



1 of 6 DOCUMENTS

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**HIGHLIGHT:**

**BODY:**

Retail clinics have grown substantially in number and popularity since their emergence in the early 2000s. Retail clinics are limited healthcare clinics that operate outside of physician offices and hospitals, typically in pharmacies, grocery stores, and "big box" stores like Target and Walmart. These clinics traditionally provide treatment of simple, acute medical conditions such as sore throats, colds, flu, cough, and sinus infections. Retail clinics may also offer expanded services like preventative care and vaccinations, but they remain distinct from urgent care facilities that provide imaging and laboratory services to treat more severe conditions. There are currently over 1,800 retail clinics operating in the United States providing approximately ten million patient visits per year. n1 The five largest operators of retail clinics, dominating 90% of the market share, are: CVS (MinuteClinic); Walgreens (Walgreens Healthcare Clinic); Kroger (The Little Clinic); Rite Aid (RediClinic); and Target (Target Clinic). n2

While retail clinics can offer significant benefits to patients and the overall healthcare system, the establishment and operation of retail clinics raises a wide range of legal issues that must be addressed, such as state licensure, corporate practice of medicine, and privacy laws. Healthcare attorneys encounter retail clinics through physician or nurse practitioner clients who wish to contract with a clinic, affiliations between clinics and hospital system clients, or

consultation regarding compliance with respect to a specific legal issue discussed below. This article discusses the primary state and federal legal issues that should be considered with respect to the establishment and operation of retail clinics.

## **I. Benefits of Retail Clinics**

### **A. Benefits to Patients**

Retail clinics address a wide variety of barriers to healthcare that typically exist for many underserved patient populations. The retail clinic model seeks to provide convenient, fast access to basic medical services. Appointments are typically not required and wait times are usually short. Retail clinics are available on weekends and in the evenings when physician offices are traditionally closed. This high level of accessibility benefits patients who do not have a primary care physician, have trouble obtaining immediate access to their primary care physicians, or who need care outside of normal physician office hours. A study of retail clinic visits estimated that 45% of visits occur on weekends or after business hours on weekdays, outside of normal office hours. n3

Retail clinics can also benefit the patient population as they typically offer low costs and price transparency for patients. Prices for services are typically posted for patients to see prior to obtaining services. Retail clinics are often able to keep their costs lower than at traditional providers due to their limited scope of services, use of mid-level providers to staff clinics, and low overhead costs. The estimated cost to consumers of a retail clinic visit is only \$45 to \$75 per visit. n4 Lower costs are increasingly important to patients who are paying more out of pocket for medical services, either because they are uninsured or because of the increase in deductibles under health plans, in part due to the enactment of the Affordable Care Act or states' elections not to expand Medicaid coverage. For uninsured patients, retail clinics offer preventative and routine care at much lower prices than emergency departments and urgent care clinics.

### **B. Benefits to the Healthcare System**

Proponents of the retail clinic model believe they save money for the entire healthcare system. It has been estimated that up to 27% of emergency department visits could be appropriately handled at retail clinics, at a cost savings of \$4.4 billion per year. n5 In addition, the convenience and affordability of retail clinics may encourages patients to get routine and preventative care, preventing higher costs to treat chronic and serious health conditions later on.

Retail clinics are increasingly collaborating with health systems. n6 In a typical arrangement, health systems provide patients with a primary care relationship, but have agreements with retail clinics to provide initial appointments, routine and follow-up care. n7 Information about a patient's visits to a retail clinic is exchanged with his or her primary care provider through integrated electronic health record systems. n8 Thus, health systems are able to use retail clinics to ensure timely and convenient care for their patients without losing critical continuity of care. In fact, some of these hospital-retail clinic partnerships may allow patients to receive expanded services typically unavailable in retail settings, such as well-woman care, family planning, and ongoing management of chronic diseases. n9 In addition, the availability of retail clinics for post-discharge follow-up visits has also been shown to reduce the rate of readmissions to hospitals for inpatient care. n10

### **C. Areas for Future Growth**

The best retail clinics are continuously evolving to benefit patients and the healthcare system in innovative ways. For example, some of the more innovative retail clinics have begun offering a wider range of preventative care and management of chronic conditions, expanding from their traditional role of treating commonly spread illnesses like the cold and flu. In 2013, Walgreens announced that its clinics would begin screening for and managing chronic conditions such as asthma, diabetes, high blood pressure, and high cholesterol. n11 Some CVS clinics offer annual preventative health screenings, such as cholesterol, blood pressure, and diabetes. n12 Retail clinics are also exploring integration of telemedicine services, giving patients increased access to physicians and expanding the conditions that can be addressed

at the clinics. n13 Telehealth services are viewed by many as being particularly valuable in rural and underserved areas, providing a lifeline for patients who may not otherwise have access to a provider. n14

Finally, retail clinics are developing integrated healthcare models with related wellness services. Clinics collaborate with provider organizations or health systems to provide services such as medication counseling, chronic disease monitoring, and wellness programs for patients of the provider partner. n15

## **II. State Law Considerations**

State laws may present various barriers to the retail clinic model. As with many other parts of the industry, the healthcare landscape is different in each state, which disproportionately affects retail clinic chains that operate nationally. Some states may also have implemented unique laws affecting retail clinics. The below discussion focuses on the four most significant issues for retail clinics arising under state law, which affect both their legal and organizational structure, namely: (1) facility licensure; (2) corporate practice of medicine restrictions; (3) regulations pertaining to non-physician providers; and (4) restrictions on the physical environment of the retail clinic.

### **A. State Licensure**

The most obvious issue for retail clinics under state law is state facility licensure. It is not always clear whether a state requires retail clinics to be licensed or how they are classified for licensure purposes, making careful review of the applicable state's licensing statutes and regulations critical for healthcare attorneys. Some states now specifically license retail clinics in the same way that they often do for ambulatory surgery centers, clinics, and hospitals. For example, Kentucky regulates retail clinics as "limited health clinics." n16 The applicable Kentucky regulations provide for licensure and dictate the range of conditions and patients that may be treated at a limited health clinic. n17 Notably, patients under the age of 24 months may not be treated at limited health clinics, and treatment of chronic conditions is limited. n18 The Kentucky regulations also require clinics to have a director with specified duties, require certain patient notifications, and impose requirements for storage of medical records at the clinic. n19 Similarly, the Massachusetts Public Health Council took executive branch action to implement regulations on "limited services clinics." n20 The Massachusetts regulations restrict the conditions and patients that can be treated at limited services clinics, as well as addressing medical records and referrals. n21 However, not every state has enacted such clear regulatory schemes for licensing retail clinics. This can lead to increasing uncertainty in the establishment and operation of these important care entities as this sector of the health care industry continues to expand.

### **B. Corporate Practice of Medicine Prohibitions**

State laws prohibiting the corporate practice of medicine similarly affect the legal structure and operations of many retail clinics. Specifically, many states prohibit corporations from providing medical services or employing physicians to provide healthcare services. In states where the corporate practice of medicine doctrine is strictly enforced, the key policy rationale is often that financial considerations should not factor into a licensed healthcare provider's patient care decisions. These prohibitions are not always explicitly stated in statutes and may be found instead in a state's licensing regulations, case law, or state attorney general opinions. It is important to verify an applicable state's corporate practice of medicine doctrine, which can prohibit corporate retailers of any size from owning or operating healthcare clinics.

For example, California law states that "corporations and other artificial legal entities shall have no professional rights, privileges, or powers." n22 Only four specific types of entities may charge for professional services rendered by employed licensed healthcare professionals. n23 In addition to statute, the Supreme Court of California has affirmed California's prohibition on the corporate practice of medicine. n24 Likewise, Ohio statutes state that professional corporations may be formed by physicians to render the physicians' professional services. n25 Although the statute does not explicitly state that only such professional corporations may provide medical services, the Ohio Attorney General has clarified that corporations may not practice medicine unless they are professional corporations composed of physicians. n26 The rules in each state with respect to the corporate practice of medicine are often not clearly defined,

and a detailed evaluation is often necessary to gauge risks associated with a given corporate structure.

In states with corporate practice of medicine prohibitions, retail clinics may choose to use enhanced management relationships between the corporate entity and the clinic. Under this model, retail clinics organize as private physician offices owned by physicians that contract with the managing entity for various management and other operational services.

There are many additional considerations if this management structure is used that healthcare lawyers must consider before advising their clients. For example, the corporate management entity must be careful not to employ any clinical staff or otherwise be involved in the provision of healthcare services. Some states have delineated specific functions that are considered to be corporate practice of medicine if performed by the management company. The California Medical Board explicitly prohibits entities from arranging for or advertising medical services for a medical practice.<sup>n27</sup> The Medical Board delineated specific clinical decisions that must be made by licensed physicians and activities that must be reserved to the physicians, such as ownership and control over patients' medical records and approving the selection of medical equipment and supplies.<sup>n28</sup>

In addition, the fee structure for the management relationship can result in violations of state fee-splitting prohibitions, particularly management fees that are based on a percentage of a clinic's revenue. Percentage-based fees may be viewed as impermissibly splitting income from the provision of medical services. For example, such an arrangement violates a New York law that prohibits physicians from participating in the division or splitting of a fee in connection with providing professional care or services.<sup>n29</sup> Florida also has aggressive fee-splitting laws, despite not having a traditional corporate practice restriction. The Florida Board of Medicine has disciplined physicians who paid revenue-based fees for management arrangements that involved marketing services and other services that drive patient referrals.<sup>n30</sup> The Board of Medicine found that percentage-based fees for services are illegal if they involve obligations to obtain referrals and securing payor contracts, arrange for ancillary services by third-party providers who can refer patients, or establish more extensive networks for a practice.<sup>n31</sup> Applicable state law prohibitions on the corporate practice of medicine and limitations on the enhanced management model such as these are important considerations for retail clinic formation and ownership structure.

### **C. Scope of Practice Limitations**

Regardless of their ownership, retail clinics are typically staffed by non-physician providers, such as nurse practitioners, to treat patients. Many states restrict mid-level providers in the scope of services they can provide without direct physician supervision and involvement. Approximately 35 states require some level of physician supervision of nurse practitioners.<sup>n32</sup> These restrictions are set out in varying forms. For example, certain states impose a limit on how many nurse practitioners one physician can supervise.<sup>n33</sup> States also set requirements that a supervising physician be on-site for a certain amount of time (e.g., 10% of a nurse practitioner's hours) or in specified intervals (e.g., at least once every 30 or 90 days).<sup>n34</sup> At least one state, Georgia, has initiated lawmaking directed at nurse practitioners practicing in retail clinics. Georgia lawmakers introduced a bill to ban nurse practitioners from practicing in retail locations that also house pharmacies, purportedly out of concern that the proximity of a pharmacy would lead to nurse practitioners over-prescribing drugs for retail clinic patients.<sup>n35</sup> Scope of practice restrictions must be carefully considered, as they can affect retail clinics' cost structure, choice of location, staffing decisions, and hours of operation.

### **D. Facility and Space Standards**

Depending on how retail clinics are classified under the applicable state law, certain physical standards may apply that are more onerous than the facility standards for the retail space in which clinics operate. Such standards may require a certain level of privacy for patient encounters, infection control protocols, or security measures for medical records and medical supplies. In New Jersey, private physician offices are exempted from physical facility and infection control regulations.<sup>n36</sup> Retail clinics can, therefore, organize as physician practices. On the other hand, some states have physical space requirements that are so unattainable for retail clinics, either because of the cost of compliance or

because of physical limitations in the retail space, that they preclude retail clinics from operating, at least using the organizational structure requiring licensure. For example, retail clinics fall under the definition of "organized ambulatory care facilities" in Rhode Island. n37 Rhode Island regulations require organized ambulatory care facilities to comply with the privacy and physical environment criteria for general healthcare facilities, as well as the American Institute of Architects Academy of Architecture for Health's Guidelines, which are much more onerous than those standards applicable to traditional physician practices and difficult to comply with in retail space. n38 As a result, no retail clinics currently operate in Rhode Island. n39

### **III. Federal Law Considerations**

Federal healthcare laws apply equally to retail clinics as they do to healthcare providers in traditional settings. These laws affect nearly every aspect of operation, from security requirements to compensation arrangements. Although a detailed and thorough analysis of individual retail clinic operations under each of these laws is required and is beyond the scope of this article, the following discussion provides an overview of key issues, such as patient privacy and fraud and abuse rules. It is also important to note that many states have state-level versions of these laws which may contain greater restrictions than their federal counterparts.

#### **A. HIPAA**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) contains extensive and complex requirements for healthcare providers. Significantly for retail clinics, HIPAA imposes standards for physical and electronic security requirements to protect patient information. n40 In addition to internal electronic systems, these requirements will apply to integrated electronic health record systems between clinics and health systems. Like state-level physical space requirements, these security standards may be more burdensome than those typically used for the larger retail facility. HIPAA also requires HIPAA training for employees and policies and procedures for HIPAA compliance. n41 Finally, HIPAA-compliant business associate agreements are required for vendors, management companies, or any other third parties who will handle patient information on behalf of the clinic. n42 Retailers that are already operating a pharmacy in the retail facility should be familiar with the HIPAA requirements and have these procedures in place. At a minimum, however, the existing HIPAA compliance plan must be tailored to the specific space, electronic systems, and operations of the retail clinic.

#### **B. The Anti-Kickback Statute**

The federal Anti-Kickback Statute (AKS) prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration in exchange for referrals of items or services reimbursed under a federal healthcare program. n43 If services provided at retail clinics are billed to Medicare, Medicaid, or other government program, any compensation paid by the billing entity--whether the clinic, physician, or retailer--to a potential referral source becomes subject to AKS considerations. The AKS provides various safe harbors for such compensation relationships. n44 It is not required that an arrangement meet every element of a safe harbor, nor does compliance with a safe harbor guarantee that enforcement action will not be taken, but maximizing compliance with a safe harbor decreases the risk of a finding that the arrangement constitutes an illegal relationship under AKS. The most relevant safe harbors to retail clinics are (1) leasing of office space, related to leasing the space in which a clinic operates; (2) personal services and management contracts, related to management arrangements or other services agreements with potential referral sources; and (3) bona fide employment, related to the employment of physicians and other staff. n45

#### **C. The Stark Law**

The federal Stark Law prohibits a physician from referring patients for certain designated health services reimbursed by Medicare at a facility with which the physician or an immediate family member has a financial relationship. n46 The Stark Law affects reimbursement for designated health services reimbursed by Medicare under a financial relationship between a physician and a retail clinic, including the physician's ownership, leasing of clinic

space, or employment of the physician by a clinic. Financial relationships between physicians and clinics must be structured to fit into a Stark Law exception. Unlike the AKS safe harbors, arrangements must meet every element of a Stark Law exception to avoid a violation because the Stark Law is a strict liability statute. The most relevant Stark Law exceptions, similar to AKS safe harbors, are likely to be those applicable to office space and equipment rentals; bona fide employment of physicians; and personal services arrangements, related to compensated services provided by a non-employee physician such as clinic directorship. n47

#### **IV. Other Legal Considerations**

There are various additional legal considerations that should be addressed with respect to retail clinics or relationships with them. If a clinic is organized as a physician practice and leased from a corporate retailer, leases must involve set in advance, fair market value rental compensation to avoid a risk of violating AKS, the Stark Law, and state fee-splitting requirements. Any applicable facility and physical space standards for healthcare facilities, or tenant improvements that are required to meet such standards, may need to be written into a lease. Zoning should also be considered, as retail space may not be properly zoned for a medical facility in certain localities.

Payor contracting and reimbursement are also concerns for retail clinics. It is valuable to communicate with potential payors regarding contracts and rates when determining the legal and operational structure of a retail clinic. Payors may require a licensed person or entity to be the contracting party, which is not feasible for retailers in all states, resulting in physicians or physician groups contracting with payors instead. To the extent that retail clinics enroll in Medicare or Medicaid programs, they will be subject to rigorous requirements and surveys to obtain enrollment status.

#### **V. Conclusion**

Retail clinics implicate myriad state, federal, and reimbursement issues in unique ways that must be considered in advising on the operation of and relationships with retail clinics. Although there are limitations, retail clinics have demonstrated that they can evolve to meet changing demands and health care climates. The need for low-cost, convenient health care services and a decrease in accessibility to office-based physician services makes it likely that retail clinics will only continue to grow and that healthcare attorneys will encounter these clinics in some capacity. Being aware of the complex regulatory environment for retail clinics is a critical first step in effectively serving this growing sector of the healthcare market.

#### **FOOTNOTES:**

(n1)Footnote 1. Bruce Johnson, *Retail Clinics Hit 10 Million Annual Visits*, Forbes, Apr. 23, 2015, <http://www.forbes.com/sites/brucejapsen/2015/04/23/retail-clinics-hit-10-million-annual-visits-but-just-2-of-primary-care-market/>.

(n2)Footnote 2. "Retail Health Clinics: State Legislation and Laws," National Conference of State Legislatures, <http://www.ncsl.org/research/retail-health-clinics-state-legislation-and-laws.aspx> (last visited Dec. 10, 2015).

(n3)Footnote 3. Avinash Patwardhan et al., *After-Hours Access of Convenient Care Clinics and Cost Savings Associated with Avoidance of Higher-Cost Sites of Care*, J. of Primary Care & Community Health, October 2012.

(n4)Footnote 4. "Retail Health Clinics: State Legislation and Laws," National Conference of State Legislatures, <http://www.ncsl.org/research/retail-health-clinics-state-legislation-and-laws.aspx> (last visited Dec. 10, 2015).

(n5)Footnote 5. Robin M. Weinick et al., *Many Emergency Department Visits Could Be Managed At Urgent Care Center And Retail Clinics*, Health Affairs 29, no. 9 1630-1639 (2010), available at <http://content.healthaffairs.org/content/29/9/1630.full> (last visited Dec. 10, 2015).

(n6)Footnote 6. Convenient Care Ass'n, *Retail Clinic Partnerships: The Value Proposition for Hospital and Health Systems*, Appendix A (September 2015), [http://www.ccaclinics.org/images\\_specific/RetailClinicPartnershipsReportSept15Updated.pdf](http://www.ccaclinics.org/images_specific/RetailClinicPartnershipsReportSept15Updated.pdf) (Appendix A provides a

listing of hospital and health system partnerships with retail clinics).

(n7)Footnote 7. *Id.*

(n8)Footnote 8. *Id.* at 3, 5.

(n9)Footnote 9. *See id.* at 3-4 (describing general collaboration and one new partnership between Target Clinics and Kaiser Permanente).

(n10)Footnote 10. *Id.* at 4.

(n11)Footnote 11. *Id.* at 3; Press Release, Take Care Clinics Expand Scope of Health Care Services to Include Chronic Condition Management and Additional Preventative Health Offerings (Apr. 4, 2013), *available at* <http://news.walgreens.com/press-releases/general-news/take-care-clinics-expand-scope-of-health-care-services-to-include-chronic-condi> (last visited Dec. 10, 2015).

(n12)Footnote 12. *See* <http://www.cvshealth.com/about/our-offerings/cvs-pharmacy/project-health>.

(n13)Footnote 13. Convenient Care Ass'n, *Retail Clinic Partnerships: The Value Proposition for Hospital and Health Systems*, 2-3 (September 2015), [http://www.ccaclinics.org/images\\_specific/RetailClinicPartnershipsReportSept15Updated.pdf](http://www.ccaclinics.org/images_specific/RetailClinicPartnershipsReportSept15Updated.pdf).

(n14)Footnote 14. *Id.*

(n15)Footnote 15. *Id.*

(n16)Footnote 16. *902 K.A.R. 20:400.*

(n17)Footnote 17. *Id.*

(n18)Footnote 18. *Id.*

(n19)Footnote 19. *Id.*

(n20)Footnote 20. *105 CMR 140.1000-140.1002.*

(n21)Footnote 21. *Id.*

(n22)Footnote 22. *California Business and Professions Code 2400.*

(n23)Footnote 23. *Id.* at 2401.

(n24)Footnote 24. *People v. Cole, 135 P.3d 669, 671 (Cal. 2006) .*

(n25)Footnote 25. *Ohio Rev. Code Ann. § 1785.02 (2009).*

(n26)Footnote 26. *Op. Atty. Gen. No. 52-1751 (1952).*

(n27)Footnote 27. Medical Board of California, Corporate Practice of Medicine, [http://www.mbc.ca.gov/Licensees/Corporate\\_Practice.aspx](http://www.mbc.ca.gov/Licensees/Corporate_Practice.aspx) (last visited Dec. 9, 2015).

(n28)Footnote 28. *Ohio Rev. Code Ann. § 1785.02 (2009).*

(n29)Footnote 29. *N.Y. Educ. Law § 6513*.

(n30)Footnote 30. *See In re* Petition for Declaratory Statement of Magan L. Bakarania, M.D. (BOM 1999) (*aff'd. Phymatrix Mgmt. Co. v. Bakarania*, 737 So.2d 588 (Fla. Ct. App. 1999)) .

(n31)Footnote 31. *In re* Petition for Declaratory Statement of Raw, Rogers, and Silver, M.D.s, P.A. (BOM 1999).

(n32)Footnote 32. Convenient Care Association, State-by-State Guide to Laws Regarding Nurse Practitioner Prescriptive Authority and Physician Practice (July 2014), *available at* [http://www.ccaclinics.org/images/Documents/NPPracticeRegulationsChart\\_July2014.pdf](http://www.ccaclinics.org/images/Documents/NPPracticeRegulationsChart_July2014.pdf).

(n33)Footnote 33. *Id.*

(n34)Footnote 34. *Id.*

(n35)Footnote 35. 2005-2006 SB 603.

(n36)Footnote 36. California HealthCare Foundation, *Retail Clinics: Six State Approaches to Regulation and Licensing*, at 10 (Feb. 2009).

(n37)Footnote 37. R.I. Admin. Code 31-4-13:1.10.

(n38)Footnote 38. *Id.* 31-4-13:21.0

(n39)Footnote 39. "Retail Health Clinics: State Legislation and Laws," National Conference of State Legislatures, <http://www.ncsl.org/research/retail-health-clinics-state-legislation-and-laws.aspx> (last visited Dec. 10, 2015).

(n40)Footnote 40. *45 C.F.R. § 164.306-.312*.

(n41)Footnote 41. *45 C.F.R. §§ 164.316; 264.530(b)*.

(n42)Footnote 42. *45 C.F.R. § 164.308(b)(1)*.

(n43)Footnote 43. *42 U.S.C. § 1320a-7b*.

(n44)Footnote 44. *42 C.F.R. § 1001.952*.

(n45)Footnote 45. *42 C.F.R. §§ 1001.952(b), (d), & (i)*.

(n46)Footnote 46. *42 U.S.C. § 1395nn*.

(n47)Footnote 47. *42 C.F.R. §§ 411.357(a), (c), & (d)*.

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