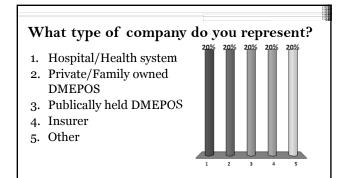
Fighting for Survival – DMEPOS

Wayne van Halem, President, The van Halem Group Paula Koenig, Corporate Compliance Officer, Numotion Ruth Krueger, Compliance Program Administrator, Sanford Health

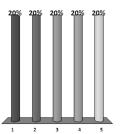
Objectives

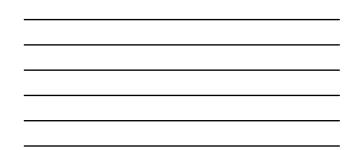
- Understand the Impact of competitive bid-derived pricing on products in non-bid areas plus future of competitive bid rounds
- Investigate Alternative payment arrangements, including the pros and cons of submitting non-assigned claims
- Learn how to manage the continued impact of Medicare/RAC audits and new program integrity contractors
- Hodge Podge of compliance issues discussions



How long have you worked in DMEPOS?

- 1. <1 year
- 2. 1-5 years
- 3. 6-10
- 4. >10
- 5. DME? I'm in the wrong room!!





How many employees in your operation? 25% 25% 25% 25

- 1. <20
- 2. 20-50
- 3. 51-100
- 4. >100

DMEPOS historical perspective

- DME = big business
- Customers ...then and now

DMEPOS Customers

- 23 million of the Greatest Generation
- 20 million of the Korean War generation
- <u>78 million</u> Baby Boomers (those born between 1946 and 1964).

CBS News Report

<u>Amazing aging athletes</u>



Many customers

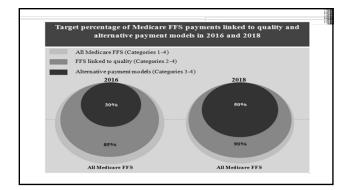
• Why the struggle to survive?





Alternative Payment Arrangements

- HHS categorizations for health care payments:
 - Category 1 Fee-for-service no link to quality
 - Category 2 Fee-for-service with link to quality
 - Category 3 Alternative payment models built on fee-for-service architectures
 - Category 4 Population-based payment



Alternative Payment Models

- Accountable Care Organizations
- Bundled Payment Arrangements
- Hospital Value-Based Purchasing
- Hospital Readmission Reduction Programs

The Rise of Value-Based Care Delivery

15

	Healthcare Market Trends							
jès.	Current models of care are becoming unsustainable. The number of people needing care is set to quadruple by 2050, placing extreme demands on access to care and creating a looming physician shortage.							
	Patients are getting sicker. According to the CDC, 25% of Americans have two or more chronic conditions, and the number is rising.							
°\$ \$ \$	The cost of healthcare is expected to increase annually by $>5\%$ through 2020.							
2	Re-admission penalties for hospitals require farther-reaching and longer-term care management capabilities.							
	Healthcare providers are at direct financial risk for the care of patients, requiring careful evaluation of value-based care pathways and settings. 6							
*`0	Reimbursement is shifting to reward progress toward the "triple aim" of care: access to care, clinical outcomes, and cost-effectiveness.							

Value-Based Reimbursement

- Value = quality / cost (over time)
- Insurers pay for value delivered, not for services rendered
- Financial risk shifts to providers for whole-patient, costeffective care
- Health management and prevention becomes more important
- Populations are managed across providers: "It takes a village"
 Poyter
 Poyter
 Poyter



Value-Based Plans Becoming the Norm

Medicare Pilot Programs

- Bundled Payment for Care Initiatives (BPCI)
- Comprehensive Care for Joint Replacement (CJR)
 - Hip and knee replacements
 - Proposing hip and femur fractures
- Cardiac Procedure Bundle (proposed)
 - Includes incentive for cardiac rehab
- Value Based Payments for Home Health
- Value Based Reimbursement for SNFs



Value-based plans becoming the norm

Self Funded Employers and IDNs

- Generally bundled payments
- Cardiology and Orthopedic procedures
- Cleveland Clinic, Lowe's, others
- Intermountain Healthcare, Kaiser
- Medicare • By the end of 2016, 85% of Medicare payments tied to quality or value • By the end of 2018, 90% of Medicare payments tied to quality or value

Insurance Trend Estimates

 Commercial Plans
 By the end of 2020, 75% of businesses will be operating under value-based payments.

Understanding Bundled Reimbursement

A financial incentive for providers to coordinate care, keep costs down

How Medicare Bundling Programs Work

- Providers and suppliers bill and paid as usual under regular payment systems.
- Single "price" to hospital performing surgery (knee replacement, cardiac bypass) for any services rendered as part of that procedure (through 90-days post d/c)
- End of year reconciliation between claims payment and target "price"

Bundled Reimbursement, continued

How payments are distributed

- · Savings to be shared with all post-acute providers
- Hospital negotiates criteria and shared savings with each provider

Implications of for the Industry

- Efficacy of post-acute care and appropriateness of setting is center stage
- Hospitals incented to select and work closely with most valuable post-acute partner
- · PAC providers incented to deliver and demonstrate value

Value-Based Reimbursement

How is this changing care delivery?

- •Conscientious discharge planning
- •Cross-Provider Collaboration
- •Use of protocols that deliver value over time
- Complex Care Management

Value-Based Reimbursement

How is this changing care delivery?

- "There is no standardized process for determining post-acute destination...Patients with same discharge diagnosis may be referred to different PAC settings." *AHA Trendwatch*
- In 2014, hospitalizations for heart attacks cost Medicare over \$6 billion. Yet for every treatment, the cost could vary by as much as 50%

How is Value-Based Care Delivery changing the value proposition of home care providers?

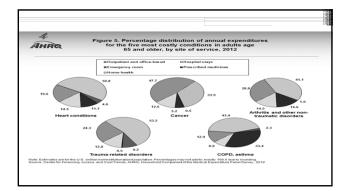


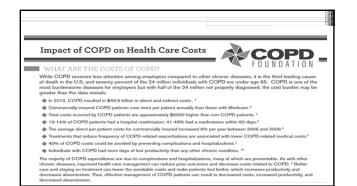
Hospital & Primary Care Physician Conundrum

Which <u>setting(s)</u>, <u>services</u>, and <u>provider(s) of services</u> will:

- Provide the best long-term outcomes for my patient ...at the best price
- · Prevent readmissions, ER visits, or reduce hospital LOS
- Provide the greatest level of patient satisfaction
- Be easy for me to work with

"HCOs that do not adapt to the home care imperative risk becoming irrelevant. It seems inevitable that health care is going home." -New England Journal of Medicine





Chronic Conditions and Hospital Admissions

Diagnoses producing greatest number of hospital readmissions (2010)

Dringing Dy for Up prite Star	# - C C	# of	Readmission				
Principal Dx for Hospital Stay	# of Stays	Readmissions	Rate				
Congestive Heart Failure	847,073	209,017	25%				
Septicemia	696,122	145,896	21%				
COPD	606,186	126,443	21%				
Complication of Device, Implant, Graft	596,062	121,036	20%				
Diabetes Mellitus, w/ complications	480,958	97,784	20%				
Souce: HCUP/AHRQ Statistical Brief, April 2013							
otatistical shell, i pr		2					

Cost Effectiveness of Homecare

- Need Cost-Effective Solutions
- · Studies show home-based care is cost-effective
- · Overall Medicare spending increased over 175% from 2000 - 2014.
- By contrast, DME spending only increased 3% overall in the past 5 years and actually declined 4% between 2012 and 2014.
- DME % of Medicare spending has declined for 10 years from 2.0% in 2004 to 1.25% (\$7.7 billion) of the Medicare budget in 2014.

Cost Effectiveness of Homecare

- Oxygen therapy can be provided for one year for the cost of one day's stay in the hospital
 For every dollar spent...
 \$1 spent on mobility DME saves \$16.78 in fall-related recovery
 \$1 spent on supplemental O2 therapy for COPD saves \$9.62 in complications
 \$1 spent on CPAP therapy saves \$6.73 in Obstructive Sleep Apnea complications

- complications

Source: http://www.vgmdclink.com/uploads/Document-Library/d1306dfcd9db67830ba14d4cd5b3be8c.pdf

Redefine Your Role in the Healthcare Value Equation

• Imperatives

Increase patient adherence to plan of care Help patient avoid exacerbations

· Leverage your core competencies: equipment selection,

- delivery, maintenance

- Equipment that patients will USE Equipment for full range of conditions Equipment with monitoring capabilities Remote monitoring / telehealth technologies; partner with home care agencies/vendors for actual monitoring 0
- Be intentional and exceptional in set up, training, and follow up

Redefine Your Role in the Healthcare Value Equation

• Market to providers in terms of value of home care, and of YOUR CARE



Assigned vs. Non-Assigned Claims



 DME Suppliers have historically accepted assignment; however, increased regulatory oversight and reimbursement reductions have made suppliers question assignment.

Assigned vs. Non-Assigned Claims

- Participating
- Agrees to accept assignment on all claims Agrees to accept the Medicare allowed amount as payment in full Can only collect co-payment and deductibles and for non-covered services M-2:
- Medicare payment is sent to the supplier
 Non-Participating Can elect to accept assignment or not on a claim by claim basis · A supplier can submit either assigned or non-assigned claims
 - Beneficiary can be charged up front and be billed the difference between the billed and allowed amounts

 - · Payment is sent to the beneficiary

Submitting Non-Assigned Claims

- · You must submit claims per the mandatory claim submission rule, but you don't have to accept assignment
 - You do not have to submit claims for non-covered services
- You must be non-participating (update status with NSC during the enrollment period)
- · You can charge the beneficiary up front
- You are not bound by the "limiting charge" rule

Mandatory Assignment Situations

- Section 114 of the Benefits Improvement and Protection Act of 2000 (BIPA) says mandatory assignment applies to Medicare-covered drugs Competitive Bid Suppliers must accept assignment
- Non-contract suppliers must accept assignment for competitively bid items

 - Traveling beneficiaries
 - Grandfathering
 - Repairs to bid equipment in CBAs
- Dual-Eligible Beneficiaries (Medicare/Medicaid)

Fragmented Billing

- · A non-participating supplier accepts assignment for some services and requests payment from the beneficiary for other services performed at the same place and at the same time.
- · A supplier may accept assignment on a claim by claim basis, but the decision applies to all services performed at the same place and on the same occasion.
- Exception A supplier may choose not to accept assignment for other services as the same place or occasion in a mandatory assignment situation.

Oxygen

- · Nonparticipating suppliers may accept assignment on a claim by claim basis. However, 42 CFR Section 414.226 (g)(3) requires that "before furnishing oxygen equipment, the supplier must disclose to the beneficiary it's intentions as to whether it will or will not accept assignment of all monthly rental claims for the duration of the rental period."
 - · So.... you cannot switch assignment for oxygen claims during the 5 year period.

Beneficiary Authorization

- Beneficiary Authorization All claims require an one-time authorization - later claims for the same services can be billed without an authorization.
- · One-time authorization does not apply to non-
- assigned DME rental claims;
- requires a separate authorization for payment of each claim
- can not have the patient sign all authorizations up front although industry is challenging this

Capped Rental

- Allows billing capped rental items as nonassigned, but must submit monthly rental claims just like assigned claims.
- Cannot charge the beneficiary for all months up front
- · Consider getting a credit card to charge monthly

Advanced Beneficiary Notices

- ABNs apply to both assigned and non-assigned claims
 Lack of medical necessity
 - Prohibited unsolicited phone contacts
 - Supplier number requirements not met
 - Denial of Advanced Determination of Medicare Coverage (ADMC) request
 - Noncontract supplier furnishing competitively bid DMEPOS items in a CBA
- Protect yourself and get an ABN when appropriate

Documentation Requirements

- Do not differ for assigned vs non-assigned claims
- Non-assigned claims can be audited- although probably less frequently
- If the claim is deemed to be denied and you do not have a proper ABN, the contractor could require you to refund the beneficiary
- Nothing is different, except who pays the supplier and the amount the supplier can charge



National DMEPOS and HHH RAC

- November 1, 2016 RAC contract awarded to Performant Recovery
- RAC set to begin outreach this month
- RAC audits start March 2017

Other RAC Program Changes

- Establishing ADR limits based on a supplier's compliance with Medicare rules
- RACs must wait 30 days to allow for a discussion request before sending the claim to the DME MAC for adjustment
 SOW also says that RACs are expected to support CMS in
- SOW also says that RACs are expected to support CMS in a minimum of 50% of the cases that make it to the ALJ.
- CMS also says in the SOW that the agency has the authority to settle appeals without RAC approval or input.

Other RAC Program Changes

- No contingency fees until after 2nd level of appeal
 Ensures RAC is properly applying Medicare rules on claims audited.
- RACs required accuracy rate of 95% and overturn rate <10%. Failure to meet =
 - Decreased ADR limits **OR**
 - Elimination of certain reviews until problems corrected

What does that mean?

RACs are back -expect more active than ever;

- likely to immediately begin automated, semi-automated and complex reviews already approved
- looking at post payment claims than have been submitted within the previous 3 years from the date the claim was paid



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

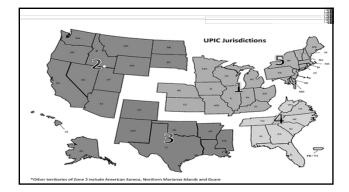
UPICs

- 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

UPICs

- 2 task orders awarded thus far:
 - AdvanceMed on 5/24/2016 for UPIC Jurisdiction 1 (Midwest)
 - Contract amount = \$76,874,623.22
 - Safeguard Services was awarded contract for Jurisdiction 5 (Northeast) but no details have been released publicly.
 - Transitioned March 1, 2017.



- 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 suppliers

Supplemental Medical Review Contractor (SMRC)

Strategic Health Solutions (SHS) performs a large volume of Medicare Part A, Part B, and Durable Medical Equipment reimbursement claims nationally;

- · focus on lowering improper payments in Medicare Fee-For-Service programs and increasing efficiencies in medical review functions.
- includes issues identified by the OIG, CERT and CMS internal data analysis
- Focus on national claims data analysis versus MAC jurisdiction data

SMRC

- Completed Projects
 - Power Mobility Devices
 - Vacuum Erection Devices (VED)
- Current Projects
- Diabetic Testing Strips
- Oxygen (50,000)
- Nebulizers (50,000)
- ^o CPAP (6,000)

SMRC

- Results on respiratory reviews coming in actual overpayments
- Review results carefully
- We don't anticipate extrapolated overpayments but it can't be ruled out
- · Appeal denials

Revocations

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."

Other High Risk Codes

- CPAP/BiPAP
- Oxygen
- High Frequency Chest Wall Oscillation
- TENS
- Support Surfaces
- Negative Pressure Wound Therapy
- Ventilators

- Appeal Changes
 October 1, 2015 CMS limits scope of review at Redetermination and Reconsideration to the reason the claim was initially denied.
- · Two instances where guideline does not apply · Claims denied in prepayment reviews (guideline applies only to post-payment denials);
- · Claims denied in post-payment review for insufficient documentation and appealed with never-before presented documents (guideline allows claims to be denied for an issue other than the issue that was initially denied).

Appeal Changes

- DME Pilot Program to allow for a discussion period at the Reconsideration level
- · QIC will be the one to initiate
- · Limited to claims for oxygen and diabetic supplies currently
- Also looking to reopen all other unfavorable claims for these products back to January 1, 2013, if they can issue a favorable decision
- Announced November 30, 2016 program has been expanded to include all suppliers in Jurisdictions C & D; all items except PMDs

Appeal Changes – Final Rule

- Published 1/13/2017
- Precedential Final Decision by the Secretary Decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.
- Attorney Adjudicators
- A licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance.

ALJ Hearings Update

- December 6, 2016 Judge issued decision in American Hospital Association lawsuit
- HHS must eliminate the backlog by 2021
 - º 30% by the end of 2017
 - 60% by the end of 2018
 - 90% by the end of 2019
 - Completely by the end of 2020
- Judge was asked by HHS to reconsider and he declined their request to do so.

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

Settlement Conference Facilitation Pilot Phase 2

- For the purposes of an extrapolated statistical sample, the individual claim 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;
- Claims will not be adjusted so subsequent supply or repair claims for that patient will not get paid.

Compliance Programs

- Proper transferring of liability
- Getting patients requalified
- Quality Assurance
- PreScreening
- Working with beneficiaries
- Data analysis
- Innovation



Paula Koenig

Corporate Compliance Officer, Numotion

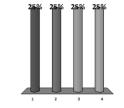


Medicare Competitive Bid

- Initial Round 1 July 1 2008-July 15 2008: 10 CBAs
 ✓ Retracted by Congress after just 2 weeks
- o Round 1 Re-Bid 01/01/2011 − 12/31/2013: 9 CBAs \checkmark average 32% reduction in allows
- o Round 2 07/01/2013 06/31/2016: 100 CBAs
 ✓ average 45% cuts
- Round 1 Re-Compete 01/01/2014 12/31/2016: 9 CBAs
 ✓ average 37% cuts
- o Round 2 Re-Compete 07/01/2016 12/31/2018: 117 CBAs
 ✓ average 7% cuts

Is Your DME business in a Round 1 or Round 2 CBA?

- 1. Yes, Round 1 only
- Yes, Round 2 only
 Yes, both Round 1
- and Round 2
- 4. No, none of our
- customers are in a CBA 5. What's a CBA?



Regional Single Payment Amounts (RSPA)

Medicare is using Bid rates to adjust allowables in non-bid areas

- Split into non-rural and rural rates by bene zip codes; rural gets 10% add-on
- 01/01/16 phased in rates; blended with 2015 allowables
- 07/01/16 full implementation of RSPAs
 2016 cuts were in many cases more than 50% lower than 2015 allowables

RSPA

Cures Act rescinded July cut; claims for DOS 07/01/16 thru 12/31/16 to re-process at January rates

• Full RSPAs in effect 01/01/2017

RSPAs reflect an average cut of 38% from 2016

Future Bidding

- 2019 will see new bid programs for both Round 1 and 2
- Bidding will start in 2017
- Could be different categories in Round 1 vs 2
- New Surety bond requirement
- 'lead item' groupings
- Bid ceiling at 2015 allowables

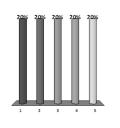
Can We Survive the Lower Allowables?

- Limit Products offered
- Non-assigned claims
- Re-define Service areas
- Retail
- On-line



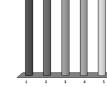
How have you dealt with lower payments?

- 1. Reduced staff
- 2. Changed product offerings
- 3. Redefined service area
- 4. Increased non-assigned
- claims
- 5. All of the above



What are the pitfalls of cash sales?

- 1. Mandatory Claim Filing
- 2. ABNs
- 3. Contract obligations
- 4. Dual-eligibles
- 5. All of the above



Cash Sales

More 'cash' business is enticing... but

- Medicaid implications
 Commercial contract obligations
- Medicare mandatory claim filing Still need documentation

On-line sales:

· How do you collect insurance info?

Solution: separate entity/Tax ID creates other challenges



Hodge-Podge: A little of this, a little of that...

- Medicare policy changes
- Modifiers the new challenge
- Documentation trends
- Prior Authorization: PWCs Ko856 & Ko861
 - starts 03/20/17
 - what items are next?

More...Compliance Issues

- Increase in social media activity challenges PHI management
- Email and Texting referral sources
 ✓ 01/09/2017 headline: Joint Commission prohibits secure texting for patient care orders
- · Acquisitions and closures: transferring patient files
- · Contract compliance non-Medicare payers

Business Trends

- Direct to Beneficiary Marketing
- National mail order bracing
- Lead generation
- Scam telehealth arrangements
- Consequences
 - ZPIC Audits
 - Prepayment Reviews
 - Revocations Suspensions
 - Extrapolated overpayment

ACA "Obamacare"

- Repeal and replace?
- Possible impact on competitive bid
- Current status of legislation/political climate



Exclusions

Anyone who hires an individual or entity on a sanctions list may be subject to civil monetary penalties (CMP). • Need to verify that new hires have not been excluded

- And re-verify all staff monthly!
- · Also: need to verify that referring practitioners have not been excluded
- · And that vendors/manufacturers have not been excluded

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL https://oig.hhs.gov/exclusions/index.asp

Medicare Enrollment

CMS appears to be getting more aggressive in revoking Medicare provider numbers

- Competitive bid contract violations
- Complaints
- Non-responses

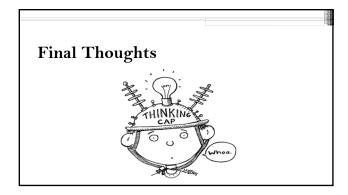
• Patterns of 'improper' billing

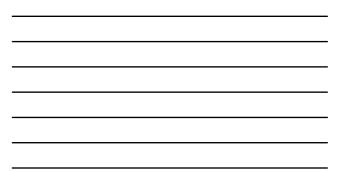


Revocation Appeals

• Applicant/supplier must submit a CAP within 30 days from the postmark of the denial or revocation letter

- Request for reconsideration must be made within 60 days from the postmark of the denial or revocation letter
- Request must have the original signature of the authorized official, owner or partner on file





Questions?

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Additional information on OIG Workplan

2017 OIG Work Plan - Power Mobility

- · Power mobility devicessupplier compliance with payment requirements
- OIG will review payments for power mobility devices (PMD) to determine whether such payments were

medically necessary.



2017 OIG Work Plan - Nebulizers

Nebulizer machines and related drugs-supplier compliance with payment requirements

- · OIG will review payments for nebulizer machines and
- Old will review payments for nebulizer machines and related drugs to determine whether medical equipment suppliers' claims are medically necessary and are supported in accordance with Medicare requirements.
 For calendar year (CY) 2014, Medicare paid approximately \$632.8 million for inhalation drugs. With an improper payment rate of 42 percent, inhalation drugs were sixth on a list of the top 20 DMEPOS services with the highest improper payments in the 2014 CERT report.

2017 OIG Work Plan -

Osteogenesis Stimulators

- From 2012 to 2014, Medicare payments for these devices were approximately \$286 million dollars.
- The OIG will examine the lump-sum purchase versus rental option to determine whether potential savings can be achieved if osteogenesis stimulators are rented over a 13-month period rather than acquired through a lump-sum purchase.

2017 OIG Work Plan - Orthotics

- Orthotic braces–supplier compliance with payment requirements
- OIG will review orthotic braces to determine whether suppliers' claims were medically necessary.
- Prior OIG work indicated that some suppliers were billing for services that were medically unnecessary (e.g. beneficiaries receiving multiple braces and referring physician did not see the beneficiary)

2017 OIG Work Plan – SNF Payments

- 2009 OIG report found Medicare Part B allowed inappropriate payments of \$30 million for DMEPOS provided during non-Part A SNF stays.
- OIG intent study the extent of inappropriate payments to nursing home patients during non-Part A stays in 2015.
- Spotlights CMS ability to determine if they have appropriate systems in place to identify improper payments and initiate recoupments.

2017 OIG Work Plan – PAP Supplies

- Medicare payments for CPAP and BiPAP supplies in 2014 and 2015 -\$953 million.
- Prior OIG work found suppliers auto-shipped supplies when refills were not requested by the beneficiary and also that the physician orders were incomplete in regards to the types of supplies needed and frequency of use.
- The OIG will review supplier compliance with documentation requirements for frequency and medical necessity.