Healthcare on Aisle Five: Promises and Risks in Retail Clinics

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Retail Health Clinics 101

Market Size, Industry Characteristics, Trends
What Are Retail Health Clinics?

- Clinics located in retail settings such as pharmacies (e.g., CVS, Walgreens, etc.), supermarkets, and “big box” retailers (e.g., Walmart, Target, etc.)

- Staffed by nurse practitioners (NPs), practice nurses, physician assistants (PAs), supervised by physicians

- Offering medical services under a limited scope of practice (e.g., simple medical conditions and basic preventive care)

- Currently more than 1,600 sites, growing rapidly

- Differ from urgent care clinics that are typically free-standing facilities, where doctors treat acute, but not life-threatening, conditions.
What Is Driving Demand?

Retailers
- Enter the “health and well-being” market
- Increase “foot traffic”

Consumers
- Accessibility
- Evidence-based care
- Reduced cost
- Transparent pricing
- High satisfaction
- Brand recognition
Market Trends

- Significant growth in number of retail clinic locations
- Growth in number of competitors entering market
- Expansion in type of services provided
  - Telemedicine
  - Primary care
  - Mental health
- Increasing collaboration between clinics and other providers
- Improving relationships with payors
- Partnering with employers to offer workplace clinics
- Escalating debate over scope of practice
- Potential for greater state regulation
Retail Health Clinic Models

- Lease Arrangement
- Practice Management / MSO
- Ownership
Medical Community Reactions/Concerns

• Qualifications of staff to accurately diagnose patients
• Interrupts relationship patient has with primary care provider
• Retailers’ interest in selling products/increasing foot traffic*
• “Fragmentation” of services
• New utilization versus a substitute for more expensive care

Competing Interests in Expansion of Retail Clinic Model

Consumers

Payors

Physicians

APRNs

Health Systems

LPNs/LVNs

Licensing Boards
Physician Perspective: AMA and AAFP Guidelines

AAFP opposes the expansion of the scope of services of retail clinics beyond minor acute illnesses and, in particular, opposes the management of chronic medical conditions in the retail setting.

Promoting practice guidelines

- Well-defined and limited scope of practice
- Standardized medical protocols and evidence-based practice
- Direct access to, and supervision by, MDs/DOs
- Ensure continuity of care
- Establish a referral system
- Inform patients of the health care practitioners’ qualifications
- Encourage patient relationships with primary care physicians
American Academy of Pediatrics

- Opposes retail clinics as a source of primary care for pediatric patients, citing concerns over fragmented care
- Also opposes payers offering lower copays or financial incentives for patients to receive care at retail clinics in lieu of their pediatrician or primary care physician
Nursing Perspective: AANPs and Campaign for Action

- Advocates for NPs to have unlimited prescriptive authority in their scope of practice
- NPs consulted regarding the development of clinics, their policies, practice guidelines and operations procedures
- NPs integral part of management activities
- Functions of clinic should be based on NP's full (and independent) scope of practice
- NPs permitted to establish ongoing program for quality assurance through peer review
- Competitive salaries and benefits
Convenient Care Association

• Physician oversight should be part of the practice to the extent that it adds value but not unnecessary costs

• NPs are highly qualified to deliver patient care at CCCs without the onsite presence of a PCP

• CCA adopted specific Quality and Safety Standards applicable to its members, available at http://ccaclinics.org/about-us/quality-of-care
Federal and State Regulations

Regulatory and legislative landscape
State Regulations Impacting Retail Clinic Development

- Scope of Practice
- Facility Licensing Requirements
- Anti-kickback Laws
- Corporate Practice of Medicine
- Telemedicine Rules
- Beneficiary Inducement
Corporate Practice of Medicine (CPOM)

- CPOM requirements vary from state to state
  - Some states strictly prohibit corporate ownership of retail clinics or employment of supervising physician (e.g. California and Texas)
  - Some states allow exceptions for “health care facilities” (i.e., New Jersey)
  - Some states outright permit employment of the supervising physician (e.g. Louisiana)
- Degree of physician involvement varies across the country
- Restrictions might also apply directly to NPs and PAs (i.e., Tennessee)
- Restrictions on fee splitting with other individuals or entities
Scope of Practice Laws and Regulations

• Determine range of health care services that HCPs are licensed to provide (NPs, PAs, LPN/LVNs)

• Limit the supply of health care services, raising serious competition issues

• Vary widely from state to state:
  – Independent practice / collaborative practice / physician supervision
  – Prescription privileges
  – Authority to order tests or refer to specialists

• FTC’s anti-competitive concerns
Note: Nebraska is now considered a full practice state. Effective June 5, 2015, Nebraska Legislative Bill 107 eliminated the requirements for integrated practice agreements for nurse practitioners who have 2000 practice hours.
## Physician Oversight of Nurse Practitioners in Six States

<table>
<thead>
<tr>
<th>State</th>
<th>Ratio (NP:MD)</th>
<th>Requirements</th>
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<tbody>
<tr>
<td><strong>California</strong></td>
<td>4:1</td>
<td>- Physician supervision required</td>
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<tr>
<td><strong>Florida</strong></td>
<td>4:1</td>
<td>- Physician may not supervise more than four offices in addition to the physician's primary practice location</td>
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<td><strong>Illinois</strong></td>
<td>None stated</td>
<td>- Physician delegation required</td>
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<td>- Physician must be on-site once per month</td>
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<tr>
<td><strong>Massachusetts</strong></td>
<td>None stated</td>
<td>- Physician supervision required</td>
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<td></td>
<td></td>
<td>- Physician must review charts once every three months</td>
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<tr>
<td><strong>New Jersey</strong></td>
<td>None stated</td>
<td>- Physician collaboration required</td>
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<td>- Physician must review charts (percentage or frequency not specified)</td>
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<tr>
<td><strong>Texas</strong></td>
<td>3:1</td>
<td>- Physician delegation required</td>
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<td>- Physician must be on-site 20 percent of the time (less in underserved areas)</td>
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<td>- Physician must review 10 percent of all charts (less in underserved areas)</td>
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Pressure to Reduce Costs

- Unmanned telehealth
- Medical assistant
- LVN/LPN
- Nurse practitioner
- Physician
Anti-Kickback Laws

Federal and state anti-kickback laws may be implicated by relationships between pharmacy and clinic or practitioners

• Prohibits:
  – Knowingly and willfully
  – Paying or offering, soliciting or receiving
  – Remuneration (anything of value)
  – To induce another to
  – Refer, purchase or order, arrange for or recommend
  – Federal health care program patients or business

• UNLESS a statutory exception or regulatory safe harbor protects the arrangement

• Small investments safe harbor unlikely to protect arrangements between pharmacies and clinic owners

• Parallel state anti-kickback statutes exist and may apply to all payors
Beneficiary Inducement Law

• Prohibits any person who offers or transfers to a Medicare/Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services payable by Medicare or Medicaid.

• “Remuneration” includes transferring any item or service for free or for other than fair market value.

• Penalties: civil money penalties of up to $10,000 for each wrongful act.

• Limited Exceptions: items worth $10/$50 per year, waiver of copay for indigent persons, limited preventative services.
Clinical Affiliations with Health Systems

• Health system may provide supervising physicians and NPs
• Health system and/or its medical group receives preferential referrals for patients who present out of scope
• Clinic benefits from name recognition
  – Example: Florida Hospital and Walgreens announced collaboration where Florida Hospital will operate and provide all clinical services at 15 retail health clinics located within Walgreens stores across Tampa. Walgreens plans to open a pharmacy at Florida Hospital Tampa, located at 3100 East Fletcher Avenue.

• Affiliations between health systems and pharmacies require analysis under the anti-kickback statute and privacy laws.
State Spotlights

Varying Requirements By State
Massachusetts

Department of PH Regulation
- 105 MASS. CODE REGS. 140. 1001 (2008)

Licenses “limited service clinics,” requiring them to:

• Limit their scope of practice, referring patients outside of this scope to a primary care physician
• Maintain roster of PCPs and community health centers willing to accept referrals
• Reduce “repeat encounter” patients
• Provide referral reports to patients without primary care physicians
• Prohibit clinic personnel from incentivizing patient utilization of services offered by the host retailer
Illinois

HB 1885 (stalled indefinitely)
- Would have required a permit to operate retail health clinic at cost of $2,500 per location for permit
- Required clinics to allow patients to use pharmacy of choice; clinic must notify patient’s physician of visit

HB 5372 (stalled indefinitely)
- Regulates patient safety and follow-up care
- Requires medical director
- Prohibits advertising fee comparison
- Prohibits locating retail health clinic in facilities selling tobacco or alcohol
- Prevents insurers from negotiating different terms

FTC advisory letter to Illinois Assembly
- Noted concerns and potential negative consequences of HB 5372
Florida

HB 699
• PCP can supervise no more than one facility, and no more than four health care professionals

Health Care Clinic Act
• Corporately owned clinics must be licensed by state; license renewal every two years for $2,000 fee per license
• Applicants must provide sufficient assets to cover liabilities for first 12 months

Scope of Practice
• Can be owned by NPs but must be supervised by physicians
• Physicians may supervise NPs and PAs at no more than four satellite offices
Rhode Island Department of Public Health Decision (5/2014)

Approved pre-licensure of MinuteClinics, but noted 22 stipulations, including:

- Enroll in the Kidsnet vaccine system
- Contribute $25,000 annually to the Rhode Island Physician’s Loan Replacement Fund for each MinuteClinic where the MinuteClinic cannot locate a primary care provider within a five-mile radius
- Limit each patient to three repeat encounters each year for the same treatment condition or illness
- Provide medical records to patients free of charge at end of each visit
- Post signs in both English and Spanish outlining scope of services
Moving Beyond the Box Store with **Telemedicine**

- In 2013, **Rite Aid** became the first retailer to enter telemedicine, rolling out its **NowClinic** program to in-store health clinics in Boston, Baltimore, Philadelphia and Pittsburgh
  - **NowClinic** is a 24/7 online service that allows members to connect with health care professionals through secure webcam, chat, or phone
- **HealthSpot** Stations - private, walk-in kiosk with integrated medical devices and staffed by a medical attendant – filed Chapter 7 bankruptcy liquidation in 2016
- **Medex Spot** - unmanned clinic is connected by satellite to a hospital call center
Privacy and Security Issues

• Impact of HIPAA and state privacy laws on use and disclosure of PHI in an environment of increased regulation and enforcement
  – Restrictions on marketing activities
  – Hybrid entity / health care component of the retailer?

• Interoperability - MinuteClinic announced in March 2014 that its clinics will switch to the Epic EMR. MinuteClinic expects the Epic EMR will help promote continuity of care with primary care providers.

• Heightened privacy issues in worksite clinics operated by retail clinics
Malpractice Considerations

• No reported malpractice liability claim against retail health clinic to date

• Because of current scope of practice laws requiring physician involvement, physicians face potential liability from allegations that standards were not met

• Risk factors enhanced by potential to underdiagnose patients and not follow up on discharge plan

• Risk may depend on whether or not state legislatures expand ability of APRNs
Questions?

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