Retail Clinics in Healthcare: Overcoming Complex Legal Challenges

Complying With Corporate Practice of Medicine, Licensure, and Scope of Practice Laws; Negotiating Shopping Center Leases

WEDNESDAY, MARCH 11, 2015

1pm Eastern    |    12pm Central   |   11am Mountain    |    10am Pacific

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Retail Clinics in Health Care: Overcoming Complex Legal Challenges

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What is Retail Medicine?

• Walk in healthcare delivered in retail setting
• Limited scope of services
• Usually staffed by a Physician’s Assistant or Nurse Practitioner
• Services:
  • Primary care
  • Dental
  • Optical
  • Hearing
STATE REGULATION OF RETAIL MEDICINE
Licensure Requirements

• States may require retail clinics to be licensed as specific health care entities
• Florida
  • Health Care Clinic Act + corresponding regulations
  • Clinic: an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services that are not owned by certain enumerated licensed professionals, including nurse practitioners, or licensed facilities such as hospitals.
• Other unique licensure states:
  • Massachusetts (separate licensure category for retail clinic)
  • California (retail clinic exempt from licensure)
Medical Directors

• Many states require a physician to act as the Medical Director
  • Florida: a licensed health care clinic requires a physician medical director
• The Medical Director may or may not need to be present depending on state law
  • Florida: Physical presence is not required
Fee Splitting Prohibition

- States have fee-splitting provisions that prohibit licensed medical professionals from splitting professional fees with other individuals or entities in exchange for referrals.
- Example: Florida
  - Patient Brokering Act: prohibit split-fee arrangements (Fla. Stat. 817.505)
  - Fee-Splitting prohibitions in individual acts as well
State Prohibition on Self Referral

• Many states have equivalents of the Stark law that prohibit self referrals or patient brokering

• Examples:
  • Florida (Florida Patient Self Referral Act, disclosure of financial interest)
  • Georgia (Patient Self-Referral Act of 1993)
  • North Carolina (self-referrals prohibited)
  • Tennessee (investment interest only)
Professional Staff

- Mid-level non-physician practitioners
  - APRN (Advanced Practice Registered Nurse)
  - PA (Physician's Assistant)
- Supervision and collaborative agreement requirements
  - Physician supervision varies (examples below)
    - Constant on-site supervision
    - Remote telemedicine supervision
    - Specific physician/non-physician ratio (Florida: physician may not supervise more than 4 offices in addition to physician's primary practice location)
    - No specific supervision requirement
Scope of Practice

• Scope of practice
  • Each state has laws and regulations that determine services different health care professionals may provide – often vague
  • Licensure laws, rules and regulations normally outline the scope of practice for that professional

• Prescription writing
  • Many states limit who may write prescriptions; and beyond that who might write prescriptions for controlled substances
Licensure Requirements
Laboratory & CON

- Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 C.F.R. 493.2)
  - CMS regulates laboratory testing
  - Retail clinics may be eligible for CLIA certificate of waiver if it restricts lab testing to one of the waived tests found at 42 C.F.R. 493.15(c).
- Certain states may require a separate lab license
- Certificate of Need (CON)
  - Certificate of Need is a state-specific regulatory requirement in order to ensure public need and financial feasibility for health care providers
  - Some states may require a CON in order to establish a retail clinic (New York recently considered this)
Corporate Practice of Medicine

• Corporate Practice of Medicine is a state specific doctrine that imposes restrictions of the ability of business entities to provide medical services
  • The scope and manner of the potential restrictions vary from state to state
    • Certain states have no CPOM restriction (Florida)
    • Others have CPOM restrictions to prevent unlicensed practice (CA)
    • Some states allow exceptions if the entity is licensed as a health care facility (NJ)
Pharmacy Referrals

- Practitioners cannot be compensated based on services provided, including the number of prescriptions filled in the landlord/retail space.
Transfer Agreements

• A transfer agreement is entered into between the entity and a nearby hospital to transfer patients to the hospital in appropriate circumstances
  • In theory this is not necessary because under EMTALA hospitals must accept patients through the emergency department
• State law or accrediting bodies may require a transfer agreement with a hospital
• Florida Health Care Clinic Act does *not* require this... nonetheless it may be a practically reasonable thing to have in place
Medical Records

- States have varying records retention policies for health care entities and may have specific requirements for what is included in the medical record and their ownership.

- Florida:
  - Policies, procedures and other compliance documents: 5 years
  - Medical Records: 7 years
  - Fla. Stat. 456.057 – Medical record belongs to practitioner who created it unless there is a written agreement stating the record belongs to the practitioner's employer.

- Massachusetts:
  - Diagnosis and treatment records: 20 years after the discharge or final treatment of patient;
  - Certain records like radiological films and image records: 5 years following date of service.
FEDERAL LAW CONSIDERATIONS
Stark Law

- Not Applicable
- Unless a physician refers patients to a retail clinic where physician or physician’s organization has a financial relationship
Anti-Kickback

- Host retailer avoid paying for referrals
- Avoid revenue based lease payments
- Comply with safe harbor for space, equipment rental and personal services
- Implement business conduct rule to assure compliance
HIPAA Privacy and Security

- Record Management
  - Electronic Health Records
- Restrictions on marketing activities
- Consents and Authorizations
  - Transmitting information to patient’s primary care physician
Handicapped Accessibility

- https://www.ada.gov/medcare_mobility_ta/medcare_ta.htm
Key Points

• Accessibility is essential
• Medical care provides required to make services available in an accessible manner
• Any private entity that owns, leases, leases to or operates a place of public accommodation must comply
• Tenants and landlords
Accessible Exam Rooms

• An accessible route to and through the room
• Entry door with adequate clear width, maneuvering clearance and accessible hardware
• Appropriate and accessible examination equipment
• Adequate clear floor space for side transfers and lift equipment
Accreditation

- Convenient Care Association certification
- Joint Commission
- Accreditation Association for Ambulatory Health Care
COMPLIANCE, QUALITY ASSURANCE AND PEER REVIEW
Compliance

• A compliance program is an internal program the clinic should implement in order to meet governmental standards as determined through federal and state laws and regulations
• A compliance program begins with established policies and procedures and becomes effective if the organization has a culture of compliance
Elements of an Effective Compliance Program

1. Establish policies, procedures and controls
2. Exercise effective compliance and ethics oversight
3. Exercise due diligence and avoid delegation of authority to unethical individuals
4. Communicate and educate employees on compliance and ethics programs
5. Monitor and audit compliance and ethics programs for effectiveness
6. Ensure consistent enforcement and discipline of violations
7. Respond appropriately to incidents and take steps to prevent future incidents
Quality Assurance

• Convenient Care Association Quality and Safety Standards
• https://ccaclinics.org/about-us/quality-of-care
Mechanisms of Review

- Formal chart review by experienced clinicians
- Peer-review by clinicians
- Medical diagnosis and treatment code auditing
- Processes to ensure that all clinicians are certified and credentialed in their specialty by their respective governing bodies
- Compliance with state regulations regarding the practice of health care clinicians
Liability and Risk Management

- Supervising physicians face potential liability from allegations that standards were not met
- Potential liability of retail host
REIMBURSEMENT
Medicare Enrollment Requirements

- 855-B Enrollment Requirements:
  - National Provider Identifier (NPI)
  - Submit enrollment application and supporting documentation to the fee-for-service contractor
  - Sign certification statement
  - Submit verifiable information to CMS
  - Complete applicable state surveys, certifications and provider agreement
  - Be operational to furnish Medicare covered items or services
  - Meet additional compliance and reporting obligations
  - Prepare for an on-site review (CMS has discretion)
Medicare Enrollment

• Clinic must enroll in Medicare using the 855-B form
• Medicare does not recognize a retail clinic as a separate provider; must likely enroll as a "clinic/group practice"
• Group practice defined by Medicare:
  • A group practice is a group of two or more physician and non-physician practitioners legally organized in a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association (Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, Sec. 90.4 for more details)
• Other practitioners:
  • Advanced Practice Nurse Practitioners can operate independently subject to compliance with state law
  • PAs may only bill through their employer
• Hospital Outpatient Department status
  • If a hospital operates the clinic – it could be treated as either a group practice OR as a provider-based clinic
Medicare Reimbursement

• Group practice reimbursement:
  • Fee for service based on the Medicare Physician Fee Schedule (MPFS).
  • Mid-level practitioners will also be reimbursed on the MPFS, however at a 15% reduction rate
  • Incident-to services reimbursement
  • A provider-based clinic would be on the Outpatient Prospective Patient System (OPPS), not the MPFS
Medicaid Enrollment

• The clinic will need to enroll in Medicaid similarly to Medicare
• Many states may not recognize "retail clinic" as a separately category; use group practice
  • Some states may specifically use retail clinic terminology (Massachusetts)
Medicaid Reimbursement

• Like Medicare, Medicaid normally pays mid-level practitioners differently than physicians
• Each state will have different Medicaid payment policies
• Example: Florida
  • Practitioner handbook with separate chapters for different providers
Other Third Party Payers

• Contract concerns
• Reimbursement and coverage
• Still must comply with various federal laws and meet state licensure requirements
Collection of Co-Payments and Deductibles

• Routine waiver
  • Implicates the anti-kickback statute (specifically addressed at 42 CFR 1001.952(h)(5)(iv)).
  • Medicare contractor may investigate if the waivers constitute a reduction of the provider's actual charges in violation of Medicare rules requiring physician services reimbursement to be based on the lesser of actual charges or the applicable fee schedule amount.

• Financial hardship exception to routine waiver prohibition
  • Must be based on objective standards

• State law potential insurance fraud and unlawful patient inducement concerns
Key Business Issues

- Zoning
- Business Use
- Hazardous Waste
- Leases
  - Subleases
Questions?

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