




Agenda

- Durable Medical Equipment (DME) overview
- Healthcare industry transformation
- DME industry trends and challenges
- OIG work plan and recent DME enforcement cases
- Compliance challenges with DME products and control considerations






Durable Medical Equipment (DME) overview

What is DMEPOS?

Durable medical equipment, prosthetics, orthotics and supplies (hereafter, DME)

Criteria
<ul style="list-style-type: none">— Durable (can withstand repeated use)— Used for a medical reason— Not usually useful to someone who isn't sick or injured— Used in your home— Has an expected lifetime of at least three years

Covered by Medicare Part B
<ul style="list-style-type: none">— Rent— Buy



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

4

Examples of DME

Oxygen equipment

Hospital beds

Mobility assistive equipment (canes, wheelchairs, walkers, power mobility devices)

Diabetic supplies (insulin pumps, monitors, test strips)

Infusion pumps and supplies



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

5


DME Industry primer

- Valued at \$140.9 billion in 2015; expected to reach \$242.1 billion by 2024
- Chronic conditions, such as heart disorders, cancer, gynecological disorders, and neurological disorders are on a rise
- Home health is a cost effective alternative to lengthy hospital stays

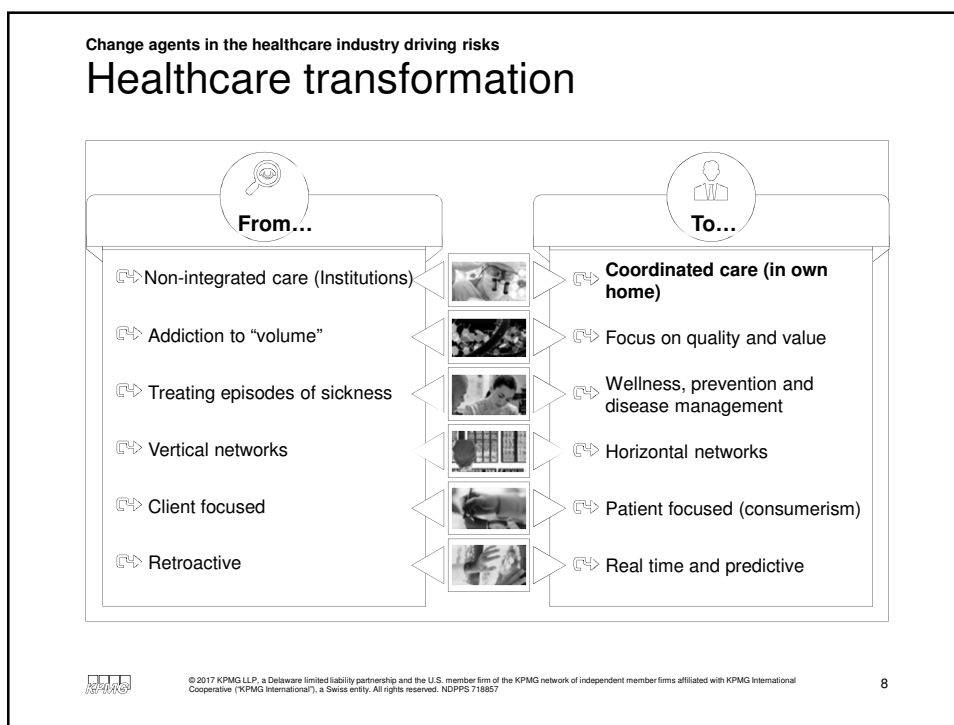


© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

6



Healthcare industry transformation



Change agents in the healthcare industry driving risks

Healthcare transformation (continued)


Unsustainable **COST** driving reform


REFORM focuses on improving cost efficiency and quality of care via initiatives

INITIATIVES challenge traditional insurer and provider model

MODELS require greater focus on data, population health dynamics and business-to-consumer interaction

REGULATORY UNCERTAINTY – Repeal and replace of ACA

 © 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857 9



DME industry trends and challenges

DME Macro Trends

Spending on DME is expected to accelerate

- Demographic trends
- Preference for home-based care
- Increase in insured populations

Regulatory changes are impacting reimbursement

- Competitive bidding is now the norm (respiratory, mobility, & beds)
- Bidding to extend to other categories
- Reduced reimbursement pressures providers to reduce costs

Greater risk-sharing and pay for performance drive new contract models

Decreasing operating margins challenge management teams

- Aggressive cost optimization
- Leveraging technology, analytics and and business intelligence
- Optimize revenue cycle and reduce leakage



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

11



OIG work plan and recent DME enforcement cases

Why are we still talking about DME?

2017 OIG work plan

New focus areas

- **Part B services during non-Part A Nursing Home Stays**
 - Study will determine the extent of inappropriate Part B payments for DME provided to nursing home residents during non-Part A stays in 2015.
- **Positive Airway Pressure Device (PAPs):** supplier compliance with documentation requirements for frequency and medical necessity
 - Orders must specify type of supplies and the frequency with which the supplies must be replaced
 - Beneficiaries (or caregivers) must request refills of repetitive supplies before suppliers dispense them
- **Orthotic Braces:** Reasonableness of Medicare payments compared to amounts paid by other payers
 - Since 2009, Medicare payments for certain knee braces has almost tripled.
 - Compare Medicare payments for orthotic braces to amounts paid by non-Medicare payers to identify potentially wasteful spending.
 - Estimate financial impact of aligning Medicare fee schedule with those of non-Medicare payers.



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

13

2017 OIG work plan (continued)

New focus areas

- **Supplier compliance with payment requirements**
 - Orthotic braces
 - Nebulizer machines and related drugs
 - OIG is going to review Part B payments for these items to determine if they were medically necessary and supported in accordance with Medicare requirements
- **Rent vs. lump sum payment**
 - Power mobility devices
 - Osteogenesis stimulators
- **Power mobility devices**
 - Identify trends in payment, compliance, and fraud vulnerabilities and offer recommendations to improve detected vulnerabilities



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

14

Recent cases

- Owner sentenced to jail for submitting false and fraudulent claims to TX Medicaid - June 2017
 - Owner was convicted of submitting false and fraudulent claims to Texas Medicaid for DME that were not provided and/or not authorized by a physician
 - Forged and/or caused others to forge the signatures of physicians on the required prescription forms
 - Billed for larger, higher-paying sizes of pull-ups and diapers regardless of whether those sizes were needed or provided

RGV Durable Medical Equipment Company Owner and Four Others Sentenced in Health Care Fraud Scheme

McALLEN, Texas - The owner of a Rio Grande Valley area durable medical equipment (DME) company has been ordered to federal prison for her role in a scheme to defraud Texas Medicaid through fraudulent



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

15

Recent cases (continued)

- DME Manufacturer Agrees To Pay \$2.715 Million To Resolve False Claims Allegations - June 2017
 - The company caused the submission of false claims to Medicare through their marketing of certain devices as DME despite knowing that these devices did not have the expected life of a durable device.
 - Devices were pre-programmed with a specific number of therapy hours well below the expected life of a DME device, and were never used again once those hours expired

Durable Medical Equipment Manufacturer Agrees To Pay \$2.715 Million To Resolve False Claims Allegations

Innovative Therapies, Inc. ("ITI") and its ultimate parent company Cardinal Health, Inc. ("Cardinal") have agreed to pay \$2.715 million to settle False Claims Act allegations, announced Jack Smith, Acting United States Attorney for the Middle District of Tennessee. The settlement concerns conduct initiated by ITI



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

16

Recent cases (continued)

- Oxygen Equipment Provider Pays \$11.4 million To Resolve False Claims Act Allegations - April 2017
 - Government accused the entities of submitting claims for reimbursement to Medicare and other federal healthcare programs in violation of program rules and as part of a cross-referral kickback scheme with sleep clinics

Oxygen Equipment Provider Pays \$11.4 Million to Resolve False Claims Act Allegations

The Department of Justice announced today that Braden Partners, L.P., doing business as Pacific Pulmonary Services, has agreed to pay \$11.4 million to resolve allegations against it and its general partner, Teijin Pharma USA LLC, for violating the False Claims Act by submitting claims for reimbursement to Medicare and other federal healthcare programs for oxygen and related equipment supplied in violation of program rules, and for sleep therapy equipment supplied as part of a cross-



Recent cases (continued)

- Company to Pay \$34.8 million for Allegedly Causing False Claims Related to the Sale of Masks Designed to Treat Sleep Apnea- March 2016
 - Government alleges a violation of False Claims Act for paying kickbacks in the form of free call center services to DME suppliers that bought its masks for patients with sleep apnea.

Respironics to Pay \$34.8 Million for Allegedly Causing False Claims to Medicare, Medicaid and Tricare Related to the Sale of Masks Designed to Treat Sleep Apnea

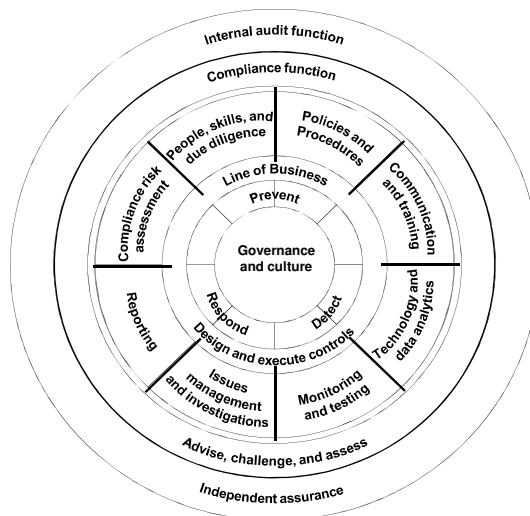
Respironics Inc., based in Murrysville, Pennsylvania, has agreed to pay \$34.8 million to resolve alleged False Claims Act violations for paying kickbacks in the form of free call center services to durable medical equipment (DME) suppliers that bought its masks for patients with sleep apnea, the Department of Justice announced today.





Compliance challenges with DME products and control considerations

KPMG's Compliance Program Framework



So what...

Risk areas and corresponding controls

- **Billing for items or services not provided**
 - Delivery ticket – date of delivery, signature of beneficiary, signature of company employee, description of DME (Prevent and Detect)
- **Billing for items that are not medically necessary**
 - Face-to-face encounters – documented within six months prior to physician's order (Prevent and Detect)
- **Sales/Referral practices**
 - Compensation structure for internal and external sales force are compliant with Stark and AKS (Prevent and Detect)
 - Analyze referral patterns (Detect and Respond)
- **Written order prior to delivery (WOPD)**
 - Training on requirements (Prevent)
 - Prior authorization (Prevent and Detect)
 - Controls built into order entry and dispatch systems (Prevent and Detect)



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

21

So what...

Risk areas and corresponding controls (continued)

- **Excluded individuals**
 - Pre-employment screening checks (Prevent)
 - Routine screening (e.g., monthly) (Detect)
- **Complete and accurate Certificate of Medical Necessity (CMN)**
 - Controls built into order entry and dispatch systems (Prevent and Detect)



© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 718857

22



Jerod J. Holloway

Managing Director Healthcare IARCS
Nashville, TN
jerodholloway@kpmg.com
615-393-2846

Sarah Jacobs Beard

Director Healthcare Investigations and Disputes
Atlanta, GA
sjbeard@kpmg.com
404-222-7209



kpmg.com/socialmedia

The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavor to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

© 2017 KPMG LLP, a Delaware limited liability partnership and the U.S. member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity. All rights reserved. NDPPS 701088

Some or all of the services described herein may not be permissible for KPMG audit clients and their affiliates..

The KPMG name and logo are registered trademarks or trademarks of KPMG International.