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AAST 2018 ANNUAL MEETING

Risk Management and Regulatory Compliance for Sleep Centers

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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

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

- 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

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.

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)

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.

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

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.

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.

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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