

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE  
Dental Sleep Medicine  
Mini-Residency Cohort II, Module III

**LEGAL ISSUES RELATED TO  
THE PRACTICE OF DENTAL  
SLEEP MEDICINE**

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*Via Webinar*

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# Speaker Conflict of Interest Disclosure

1. Does the CME/CEC content over which you have control contain information about healthcare products or services?  
 Yes (answer question 2)  No
2. Regarding the healthcare products or services that will be discussed in the CME/CEC content over which you have control, have you or your spouse/partner had a financial relationship in any amount in the last 12 months with the manufacturers of the products or providers of the services?  
 Yes (complete the chart below)  No
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Manufacturer or Service Provider	Nature of Relationship (e.g., employee, consultant, research grant recipient, speakers' bureau, stockholder, etc.)	I have divested myself (or my spouse/partner has divested himself/herself) of this relationship. (Circle)	
		YES	NO
		YES	NO
		YES	NO
		YES	NO

# Key Regulations Which Impact the Provision of Dental Sleep Medicine and Oral Appliances

- **Stark Law - Stark III**
- **Anti-Kickback Statute**
- **HIPAA**
- **Anti-Markup Rule**
- **2021 Physician Fee Schedule (PFS)**
- **DME Regulations**
- **State Fraud and Abuse Laws**

## **Key Compliance Issues:**

- ✓ **Medicare Coverage and Payment**
- ✓ **Billing and Reimbursement**
- ✓ **National Coverage Determination (NCD)**
- ✓ **Local Coverage Determination (LCD)**
- ✓ **OIG Work Plan for FY 2021**
- ✓ **Expanded Enforcement Activities**

# KEY CONSIDERATIONS

- Oral Appliances can be an ancillary revenue stream to your practice.
- CMS requires DME suppliers to meet very specific requirements, including accreditation, in order to receive Medicare reimbursement.

# LEGAL LANDSCAPE FOR DENTAL SLEEP MEDICINE

## Due Diligence

- Legal Viability
- Market Analysis
- Payor Feasibility
- Pro Forma
- Business Plan

## Legal Issues

- State Licensure
- Medicare Coverage for DME
- Medicare Conditions of Coverage
- Documentation
- Fraud and Abuse in DME
- Telehealth/Telemedicine
- HST
- Accreditation

## Contracting, Coding and Reimbursement

- Cost Structure
- Coding
- Contract Negotiations
- Setting up a Fee Schedule

## Payment Denials

- Insurance Verification
- Monitoring Claims
- Appeal Process

## Policies and Procedures

- DME Services and Staff
- Personnel Policies
- Operational Policies
- Regulatory Compliance
- Compliance Plan
- HIPAA
- Forms

# STARK SELF-REFERRAL LAWS

- Is the PSG Test a “Designated Health Service?”
- Is supplying DME a “Designated Health Service?”
- State self-referral laws often are more restrictive than the federal Stark Law.
- Make sure your practice complies with all state and federal regulations.

# STARK

Stark Law prohibits a physician from making a referral for a designated health service (DHS) to an entity in which the physician (or the physician's immediate family member) has a financial relationship, including a compensation arrangement, if the DHS is reimbursed by a governmental program (42 U.S.C. § 1395 nn(a)(1)).

Bottom Line: Only referrals for DHS are prohibited.

PSG ≠ DHS for Stark purposes

DME = DHS

Outpatient and Inpatient Hospital Services = DHS

# STARK



- Penalties/Sanctions
  - denial of payment
  - refunds of amounts collected for services performed in violation of the statute
  - civil money penalty of up to \$15,000 for reach bill or claim for a service a person knows or should know is for a service for which payment may not be made under the statute
  - civil money penalty of up to \$100,00 for each arrangement or scheme which the physician or entity knows or should know has a principal purpose of assuring referrals which, if directly made, would be in violation of the statute
  - exclusion from the Medicare, Medicaid and/or other federally funded health care programs



# ANTI-KICKBACK LAW

- It is unlawful for anyone to knowingly and willfully solicit or receive any payment in return for referring an individual to another person or entity for the furnishing, or arranging for the furnishing, of any item or service that may be paid in whole or in part by any federally-funded health care program.  
(42 U.S.C. § 1320a-7b(b)(1)).



# ANTI-KICKBACK STATUTE PROHIBITS

- Knowingly and willfully
- Offering or receiving
- Remuneration (including any kickback, bribe or rebate)
- To induce
- Referral of federal health care program or business (42 U.S.C. § 1320a-7b(b)(1)).

# ANTI-KICKBACK – FRAUD AND ABUSE

- Prohibits payment for referrals
- Criminal statute – up to five years in prison and/or \$25,000 fine
- Intent-based statute
- Applies to both physicians and hospitals
- Government priority for enforcement – use of wires for immunity
- Exclusion from the Medicare, Medicaid and/or other federally-funded health care programs
- Safe Harbors
- Fraud Alerts



# JOINT VENTURES

- ◆ Structuring Joint Ventures to fit within the Small Investment Interests Safe Harbor.
- ◆ Small Investment Interests Safe Harbor includes the “60-40 rules:”
  - No more than 40% of the investment interests may be owned by persons who can generate business for or transaction business with the entity.
  - No more than 40% of the gross revenues resulting from the furnishing of health care items or services may come from business generated by investors.

# SAFE HARBORS

- Equipment Rental
- Space Rental
- Personal Services and Management Contracts
- Employees

# OIG SPECIAL ADVISORY BULLETIN – APRIL 2003

- OIG identified the following characteristics of suspect arrangements:
  1. New Line of Business – An owner enters into a new line of business that can be provided to the owner’s existing patients.
  2. Captive Referral Base – The newly-created business predominantly or exclusively serves the owner’s existing patient base.

# OIG SPECIAL ADVISORY BULLETIN – APRIL 2003

3. Little or No Bona Fide Business Risk – The owner’s primary contribution to the venture is referrals and the owner has little or no financial or other investment in the business. The owner delegates the entire operation of the new line of business to the manager and yet retains the profits.
4. Status of the Manager/Supplier – The manager/supplier is a would-be competitor of the owner’s new line of business and would normally compete for the captive referrals.

# OIG SPECIAL ADVISORY BULLETIN – APRIL 2003

## Characteristics of Suspect Arrangements:

5. Scope of Services Provided by the Manager/Supplier – The manager provides all or many of the following services:
  - day-to-day management;
  - billing services;
  - equipment;
  - personnel and other related services;
  - office space
  - training and
  - health care items, supplies and services.



# OIG SPECIAL ADVISORY BULLETIN – APRIL 2003

## Characteristics of Suspect Arrangements:

6. Remuneration – The practical effect of the arrangement, viewed in its entirety, is to provide the owner the opportunity to bill insurers and patients for business otherwise provided by the manager/supplier.
7. Exclusivity – The owner and manager may agree to a non-compete clause that prevents the owner from providing items or services to any patients other than those coming from the owner and/or barring the manager/supplier from providing services in its own right to the owner's patients.

# CONSIGNMENT CLOSETS AND “STOCK AND BILL” ARRANGEMENTS

- DMEPOS place inventory in space rented from a doctor’s office.
- This arrangement allows patients to receive equipment or devices that they need as they leave the doctor’s office.
- the DMEPOS, not the doctor, bills the third party payors for the devices.
- Patient must be given a choice as to where the patient will receive OAT or other DME.
- Arrangement between doctor and DME Company must comply with the Stark laws.

# CONSIGNMENT CLOSETS AND “STOCK AND BILL” ARRANGEMENTS

## ➤ Personal services exception:

- The arrangement is in writing and specifies the services covered by the arrangement.
- The term of the arrangement is for at least one (1) year.
- The arrangement covers all of the services to be furnished by the doctor to the entity.
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- The compensation paid is set in advance and is of a fair market value for the services provided and is not conditioned on the volume or value of any referrals or other business generated between the parties.

# CONSIGNMENT CLOSETS AND “STOCK AND BILL” ARRANGEMENTS

- For the rental of the office space to store inventory, the Stark Safe Harbor is met if:
  - A written agreement for a period of at least one (1) year exists.
  - The compensation is a fair market value based on usual rental rates for comparable office spaces in the community.
  - The transaction is commercially reasonable and furthers the legitimate business purposes of the parties.
  - The arrangement does not violate the federal Anti-Kickback Statute.
- Bottom Line: All consignment closets and “stock and bill” arrangements must comply with the federal Stark and be in compliance with the applicable Anti-Kickback regulations and applicable state regulations to pass the scrutiny of federal regulators.

# KEY CONSIDERATIONS PRIOR TO PROVIDING DENTAL SLEEP MEDICINE

- Can the market support the provisions of oral appliances?
- Is the proposed business model legally viable?
- Who are my competitors?
- Can I get managed care contracts and get paid for my services?
- What are the costs of providing Oral Appliance Therapy?
- What is my projected revenue?



# POTENTIAL DENTAL SLEEP MEDICINE MODELS

- Dental Sleep Practice
- Provision of OAT as an extension of a physician practice
- Dental Sleep Medicine as an extension of a hospital-based sleep lab
- Dental Sleep Medicine as an independent free-standing business entity

# STATE LICENSURE

- Key Issues:

- Licensure
- Reimbursement
- Government paid DME
- State self-referral laws
- State Anti-Kickback laws
- Telehealth/Telemedicine

- Bottom Line: Check your state law to determine whether or not you are required to have a state license to provide DME.



# KEY FORMS TO CONSIDER FOR THE PROVISION OF DENTAL SLEEP MEDICINE TO YOUR PATIENTS

- Freedom of Choice Letter
- Patient Acknowledgment Form
- HIPAA Privacy and Security Form
- Insurance Letter
- Patient Instructions and Troubleshooting Guide
- Patient Follow-up Report



# PATIENT FOLLOW-UP IS ESSENTIAL FOR A SUCCESSFUL DENTAL SLEEP MEDICINE PRACTICE

- Assessment of patient.
- Patient's perspective of therapy.
- Avoid and minimize objections and patient complaints.
- Documentation for regulatory reimbursement and accreditation purposes.

# STRATEGIC STEPS FOR IMPLEMENTING A SUCCESSFUL DENTAL SLEEP MEDICINE PRACTICE

- Patient Care
- Regulatory Compliance
- Operational Structure
- Marketing Plan
- Financial Considerations

# HOW TO HANDLE DENIALS

- Insurance Verification and Pre-Certification
- Claims Monitoring → Explanation of Benefits (EOBs) and corresponding claims need to be monitored at the time the payment is posted to the patient's account.
- Evaluate EOBS:
  - Full payment → Has the fee been properly selected?
  - No payment → Has there been a coding error?
  - Reduced payment → Has there been improper coding of the codes or by a fee schedule?
- Bottom Line: Every insurer has a time limit on claim recertification.

\*Check state laws for prompt pay statutes.

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