
- “Provider-friendly” equates to reducing appeal backlog
- DMEPOS is the largest contributor to the appeal backlog
 - Account for approximately 50% of all pending hearings
 - 7 of the top 10 appellants at OMHA are DME suppliers



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Impact of “Provider- Friendly” Approach

- New, friendlier appeal processes
- New Change Requests reducing unnecessary burden
 - CPAP suppliers can assume medical necessity if 13 rental payments made to other suppliers (CR 9741)
 - No new order for change in supplier (CR 9886)
 - Reduced POD requirements (CR 10324)
 - Improvements in O & P
- Will it last?



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POD Requirements

- Effective/Implementation Date: November 20, 2017
- Date of delivery may be entered by the beneficiary, designee, or the supplier
- Date of delivery may be the **date the beneficiary received the item**, or
- Date of delivery may be **the date the supplier shipped the item** when using a delivery/shipping service, shall be the date of service on the claim.
 - Note: The shipping date may be defined as the date the delivery/shipping service label is created or the date the item is retrieved for delivery
 - Exception: Two-day rule, The supplier shall bill the date of service on the claim as the date of discharge



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Legislation in the works for O & P

- O&P Medicare Improvements Act
- Medicare O&P Improvement bill section 50402
 - Section 1834(h) of the SSA is amended by adding at the end the following paragraph:
 - Documentation created by Orthotists and Prosthetists-For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B)



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President's 2019 Budget – DMEPOS Implications

- **Reform and Expand Durable Medical Equipment Competitive Bidding** - This proposal eliminates the requirement under the DME competitive bidding program that CMS pay a single payment amount based on the median bid price, and instead, pay winning suppliers at their own bid amounts.
- Additionally, this proposal expands competitive bidding to all areas of the country, including rural areas. Expanding competitive bidding to rural areas will set prices for items and services in rural areas based on competitions in those areas rather than on competitions in urban areas.
- In the event that in a rural area less than two suppliers submit bids, CMS will use a reference price from other, similar rural areas. [\$6.5 billion in savings over 10 years]



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President's 2019 Budget – DMEPOS Implications

- **Address Excessive Billing for DME that requires refills or serial claims** - This proposal uses Medicare demonstration authority to test whether using a benefits manager for serial durable medical equipment claims results in lower improper payments and reductions in inappropriate utilization. The benefits manager would be responsible for ensuring beneficiaries were receiving the correct quantity of supplies or services for the appropriate time period. [Budget impact not available]
- **Eliminate the Unnecessary Requirement of a Face-to-Face** - Currently, physicians must document a beneficiary's face-to-face encounter with a physician or nonphysician practitioner as a condition for Medicare payment for a durable medical equipment order, which can be overly burdensome on providers and suppliers. This proposal enables CMS not to impose this face-to-face requirement on all providers. [No budget impact]



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President's 2019 Budget – DMEPOS Implications

- **Address Overutilization and Billing of Durable Medical Equipment, Prosthetics, and Orthotics by Expanding Prior Authorization** - This proposal expands prior authorization to additional items and services that are at high risk for improper payments. In FY 2016, CMS finalized a regulation that established a master list of items that are both high-cost and high-risk for improper payments and therefore could be subject to prior authorization. This proposal would expand the number of items on the list subject to prior authorization. [Budget impact not available]



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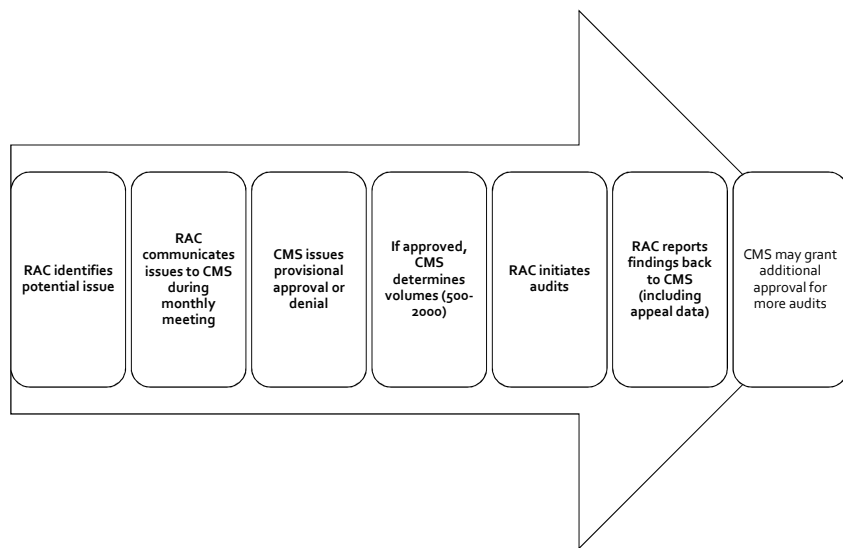
National DMEPOS and HHH RAC

- Performant Recovery
- Identified focused areas for new RACS and will be meeting monthly with CMS to identify audits
- Will be looking at post-payment claims that have been submitted within the previous 3 years from the date the claim was paid



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RAC Identified Issues Process



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RAC Issues - Automated

Automated	Date Posted
CPAP without OSA Diagnosis	9/8/2017
Group 3 PWC Underpayments	5/17/2017
Multiple DME Rentals in one month	3/31/2017
DME while beneficiary is in an inpatient stay	2/16/2017
Nebulizers	2/2/2017
CPM Billed without Total Knee Replacement	2/2/2017
Glucose Monitor	1/5/2017
Spring Powered Devices Billed for >1 in a 6 Month Period	1/5/2017



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RAC Issues - Complex

Complex	Date Posted
Ventilators submit to DWO Requirements on or after January 1, 2016	1/11/2018
Respiratory Assist Device	12/17/2017
PAP Devices for the treatment of OSA	9/19/2017
Spinal Orthoses	8/2/2017
AFO/KAFO	7/7/2017
PMDs not subject to PA Demonstration	6/6/2017
Blood Glucose Monitors with Integrated Voice Synthesizer	5/12/2017
Enteral Nutrition Therapy	5/11/2017
Negative Pressure Wound Therapy Pumps	4/28/2017
Nebulizers	4/14/2017
Group 2 Support Surfaces	2/15/2017
Osteogenesis stimulators	2/14/2017
Chest Wall Oscillation Devices	2/8/2017
Tracheotomy suction catheters, suction pumps, catheters and other supplies	2/8/2017



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The audit numbers...

- They have sent a low volume of audits comparative to first round (just about 6,000 by the middle of last year)
- Audit volume rankings:
 1. DME while Inpatient
 2. Multiple DME rentals in 1 month
 3. Hospital beds with mattresses billed with Group I or II support surfaces
 4. Group III PMD Accessories Underpayment
 5. Chest Wall Oscillation Devices
 6. Automated Nebulizer review



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Unified Program Integrity Contractors

- Implementation of the UPIC initiative began in 2016
 - Combines the audit and investigation work currently conducted by the ZPICs (and their responsibilities) with the Audit Medicaid Integrity Contractors (Audit MICs) to form the UPIC
- Contracts with ZPICs/PSCs and MICs will end as the UPIC is implemented in specific geographic regions
- Implementation of the UPICs will be over a multi-year period in order to allow current contractors to transition out
- Goal: Streamline audit structure



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UPICs

- Umbrella contracts awarded in May 2016
- Potential 10 year, \$2.5 billion contract vehicle
- Awardees:
 - AdvanceMed
 - Health Integrity
 - Safeguard Solutions
 - Strategic Health Solutions
 - TriCenturion
 - HMS Federal
 - Noridian Healthcare Solutions



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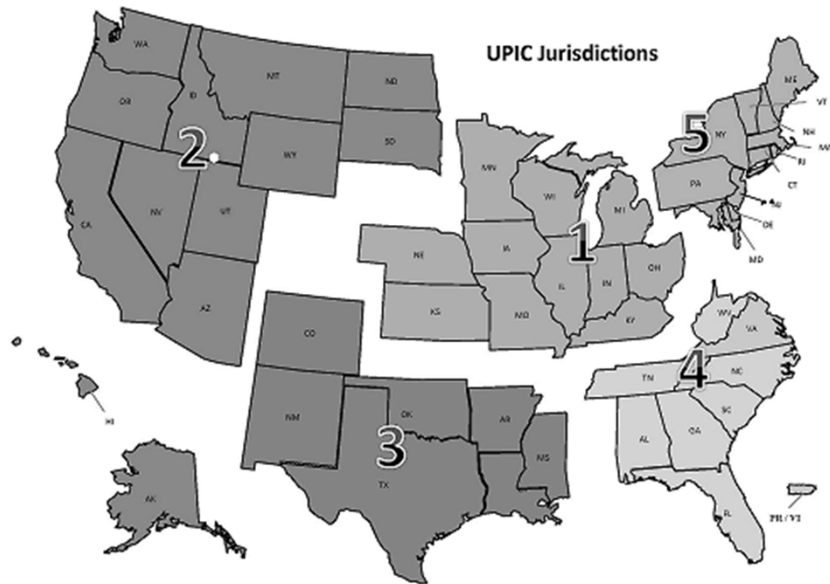
UPICs

- AdvanceMed was awarded UPIC Jurisdiction 1 (Midwest)
 - Contract amount = \$76,874,623.22
- Health Integrity was awarded UPIC Jurisdiction 2 (Western)
 - Contract amount = \$85,341,745.00
- Health Integrity was awarded UPIC Jurisdiction 3 (Southwest)
 - Contract amount = \$86,965,604.00
- Safeguard Services was awarded contracts for Jurisdiction 4 (Southeast) and Jurisdiction 5 (Northeast)



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UPIC Jurisdictions



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*Other territories of Zone 2 include American Samoa, Northern Marianas Islands and Guam

Managed Care Risk

- Increased pressure on Medicare Advantage/HMO plans to conduct program integrity functions
- Applying policies consistently as Medicare
- Increased prepayment review and extrapolated overpayments
- Must be treated the same as Medicare
- December 2015 – CMS released a request for information that outlines an expansion of Medicare’s RAC program
 - ACA requires the RAC program to be expanded into Managed Care, so the plan themselves will be audited
 - Trickle-down effect to providers



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Managed Care Risk

- In-Network providers
 - Plan determines audit and appeal process
- Out-of-Network providers
 - Medicare Managed Care Manual Publication 100-16
 - Assignment of Benefits are Critical



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Supplemental Medical Review Contractor

- Strategic Health Solutions performs a large volume of Medicare Part A, Part B, and DMEPOS claims nationally.
- Strategic will focus on lowering improper payments in Medicare Fee-For-Service programs and increasing efficiencies in medical review functions.
- Projects include issues identified by the OIG, CERT and CMS internal data analysis
- Focus on national claims data analysis versus MAC jurisdiction data
- Announced on February 17, 2018 that Noridian Healthcare Solutions won SMRC contract (5 year, \$227M)



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Supplemental Medical Review Contractor

- Completed Projects
 - Power Mobility Devices
 - Vacuum Erection Devices
 - Nebulizers and Related Drugs
 - Diabetic Testing Strips
 - Oxygen and Oxygen Equipment
 - PAP Devices and Supplies
 - Oxygen and Oxygen Equipment



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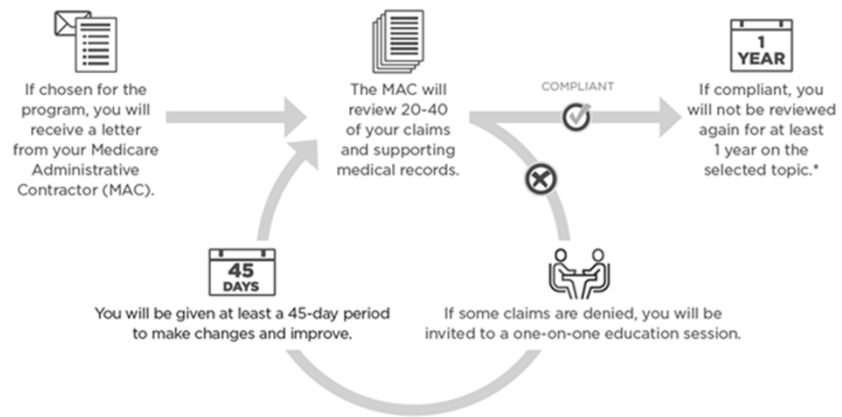
DME MAC – Targeted Probe and Educate (TPE)

- DME MACs will no longer be performing widespread reviews
- Help suppliers reduce claim denials and appeals through one-on-one help.
- MACs use data analysis to identify:
 - Suppliers who have high claim error rates or unusual billing practices, and
 - Items and services that have high national error rates and are a financial risk to Medicare.
- Providers whose claims are compliant with Medicare policy won't be chosen for TPE.
- Lessons learned from Home Health Prospective Payment System Final Rule (CMS-1611-F).
 - 5 prepayment claims reviewed to determine further level of oversight.



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TPE - How does it work?



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*MACs may conduct additional review if significant changes in provider billing are detected

TPE Common Claim Errors

- The signature of the certifying physician was not included
- Encounter notes did not support all elements of eligibility
- Documentation does not meet medical necessity
- Missing/incomplete initial certifications or recertification



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If High Error Rate Is Found

- Supplier will receive an offer for one-on-one education relative to the specific errors identified through the probe review
- Following education, suppliers are expected to make necessary adjustments/process changes with sufficient improvement demonstrated through claim review during the second-round probe review
- If improvement in the second-round probe review is not sufficient, suppliers will undergo another round of education followed by another probe review.



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Additional Information

- If selected for review, suppliers are not excluded from other Medical Review activities, such as, automated reviews, other pilot review programs, prior authorization, etc., as directed by CMS or other contractor reviews.
- Additionally, the DME MAC will continue to work with other CMS contractors and collaborate with referrals back and forth to the ZPIC/UPIC for concerns related to potential fraud/abuse and Recovery Auditor (RA) for collaboration of vulnerability and to prevent duplication of reviews.



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Referrals to CMS

- CMS may refer to ZPIC/UPIC for a more aggressive audit, which sometimes results in:
 - Payment Suspensions
 - Extrapolated Overpayment
 - 100% Prepayment Reviews
- CMS may recommend review by RAC
- CMS could exercise their revocation authority



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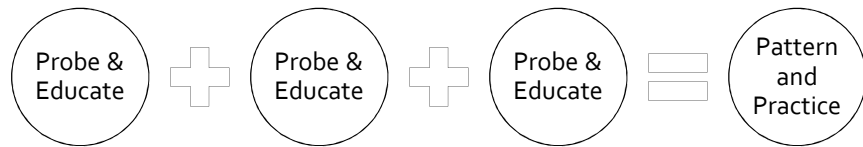
Revocations

- CMS issued a NEW Final Rule for safeguards to reduce Medicare fraud – December 3, 2014
 - Under authority of the ACA, CMS can and will deny or revoke enrollment of entities and individuals that pose a program integrity risk to Medicare for the following:
 - “... providers and suppliers that have a **pattern and practice of billing for services that do not meet Medicare requirements**. This is intended to address providers and suppliers that regularly submit improper claims in such a way that it poses a risk to the Medicare program.”



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Proving a pattern or practice



Revocations

- NSC Revocations for not being open during posted hours of operations
- 2 year revocation with no ability to submit a CAP
- Announced April 2016 – HHS revising revocation authority to allow them to revoke billing privileges for providers who have an insufficient or absent compliance program

Payment Suspensions

- 42 CFR 405.371(a)(1) affords contractors the authority to implement a payment suspension based on “reliable evidence that an overpayment exists or that the payments to be made may not be correct.
- 180 days with chance to submit a rebuttal and sur-rebuttals, if necessary.
- Can be renewed once after 180 days if not predicated on fraud; may be renewed every 180 days indefinitely if predicated on fraud.
- Claims submitted are reviewed and if paid, money is put into an escrow account until such time the audit is completed.
- Seeing this occur in instances that previously wouldn't warrant such action.



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Appeal Changes: Limiting the Scope of Review

- Since October 2016, CMS has limited the scope of appeal contractors to review additional claims and issues outside of what the previous denial reason was for prepayment of postpayment denials/overpayments.
 - Code in question
 - Date(s) of service in question
 - Denial reason
- Watch out for vague medical necessity denial reasons



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Appeal Changes: Serial Appeals

- Serial Appeals – MLN Matters # SE17010
- April 26, 2017 - CMS recently directed the DME MACs to change the process by which they adjudicate appeals of serial claims.
- Once the reason for denial for one claim in a series is resolved at any appeal level, the DME MACs will identify other claims in the same series that were denied for the same or similar reasons, and take that determination into consideration when adjudicating such claims.



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Appeal Changes: QIC Telephone Discussion

- Telephone discussion at the Reconsideration level
- Selected providers will have the opportunity to participate in a formal recorded telephone discussion with the QIC and offer verbal testimony.
- Providers will be able to discuss the facts of the case and provide any additional documentation that would assist in reaching a favorable determination.
- The Reopening process allows potential cases to be remanded back from the ALJ



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Appeal Changes: QIC Telephone Discussion

- Provider submits the initial appeal request
- C2C will determine if appeal meets the criteria for a telephone discussion
- C2C will notify the provider of the scheduled discussion date by a mailed notification letter which includes a contact information form to be remitted indicating election to participate



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Appeal Changes: QIC Telephone Discussion/ Reopening Process

- Previously completed unfavorable reconsideration decisions dated on, or after, January 1, 2013 from DME MAC Jurisdictions C (CGS) and D (Noridian) and includes:
 - Cases that have been closed by the QIC, but yet to be appealed to the Administrative Law Judge (ALJ), or
 - Cases that have been appealed to the ALJ and are currently pending an ALJ decision.
- C2C will request additional documentation, if needed, to support a favorable outcome through the reopenings process
- C2C the QIC will review the materials received to confirm all requested documentation was submitted, and will determine if a reopening is warranted.
- C2C will work with the ALJ to remand the case back to the QIC for processing of the reopening for cases pending at the ALJ.



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President's 2019 Budget - Appeals

- Include \$127 million per year in mandatory funding to invest in addressing the backlog of pending Medicare appeals.
- Change the Departmental Appeals Board's standard of review from de-novo to an appellate-level.
- Establish a post-adjudication user fee for the third level of appeals at the Office of Medicare Hearings and Appeals (OMHA) and the fourth level at the Departmental Appeals Board.
- Remand appeals to the redetermination level with the introduction of new evidence.
- Increase the minimum amount in controversy required for an adjudication to the ALJ to the Federal District Court amount in controversy requirement (\$1,600 in the calendar year 2018, and updated annually).
 - Appeals that do not meet this threshold would be adjudicated by a Medicare magistrate.



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President's 2019 Budget - Appeals

- Allow OMHA to issue decisions without hearings if there is no material fact in dispute.
- Limit the right to appeal a redetermination of a claim that was denied because no documentation was submitted to support the items or services billed.
- OMHA had requested \$251 million in program level funding, an increase of \$144 million over the funding provided in FY 2018 Continuing Resolution. According to OMHA, this request would result in 106,000 additional dispositions per year.
- Require a good-faith attestation on all appeals by appellants that they are entitled to receive Medicare reimbursement imposing liability for civil monetary penalties on appellants who submit attestations that are found to be unreasonable or made in bad faith



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Extrapolated Audits

- What is an extrapolated audit?
- How does it work?
- Strategies for defending extrapolated audits.



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Overpayment Debt on Enrollment

- CMS Transmittal 1998 - Enhancement Required for Implementation of Overpayment based Denials (Effective April 1, 2018)
- Response to the NSC denying DME Supplier enrollments or revalidations for existing Medicare overpayments that are currently under appeal or an Extended Repayment Schedule (ERS) is approved
- CMS clarified that overpayments may be used to deny enrollment if:
 - There is not an approved ERS with CMS; or
 - If the debt has not been repaid in full, and:
 - At least \$1,500 in aggregate owned
 - Has not been repaid in full at time of enrollment or revalidation application is not currently being appealed through QIC decision
 - No ERS
 - No bankruptcy



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ALJ Hearings Update

- Current cases pending for an ALJ Hearing nearing 1 million
- Average processing time for appeals decided in fiscal year 2017 is 1057.2 days
- Hired more judges
- Opened up new offices in Seattle, WA and Kansas City, MO
- Most recent quarterly update actually showed a decrease in volume for the first time.



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ALJ Hearings Update

	FY14	FY15	FY16
Average cost per appeal	\$943	\$1,107	\$1,232
Average claims per decided appeal	2.2	2.9	5.1
Average cost per claim	\$428	\$381	\$242

- Over 10 years, government will pay \$12.37 million in interest payments for all of Part B service claims that will be overturned at the ALJ.



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Settlement Conference Facilitation Pilot

- Pilot alternative dispute resolution process designed to bring the appellant and CMS together to discuss the potential of a mutually agreeable resolution for claims appealed to the ALJ
- If a resolution is reached, a settlement document is drafted by the settlement conference facilitator to reflect the agreement and the document is signed by the appellant and CMS at the settlement conference session



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Settlement Conference Facilitation Pilot – Phase 2

- The amount of each individual claim must be \$100,000 or less. For the purposes of an extrapolated statistical sample, the extrapolated amount must be \$100,000 or less.
 - At least 20 claims must be at issue, or at least \$10,000 must be in controversy if fewer than 20 claims are involved;
 - There cannot be an outstanding request for OMHA statistical sampling for the same claims;
 - One thing for DMEPOS providers to keep in mind is that claims will not be adjusted so subsequent supply or repair claims for that patient will not get paid.
- PHASE 3 UPDATES TO BE POSTED TO OMHA WEBSITE IN APRIL 2018



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Low Volume Claims Settlement

- Began February 5, 2018
- Administrative settlement process
- Total billed amounts of \$9,000 or less per appeal
- Timely partial payment of 62% of the net Medicare approved amount



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Low Volume Claims Settlement

- An appeal is eligible if:
 - The appeal was pending before the OMHA and/or Council level of appeal as of November 3, 2017;
 - The appeal has a total billed amount of \$9,000 or less;
 - The appeal was properly and timely filed at the OMHA or Council level as of November 3, 2017;
 - The claims included in the appeal were denied by a Medicare contractor and remain in a fully denied status in the Medicare system;
 - The claims included in the appeal were submitted for payment under Medicare Part A or Part B;
 - The claims included in the appeal were not part of an extrapolation; and
 - As of the date the executed Administrative Agreement (Agreement) is fully executed, the appeal was still pending at the OMHA or Council level of review.



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Low Volume Claims Settlement

- You must settle all eligible appeals. You may not choose to settle some eligible appeals and continue to appeal others.
- The option will allow for settlement of the outstanding appeal in exchange for timely partial payment of **62% of the net approved amount** of the appeal.
- Submission timeframes are based on NPI



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Low Volume Claims Settlement

- Appellants with NPIs ending in an even number (0, 2, 4, 6, 8), will be accepted between February 5, 2018 and March 9, 2018.
- Appellants with NPIs ending in an odd number (1,3,5,7,9), will be accepted between March 12, 2018 and April 11, 2018.
- Each NPI must be submitted separately to help ensure timely processing and easier payment tracking for the appellant.



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OCR/HIPAA Audits

- Performing desk audits and onsite audits
- Selected entity will receive an email requesting specific data from OCR – desk audit to follow
- OCR may follow-up a desk audit with onsite visit
- Audits are primarily a compliance improvement activity to enable OCR to better understand compliance efforts with particular aspects of the HIPAA Rules.
- In the event a serious compliance issue is identified, OCR may initiate a compliance review to further investigate.



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OCR/HIPAA Audits

- Current Focus:
 - Business Associate Agreements
 - Security and Risk Assessments
- Fines can range from \$100 to \$50,000 per violation (or per record), with a maximum penalty of \$1.5 million per year for each violation



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OIG Work Plan

- Beginning June 15, 2017, OIG will update their Work Plan continuously, with the website being updated monthly.
- This change allows the OIG to enhance transparency around their work planning efforts.
- The OIG Work Plan sets forth various projects including OIG audits and evaluations that are underway or planned to be addressed during the fiscal year and beyond.



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OIG Work Plan

Project Description	Date Posted
Questionable Billing for Off-the-Shelf Orthotic Devices	January 2018
Power Mobility Devices Equipment Portfolio Report on Medicare Part B Payments	December 2017
Home Health Compliance with Medicare Requirements	October 2017
Osteogenesis Stimulators - Lump-Sum Purchase Versus Rental	October 2017
Ventilation Devices: Reasonableness of Medicare Payments Compared to Amounts Paid in the Open Market	August 2017
High-Risk, Error-Prone HHA Providers Using HHA Historical Data	July 2017
Medicare Payments for Unallowable Overlapping Home Health Claims and Part B Claims	July 2017



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Break



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DMEPOS Legal and Compliance Issues

- Overview – Status Quo Problem and how to Increase DME Revenue
- Transitions from In-patient to Out-patient
- Preferred Provider Agreements
- Consignment Closets
- Joint Ventures



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Overview

- Healthcare systems and facilities continue to face strong headwinds
 - Reimbursement is not keeping up with inflation and staffing and technology costs are quickly rising
 - While Medicare adds over 10,000 new enrollees each day, people are living longer and care is becoming more expensive
 - Uncompensated care continues to rise
- To combat these headwinds many look to DME as additional an additional revenue stream
- How to increase out-patient DME revenue for hospitals or health systems



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Transitions from Inpatient to Outpatient

How to capture outpatient DMEPOS revenues?

- Acquire, partner or create your own supplier.

Two Day Requirement, generally:

- For a beneficiary in a Part A inpatient stay, Medicare does not make separate payment for DMEPOS when a beneficiary is in the institution.
- The institution is expected to provide all medically necessary DMEPOS during a beneficiary's covered Part A stay



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Transitions from Inpatient to Outpatient

However:

- In some cases, it would be appropriate for a supplier to deliver a medically necessary item of durable medical equipment, a prosthetic, or an orthotic – but not supplies – to a beneficiary who is an inpatient in a facility that does not qualify as the beneficiary's home if **certain conditions are met**.



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Transitions from Inpatient to Outpatient

• **Conditions for payment of DME to inpatient:**

- Item is medically necessary for use by the beneficiary in the beneficiary's home;
- Item is medically necessary on the date of discharge, i.e., there is a physician's order with a stated initial date of need that is no later than the date of discharge for home use;
- Supplier delivers the item to the beneficiary in the facility solely for the purpose of fitting the beneficiary for the item, **or training** the beneficiary in the use of the item, and the item is for subsequent **use in the beneficiary's home**;



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Transitions from Inpatient to Outpatient



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- **Conditions for payment of DME to inpatient (cont.):**
 - Supplier delivers the item to the beneficiary no earlier than two days before the day the facility discharges the beneficiary
 - Supplier ensures that the beneficiary takes the item home, or the supplier picks up the item at the facility and delivers it to the beneficiary's home on the date of discharge
 - Reason the supplier furnishes the item is **not** for the purpose of eliminating the facility's responsibility to provide an item that is medically necessary for the beneficiary's use or treatment while the beneficiary is in the facility

Transitions from Inpatient to Outpatient



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- **Conditions for payment of DME to inpatient (cont.):**
 - Supplier does not claim payment for the item for any day prior to the date of discharge
 - Supplier does not claim payment for additional costs that are incurred in ensuring that the item is delivered to the beneficiary's home on the date of discharge (beneficiary cannot be billed for redelivery)
 - Beneficiary's discharge must be to a qualified place of service, e.g., home, custodial or facility, but not to another facility (e.g., inpatient or skilled nursing) that does not qualify as the beneficiary's home

Transitions from Inpatient to Outpatient – DME Liaison

DME Liaison

- DME supplier may designate an employee to be on the referral premises for a certain number of hours each week
- The DME supplier employee may:
 - Educated hospital staff regarding DME and related services.
 - Work with a patient, after a referral is made, but before patient leaves hospital.
 - To smooth transition when the patient goes home.
- DME Liaison may **NOT** assume hospital responsibilities as to patient care



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Transitions from Inpatient to Outpatient

Tricky Scenarios: NPWTP and Ventilators

- Patient treated inpatient with the aid of negative pressure wound therapy pumps or a ventilator
- After two weeks, patient is discharged from hospital
- Patient still needs the equipment for care at home

Can the patient take the equipment home?

Who "owns" the equipment upon discharge?

How can DME supplier ease the transition?



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Transitions from Inpatient to Outpatient

- A DMEPOS supplier is required to provide and delivery the equipment out of its own inventory.
- Constructive delivery.
- Who owns the equipment and when?



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Preferred Provider Arrangements

- Current inpatient reimbursement rates motivate hospitals to discharge patients quickly
- To reduce risk and penalties associated with the Hospital Readmission Reduction Program, hospitals desire some post-discharge control
- Preferred Provider Agreements with DMEPOS suppliers
 - DMEPOS supplier monitors the patient to reduce readmissions
- Patient choice – if the patient does not choose another DMEPOS supplier, the hospital can refer the patient to its preferred DMEPOS supplier



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Consignment Closets

- Typical Arrangement
 - DME supplier places products in “closet”
 - Physician orders product for patient to wear home.
 - Typically orthotics, walkers, canes, etc.
 - At discharge – hospital or ER staff pulls product from closet and places it on patient.
 - Hospital staff leaves documentation in secure location in closet.
 - DME supplier collects necessary documents required and bills for the brace.
- Payment Issues
 - Two-day rule
 - Item cannot be something hospital is required to cover under a cost report



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Consignment Closets

- Chargeback provisions
 - What happens when equipment in the closet go missing or are provided to patients that do not qualify for the equipment (not medically necessary)?
 - If the hospital is not financially liable for the equipment, the anti-kickback statute may be violated.
 - Without a chargeback provision a regulator could determine that the DMEPOS supplier is providing remuneration for referrals



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Joint Ventures

- Example:
 - A hospital establishes a subsidiary to provide DME.
 - The new subsidiary enters into a contract with an existing DME company to operate the new subsidiary and to provide the new subsidiary with DME inventory.
 - The existing DME company already provides DME services comparable to those provided by the new hospital DME subsidiary and bills insurers and patients for them



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Joint Ventures

- Common Elements:
 - First, the Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner's existing business.
 - Second, the Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts out substantially all the operations of the new business.
 - Third, the Manager/Supplier is an established provider of the same services as the Owner's new line of business.
 - Fourth, the Owner and the Manager/Supplier share in the economic benefit of the Owner's new business.
 - Fifth, aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner.



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Joint Ventures

- Safe Harbor Potentially Unavailable
 - Many of these questionable joint venture arrangements involve contracts pursuant to which the Manager/Suppliers agree to sell items and services to the Owners at a **discounted price**.
 - The discount safe harbor does not protect – and has never protected – prices offered by a seller to a buyer in connection with a common enterprise.
 - To be protected under the discount safe harbor, a price reduction must be based on an *arms-length transaction*.



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Joint Ventures

- Suspect Characteristics
 - New Line of Business.
 - The Owner typically seeks to expand into a health care service that can be provided to the Owner's existing patients.
 - Captive Referral Base.
 - The newly-created business predominantly or exclusively serves the Owner's existing patient base (or patients under the control or influence of the Owner).
 - Little or No Bona Fide Business Risk.
 - The Owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegating the entire operation to the Manager/Supplier, while retaining profits generated from its captive referral base



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Joint Ventures

- How to structure:
 - Current DME Supplier sets up and owns 100% of New DME Supplier.
 - New DME Supplier obtains surety bond, accreditation, state licensure, and PTAN.
 - Once PTAN issued, New DME Supplier sells stock to Hospital, who pays fair market value.
 - Hospital now owns equity interest in New DME Supplier.
 - New DME Supplier has operational responsibilities and financial risk.
 - Owns delivery vehicles, employs drivers, purchases/maintain inventory, employ intake personnel.
 - If Hospital refers patient to New DME Supplier, must ensure patient freedom of choice.
 - Hospital can share in profits proportional to ownership interest.



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Break



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Federal Laws and Key Players

- U.S. Department of Justice (DOJ)
 - United States Attorneys' Office (USAO)
 - Federal Bureau of Investigation (FBI)
- U.S. Department of Health and Human Services (HHS)
 - Office of Inspector General (OIG)
 - Centers for Medicare and Medicaid Services (CMS)
- State Attorneys' General Offices
 - Medicaid Fraud Control Units (MFCUs)



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The False Claims Act

31 U.S.C. §§
3729 et seq.

The Government's primary weapon against health care fraud has been the False Claims Act ("FCA") because:

- it imposes potentially ruinous civil penalties; and
- actions under the FCA can be initiated by whistleblowers.

The FCA imposes liability for:

- (A) knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and
- (C) conspiring to commit a violation of [the False Claims Act].



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Knowing and Knowingly

- Have “actual knowledge of the information”
- Act “in deliberate ignorance of the truth or falsity of the information”; or
- Act “in reckless disregard of the truth or falsity of the information”.
- **Does not require proof of specific intent to defraud**



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Consequences of Losing FCA Case

- Treble damages
- Civil penalties of up to \$11,000 per claim.
- Program suspension, debarment and exclusion for entities, officers, directors and employees and related parties.



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Qui Tam Relators

- The federal False Claims Act is a qui tam statute, meaning that private citizens (“relators”) may file complaints alleging violations of the FCA under seal on behalf of the U.S. Government and receive at least 15%, but not more than 25%, of any amount recovered.
- Once a whistleblower files a suit, the Department of Justice must decide whether to “intervene” (i.e., take over and prosecute the suit).
- If the government does not intervene, the case is unsealed and the whistleblower may proceed on his/her own.
 - See 31 U.S.C. §3730(b)



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Anti-Kickback Statute

42 USC §
1320a-7b

- Prohibits knowing and willful solicitation of payment (1) in return for referring an individual for an item or service which may be paid in whole or in part by a federal health care program or (2) in return for leasing, ordering or arranging any good, item or service which may be paid for in whole or in part by a federal health care program.
- Prohibits making or offering payment to induce such referrals or purchases.
 - Penalties:
 - Fine up to \$25,000;
 - Imprisonment up to 5 years; or
 - Both



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OIG Exclusion Authority

- §1128 and 1156 of the Social Security Act.
- Effect of Exclusion:
 - No Federal health care program payment may be made for items or services:
 - Furnished by an excluded individual.
 - Directed or prescribed by an excluded individual, where person furnishing the item or service knew or had reason to know of the exclusion.
- Excluded individual also subject to Civil Monetary Penalty of \$10,000 for each violation, plus potential treble damages.
- 20 statutory bases for exclusion.
 - 4 bases for mandatory exclusion.
 - 16 bases for permissive exclusion.



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OIG Exclusion Authority

OIG Mandatory Exclusion

- § 1128 (c) of the Social Security Act.
 - 5 year minimum.
 - Resulting from
 - Felony convictions relate to health care fraud or controlled substances.
 - Felony or misdemeanor convictions for program related crimes or patient neglect or abuse.



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OIG Exclusion Authority



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OIG Permissive Exclusion

- Select Bases:
 - Submission of false or fraudulent claims to a federal healthcare program.
 - Engaging in unlawful kickback arrangements.
 - Performance of unnecessary or substandard services.
- § 1128 (b)(15) permits exclusion of the following individuals within a "sanctioned entity" based on the entity's conviction of certain offenses or exclusion:
 - Owners – if they know or should have known of the wrongful conduct leading to the sanction.
 - Officers and Managing Employees – based solely on their position with the sanctioned entity, regardless of their knowledge.
- Exclusion presumptively for 3 years.
 - Rebuttable presumption in favor of exclusion.

OIG Exclusion Authority



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OIG Guidance for Implementing Permissive Exclusion

- The OIG may consider:
 - Circumstances of misconduct.
 - Seriousness of offense.
 - Individuals roles in sanctioned entity.
 - Individuals response to misconduct.
 - Information about the entity.
 - OIG currently considering revisions to Guidance.

Value Based Arrangements

Value Based Contracting

- Accountable Care Organizations
 - Participation in Medicare Shared Savings Program or NextGen ACO
- Clinically Integrated Networks
 - Commercial Payors
 - Often only engaged in shared savings/shared loss contracting
 - All fraud and abuse laws apply



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Value Based Arrangements

ACO Legal Parameters

- DME Suppliers not eligible to form an ACO.
- DME Suppliers **may participate** in an ACO.

ACO Waivers

- Pre-participation Waiver
- Participation Waiver
- Physician Self-Referral Waiver
- Shared Savings Distribution Waiver
- Patient Incentives Waiver



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Value Based Arrangements



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Participation Waiver

- Applies broadly to ACO-related arrangements undertaken during the term of the ACO's MSSP Participation Agreement.
- Stark and AKS are waived for arrangements within this waiver.
- Requires a bona fide determination of the ACO governing body that the arrangement is "reasonably related" to the purposes of the MSSP.
- The description of the arrangement (including parties, date, purpose, and goods/services required, but not the financial terms) must be publicly disclosed.
- The ACO must enter into a Participation Agreement with CMS and remain in good standing.
- The ACO must meet the MSSP requirements set forth in its regulations concerning its governance, leadership, and management.
- Documentation is retained by the ACO for at least ten (10) years.
- Public disclosure is required.

Value Based Arrangements



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DME Supplier Opportunities

- Patient Education
- Discharge Planning
- Chronic disease focused initiatives
 - COPD
 - CHF

Medicaid MCOs and Commercial Payor Opportunities

Questions???



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