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Legal Update 2019: Compliance Issues and Your Practice

Jayme R. Matchinski
Greensfelder, Hemker & Gale, P.C.
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This presentation and outline are limited to a discussion of general principles and should not be interpreted to express legal advice applicable in specific circumstances.

Legal Update 2019: Compliance Issues and Your Practice

Objectives:

- Provide an Overview of Key State and Federal Regulations which Impact Physician Practices;
- Define Compliance Issues and Area of Exposure for Physicians and Practice Groups; and
- Identify Steps that Physicians and Practice Groups can take to Avoid Liability and Exposure.

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Key Factors that Impact a Physician Practice'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 Physician Practice

Hot Topics

Recent Factors that Impact Physician Practices' 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 Physician Practices

- Stark Law
- Anti-Kickback Statute
- HIPAA
- Anti-Markup Rule
- 2019 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 2019
- ✓ 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**

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 physician practice?
  - 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 2019
- Medicare Integrity Program
- RACs

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 physician practices 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.

Compliance Program

Compliance Programs → Increases staff awareness, demonstrates commitment to regulatory compliance, and may be a mitigating factor during an audit or investigation.

Compliance Programs should be designed, implemented, and enforced so that the program is effective in preventing and detecting fraud, and abuse and criminal conduct.

Health care providers should ask:

- Is the Compliance Program "effective"?
- Is the Compliance Program well designed?
- Is the Compliance Program being applied earnestly and in good faith?
- Does the Compliance Program work?

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 TAP case and pharmaceutical guidance
  - 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

- Increased Physician Shortages
- 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.

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 Physician Practices – 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: 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 Physician Practices

- 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

Jayme R. Matchinski

(312) 345-5014

jmatchinski@greensfelder.com

Linkedin.com/in/jaymematchinski

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