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Managing Risk in Sleep Centers: Legal Issues and Steps to Take to Avoid Liability

Physician, Dentist and Nursing Session

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Key Factors that Impact a Sleep Center's Viability and Bottom Line

- State and Federal Regulations
- Reimbursement Rates/billing and collections
- Payor Mix
- Revenue Sources
- Staffing
- Scope of Practice Issues
- Market Factors
- Cost of Equipment
- Physical Space Costs and Expenses
- Vendor Contracts and Expenses

Solid Bottom Line = Future Viability of the Sleep Center

Key Legal Issues Which Impact Sleep Centers and Sleep Professionals

- Regulatory Compliance
- Licensure/Accreditation
- Reimbursement
- Documentation
- Liability/Risk of Exposure
- Audits and Investigations
- Scope of Practice
- Telehealth/Telemedicine

Hot Topics

Recent Factors that Impact Sleep Centers' Bottom Line and the Future of Health Care:

- Health Care Reform
- New Regulations
- Cuts in Reimbursement
- New Care Delivery Models
- Social Media
- Expanding Government Enforcement Efforts related to Medicare/Medicaid Fraud and Abuse Issues
- Litigation
- Increasing Number of Audits and Investigations
- Whistleblower Cases → Qui Tam Actions
- OIG Advisory Opinions
- OIG Work Plans

Key Regulations Which Impact Sleep Centers

- Stark Law
- Anti-Kickback Statute
- HIPAA
- Anti-Markup Rule
- 2018 Physician Fee Schedule (PFS)

Key Compliance Issues

- ✓ Medicare Coverage and Payment
- ✓ Billing and Reimbursement
- ✓ National Coverage Determination (NCD)
- ✓ Local Coverage Determination (LCD)
- ✓ OIG Work Plan for FY 2018
- ✓ Expanded Enforcement Activities

Medicare Regulations and Coverage Guidelines

- Stark III Rules
- Anti-Markup Rule
- Physician Qualifications

* *Government is Expanding Fraud and Abuse Enforcement Efforts*

Fraud and Abuse

- **Stark Law**
  - The federal Stark Law prohibits a physician (or an immediate family member of such physician) from making a referral for a designated health service to an entity in which the physician has a financial relationship, including a compensation arrangement, if the service is reimbursed by a governmental program. (42 U.S.C. § 1395nn(a)(1))
- **Only referrals for designated health services (DHS) are prohibited.**
- **Outpatient and Inpatient Hospital Services = DHS**
- **PSG ≠ DHS**
- **DME = DHS**

Stark Self-Referral Laws

- 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 each bill or claim for a service person knows or should know is for a service for which payment may not be made under the statue.
  - Civil money penalty of up to $100,000 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 statue.
  - 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-7(b)(1)).

Anti-Kickback – Fraud & Abuse

- Prohibits payment for referrals
- Criminal statue – 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

HIPAA

- Health Insurance Portability and Accountability Act of 1996
- Privacy Regulations
  - Applies to “Covered Entities”
  - Applies to Use and Disclosure of Protected Health Information (“PHI”)

HIPAA – Business Associates

- Key Questions to Ask:
  - Is the entity or individual a business associate of Sleep Center?
  - What if the entity or individual not only performs the test for the physician, but also bills the physician's services?
  - Who has access to PHI?
  - How is the entity or individual safeguarding PHI?

HIPAA

- Security Regulations
  - Effective April 21, 2005, the HIPAA Security Regulations require covered entities to take steps to safeguard the integrity and availability of health information.
  - Covered Entities must adopt policies and procedures addressing disaster recovery plans, computer workstation use, passwords, data access, and the storage and disposal of protected health information.
  - No private cause of action
  - Complaint filed/on line for breech of HIPAA
  - Government investigation

Expanded Enforcement Activities

- HEAT
- OIG Work Plan for 2018
- Medicare Integrity Program
- RACs

Medicare Recovery Audit Contractors (RACs)

What is a RAC?

The RACs will detect and correct past improper payments to enable CMS, Carriers, F.I.s and MACs to implement actions to prevent future improper payments.

Which Providers and Suppliers May be Impacted by a RAC Audit?

All providers and suppliers who submit claims to Medicare (CMS) are subject to RAC Audits including:

- Sleep Centers
- IDTFs
- DME Suppliers
- Hospitals
- Physicians / Practice Groups
- Nursing Homes
- ASTCs
- IDTFs
- DME Suppliers

Why RACs?

CMS ⟶ Steps to identify improper Medicare payments to fight fraud, waste and abuse in the Medicare program.

Statutory Basis for RACs

Section 302 of the Tax Relief and Health Care Act of 2006 makes the RAC Program permanent and required the DHHS to expand the program to all 50 states by 2010.

- Beginning in 2010, CMS put four (4) RACs in place and each RAC is responsible for identifying overpayment and underpayment in approximately one-fourth (1/4) of the country.
- The new RAC jurisdictions match the DME MAC jurisdictions.

RAC Audits

Approximately 90% ($992.7 million) of the improper payments were overpayments collected from providers, while the remaining 4% ($37.8 million) were underpayments repaid to providers.

Improper payments = overpayments or underpayments

Overpayments can occur when health care providers submit claims that do not meet CMS' coding and/or medical necessity policies, and underpayment can occur when health care providers submit claims for a procedure, but the medical record indicates that a more complicated procedure was actually performed.

Two Types of RAC Identification

- Automated Review = performed by automated system, no human interaction
- Complex Review = determination based upon human review

Automated Review requires a certainty that the service is not covered or is incorrectly coded and a written Medicare policy exists.

Complex Review is used where there is a high probability (but not certainty) that the service is not covered or where no written Medicare policy exists. A complex review is the use of complex medical records.

The Impact of RAC Audits

RACs have an incentive to find inappropriate Medicare payments because RACs are paid by CMS based upon the amount of money RACs recover from providers or suppliers.

RAC auditors are able to retain 9% to 12.5% of recovered payments.

RACs can make the following types of determinations based upon a RAC audit:

- The service provided is not covered by the Medicare program;
- The service is not correctly coded;
- The claim was paid multiple times; and/or
- The claim was priced incorrectly.

The RAC Appeals Process

Prior to submitting an appeal, consider the following issues:

- The amount in question versus the cost of the appeal?
- Is there sufficient documentation to support the RAC's finding and claim?
- Determine the resources that would be necessary for the appeal process.
- What is the impact of proceeding with an appeal versus not pursuing an appeal?

Steps That Provider Should Consider Prior to Receiving a RAC Audit Letter

- **Educate and Train Staff.** Provide staff with the right tools to ensure accurate and proper claims coding. It is imperative that everyone involved in the submission of a Medicare claim understand the RAC program.
- **Develop a RAC Compliance Plan.** Providers should have a written RAC plan that addresses RAC compliance issues, education efforts and reviews.
- **Designate a RAC Response Team and Team Leader.** This team should consist of medical, compliance, coding and billing personnel. Providers have 45 days from the date of the initial RAC audit letter to submit a response.

Steps That Providers Should Consider Prior to Receiving a RAC Audit Letter

- **Conduct Chart Reviews and Internal Audits.** Review your Sleep Center's compliance programs and make any necessary modifications. Sleep Centers should schedule and conduct frequent reviews of issues such as compliance with CMS coverage criteria, local coverage determinations, coding, billing and coverage, utilization and patient documentation requirements.
- **Utilize Tracking and Reporting Systems.** Providers should consider using tracking and reporting systems to manage the process and analyze audit patterns. Tracking deadlines, pending requests, RAC determinations, and appeal status enables the lab to manage the process and analyze and adjust documentation as necessary.

Steps That Providers Should Consider Prior to Receiving a RAC Audit Letter

- **Develop Corrective Plans of Action.** For any issues where issues currently exist or where the likelihood of noncompliance is high, develop and document plans of action to correct the deficiencies.
- **Monitor the Trends and Enforcement in Your RAC Region.** While the RAC auditors can review any of the approved issues for your region, regularly check your region's RAC contractor's website for updated information regarding recent activity and collection efforts.
- **Involve Your Practices's Legal Counsel During the Early Stages of the Planning Phase.** The RAC auditing process is complicated and multi-faceted. Including legal counsel prior to an actual audit can be beneficial in determining areas of potential liability and steps to be taken during the audit process and future appeals.

OIG and Directive to Implement a Compliance Program

The HHS Office of the Inspector General issued a regulatory announcement on February 2, 2011, of its intent to finalize new Medicare and Medicaid enrollment standards that will establish procedures to better police fraud and abuse in these programs. This announcement notes the authority to require Sleep Centers to implement fraud and abuse compliance programs pursuant to a provision in the health system reform law. If your practice has yet to implement a compliance program, know that this will be expected in the near future. In the Federal Register notice, the OIG makes the following statement: "We are in the process of developing a new Notice of Proposed Rule Making incorporating the compliance plan provisions and comments received that will be published at a later date. The proposed rule will also have an opportunity for further public comment."

Compliance Program

Health care providers should consider implementing a Compliance Program.

Compliance Program = a system to ensure continuous compliance with all applicable laws, regulations, industry standards, organizational standards, governance principles, and community and ethical standards.

Compliance Programs may be required by law or contract.

Corporate Compliance = a term that is used to indicate that a provider runs a clean operation and does not commit fraud, waste or abuse of health care funds.

Risk Management

"Activities directed at reducing the possibility of adverse financial and other consequences from both foreseen and unforeseen events."

Source: Black's Law Dictionary, Sixth Edition (1990)

Survival Tips to Avoid Regulatory Pitfalls

- Don’t Stick Out of the Crowd or Become “Low Hanging Fruit.”
  - Avoid too many recruitments, medical directorships, etc.

- Cease and Desist All Personal Favors to Referral Sources.
  - Key message from pharmaceutical cases
  - No free vacations, computers, tickets
  - No unrestricted educational grants, etc.

Survival Tips to Avoid Regulatory Pitfalls

- Make Compliance a Priority And a Part of Everyone's Job Description.
  - Educate and train all staff about regulatory compliance and the associated risk areas.
  - Monitor compliance on an ongoing basis.
  - Frequently check documentation to ensure compliance, confidentiality, and proper.

Survival Tips to Avoid Regulatory Pitfalls

- Use Fair Market Value As a Benchmark For All Deals.
  - Overall protection if FMV is established:
    - For necessary services, expenditures and investments.
    - By independent and reliable source.
    - Using recognized and legitimate methodology.

- Ask: Does the deal / transaction / contract pass the “smell test?”

Survival Tips to Avoid Regulatory Pitfalls

- Run a Tight Ship.
  - Do not facilitate any alteration of documentation, e.g., shredding, backdating or altering.
  - Do not withhold information from the government or produce incomplete information (half truth).
  - Do not ask for numeric “odds” on being detected or being prosecuted when communicating with government agencies or officials.

Survival Tips to Avoid Regulatory Pitfalls

- Create and Maintain Good Documents
  - Document FMV, business purposes, and services to be provided and time spent providing such services.
  - Good documentation is evidence of good faith and may block an investigation and/or audit.
  - Documentation can be a pitfall if records are inaccurate or incomplete

Survival Tips to Avoid Regulatory Pitfalls

- Do Not Create or Raise Any “Red Flags.”
  - E-mail can and will be used as evidence of wrongdoing and bad intentions.
  - Any communication (verbal and written) regarding referrals, money and physicians will be scrutinized.
  - Carefully review business planning document regarding statements or guarantees about anticipated referrals.

Survival Tips to Avoid Regulatory Pitfalls

- Do Not Be Greedy.
  - Investigators will target any investment or any compensation arrangement that appears excessive.

The OIG's Seven Core Elements of an Effective Compliance Plan

1. Development and distribution of written standards of conduct.
2. Designation of a compliance officer and committee.
3. Screening employees and contractors.
4. Effective training and education of physicians and staff.
5. Development and enforcement of disciplinary procedures.
6. Auditing, monitoring, and reporting on a practice's operations.
7. Investigations and corrective action.

A Compliance Plan Should Include:

- Mission Statement/Vision Statement/Treatment Philosophy
- Designation of a compliance officer and key responsibilities
- Code of ethics
- Objectives
- Identification of internal communication system
- Policies and procedures related to: standards of conduct, billing practices, mandatory staff education and training, disciplinary action, corrective action and reporting structure
- Quality Improvement techniques used for investigation and corrective action
- Auditing, monitoring and reporting procedures

Health Care Reform Goals

- Universal Coverage
- Improve the Quality of Health Care and Public Health
- Lower the Cost of Health Care Coverage
- Establish Accountability Measures → Accountable Care Organizations
- Minimize the Inefficiency of Physicians and Hospitals
- Move from Government Reimbursement Towards Value-based Purchasing
- Developing a Payment System based upon Outcomes and Reward a Coordinated System of Care with Emphasis on Quality

Tales From the Front and Trends

- The Provision of Sleep Medicine Continues to Evolve and Change.
- Increased Physician Shortages.
- Consolidation of Sleep Centers Through Acquisitions and Mergers.
- Growth of Larger Medical Groups and Reduction of Solo and Small Group Practices.
- Physician Utilization of Hospitals is Changing.
- A Shift Toward Hospital Employment of Physicians.

Physician Shortage

- DHHS Projects a Shortage of 55,000 by 2020.

- Health Affairs Projects 200,000 by 2020.

Bottom Line = Not Enough Physicians Which Impact Patients, Hospitals, and Physicians. Fewer Board Certified Sleep Physicians.

Health Care Reform

The Balance Between Clinical Efficiency and Operational Efficiency.

Health Care Reform Focuses on patient-centered Care and Rewarding:

- Quality
- Outcomes
- Safety
- Efficiencies

Health Care Reform's Impact on Sleep Centers – Legal Issues

Overpayments

- Now health care providers must report and return any overpayment within 60 days of:
  - The date the overpayment is identified, or
  - The date a correspondent cost report is due, whichever is later.
- Retaining an overpayment creates potential False Claims Act liability.

Health Care Reform's Impact on Sleep Centers – Legal Issues

Civil Monetary Penalties Law

- Health care reform expands liability to health care providers by adding civil monetary penalties to criminal penalties under the False Claims Act for submitting false claims or retaining overpayments.

Enforcement

- The government has allocated $100 million for fiscal years 2011 through 2020 to cover administrative and operational costs for health care fraud and abuse control programs.

Takeaways

- Reform and health care in general is a multi-faceted, complex issue. This does not lend well to mass-media analysis.
- Very few parties are actually informed on the actual components of Reform.
- Health Care Providers are still exploring the potential impacts on themselves, let alone on others.
- Stay tuned ⟶ there will be changes to Health Care Reform.
- The provision of Sleep Medicine is impacted by Health Care Reform.

What Does the Future Hold?

- **GOP Controlled House of Representatives/Democratic Senate**
  - The debate will continue with new Administration.
  - Total repeal very unlikely; partial amendments probable in next Congress.
  - Constitutionality challenges likely to reach Supreme Court.
  - CBO estimate of cost of full repeal: $230B by 2021
    - Take these estimates with a grain of salt, but they're better than either party's estimates.
- **Public Split over Reform**
  - Proponents want to realize any benefits more quickly; opponents want to point out implementation costs/burdens.
- **Insurer and State Concerns**
  - Increasing pressure to meet "80%" MLR threshold.
    - Are providers happy to oblige with higher pricing?
  - Are states likely to turn down federal funds of any sort?
  - June 28, 2012 – U.S. Supreme Court upholds the constitutionality of PPACA with a 5-4 vote..

Health Care Reform: Milestone or Mistake?

- By 2019, over 30 million people who were formerly uninsured are expected to be covered. This could increase health care provided to insured patients and decrease charity care.
- Pay-for-Performance based upon a certain percentage of the payment made to health care providers which is related to quality measures.
- Medicare re-validation and enrollment process for providers, including IDTFs.

The Impact of Health Care Reform on Sleep Centers

- Reimbursement
- Care delivery models
- Measurement of patient care outcomes
- Coverage/pre-exiting conditions
- Cost containment
- Shared savings programs
- Patient-centered model
- ACOs
- Co-management of patients by specialists and primary care physicians
- Quality of care measurements
- Transparency among providers

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