

## **RETAIL HEALTH CLINICS: OPPORTUNITIES AND CHALLENGES**

**By: Heather Siegelheim**

An emerging issue in health care is the proliferation of retail health clinics and the legal and regulatory issues they implicate. Retail health clinics are walk-in health care clinics operating out of pharmacies, grocery stores, and other major retailers, such as CVS, Walgreen's and Target.

### ***Retail Health Clinics: A Primer***

Retail health clinics typically diagnose and treat simple acute conditions, such as strep throat, bronchitis, minor wounds, rashes, or infections. Many offer a range of wellness services, such as sports physicals and smoking cessation programs, while some also offer routine vaccinations for flu, pneumonia, pertussis, and other fairly common conditions. Most recently, retail clinics have started expanding into dental, optical, and hearing services. As a general rule, retail health clinics provide basic health care and do not treat urgent, traumatic injuries or illnesses. Most retail clinics do not provide any designated health services ("DHS") either, the exception being that some retail health clinics may offer routine laboratory services.

When retail clinics first started, many did not accept public or private insurance, and required patients to pay for services. Today, most retail clinics accept private insurance and some even accept Medicare, making them appeal to a much broader audience.<sup>1</sup>

Two factors that have led to the growth of retail clinics are 1) convenience and 2) lower costs. Most retail health clinics offer services on a walk-in basis, and many have extended weekend hours to accommodate patients' schedules. Not only is it typically easier and more efficient to walk in to a clinic located inside a local grocery store or pharmacy than it is to get to an emergency room or urgent care center, it is also less costly. The lower cost of care is due in part to the fact that retail clinics are typically staffed by nurse practitioners and other non-physician medical providers who are paid less than physicians and receive lower reimbursement rates from third-party payors. "The bottom line is that retail medical clinics provide quality medical care at a reasonable cost with the potential to increase access to basic health services in underserved populations."<sup>2</sup>

Retail health clinics are regulated by the same body of state and federal laws and regulations as those applicable to more traditional health care settings, so it is important that retail clinic operators are also aware of the potential implication of state and federal licensing, scope of practice, corporate practice of medicine, and fraud and abuse laws. With respect to state laws, there is great variation across states, making it imperative that an operator looking to establish a clinic is knowledgeable about and adheres to the laws, regulations, and licensure

---

<sup>1</sup> California Healthcare Foundation (CHCF), Issue Brief, Retail Clinics: Six State Approaches to Regulation and Licensing, pp. 4-5 (February 2009), <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/R/PDF%20RetailClinicsSixStateApproaches.pdf>

<sup>2</sup> Kristin E. Schleiter, "Retail Medical Clinics: Increasing Access to Low Cost Medical Care Amongst a Developing Legal Environment," American Medical Association, Annals of Health Law, Vol. 19 (2010), Iss. 3, Art. 9, at p. 528.

requirements of the state(s) in which it intends to establish a clinic.<sup>3</sup>

### ***Federal Considerations***

Retail health clinics may implicate a host of federal laws and regulations. One such law is the federal Anti-Kickback Statute, which prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals for any item or service that is reimbursable, in whole or in part, by a federal health care program.<sup>4</sup> If a retail health clinic is owned by the host retailer, the clinic and retailer may refer federal health care program patients to each other, thus potentially implicating the Anti-Kickback Statute.<sup>5</sup> Thus, retail health clinics and their owners/operators should take certain precautions to avoid implicating the Anti-Kickback Statute and to structure the arrangement to fit within a safe harbor whenever possible. For one, the host retailer should avoid paying any remuneration for referrals of federal health care program patients for services offered by the clinic. In the same vein, the host retailer should avoid revenue-based lease arrangements with the clinic. A retail clinic can mitigate potential risks by structuring the arrangement with the host retailer to fit within the safe harbors for space and equipment rental and/or personal services, where applicable.<sup>6</sup>

Another federal law retail clinics must consider is the Stark Law, which prohibits physicians from referring patients to an entity for certain DHS payable by Medicare or Medicaid, if a physician or family member has a financial relationship with the entity.<sup>7</sup> Most retail health clinics do not offer DHS, and thus do not implicate the Stark Law. However, some retail clinics may offer routine laboratory services, which are DHS, and many may eventually offer other DHS, such as radiology or other imaging services or durable medical equipment and supplies (“DME”).<sup>8</sup> If DHS were offered by a retail clinic, then the analysis of whether the structure violates the Stark Law may turn on whether a physician who is either employed by or contracted with the clinic, or who owns a share of the clinic either directly or through the physician’s stake in a physician organization, refers patients to the clinic. If so, then the arrangement must squarely meet one of the specifically enumerated exceptions, such as the exception for personal services or the in-office ancillary services exception.<sup>9</sup>

Retail health clinics also raise issues related to privacy and security. As health care providers that electronically transmit standard transactions (e.g., payment, enrollment, eligibility, etc.), retail health clinics are covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations, and thus are subject to HIPAA’s Privacy and Security Rules.<sup>10</sup> Under certain circumstances, a retail health clinic may also be a business associate under HIPAA if, for example, it is performing a service or function for another covered entity (e.g., a health plan) that requires it to receive protected health

---

<sup>3</sup> Patricia S. Hofstra and Lester J. Perling, *Strafford Live Webinar, Retail Clinics in Healthcare: Overcoming Complex Legal Challenges* (March 11, 2015).

<sup>4</sup> 42 USC § 1320a-7b(b).

<sup>5</sup> Schleiter, *supra*, at p. 572.

<sup>6</sup> *Id.*; Hofstra and Perling, *Retail Clinics in Healthcare Webinar, supra*.

<sup>7</sup> 42 USC § 1395nn.

<sup>8</sup> Schleiter, *supra*, at p. 570; Hofstra and Perling, *Retail Clinics in Healthcare Webinar, supra*.

<sup>9</sup> Schleiter, *supra*, at p. 570.

<sup>10</sup> 45 C.F.R. Part 160 and Part 164, Subparts A, C and E; Hofstra and Perling, *supra*.

information (PHI). The Privacy Rule sets forth how covered entities and business associates can use or disclose PHI. It also defines patient rights with respect to issues including, but not limited to, notices of privacy rights, access to health information, and requests for restrictions on uses and disclosures and communications of PHI. The Security Rule establishes national standards for how electronic PHI or “e-PHI” must be stored or maintained by covered entities and business associates. The Security Rule mandates the use of policies and procedures, as well as the implementation of appropriate administrative, physical and technical safeguards, to ensure the confidentiality, integrity, and security of PHI. Retail health clinics are likely to store and maintain PHI, and may also transmit PHI to patients’ primary care physicians or specialists. For these reasons, retail health clinics should be sure that they maintain and distribute to patients a Notice of Privacy Practices, and that they utilize patient authorizations when necessary. Retail health clinics should also be aware of and knowledgeable about state laws on patient privacy and confidentiality, as state laws may take precedence over HIPAA if they are more stringent or offer more privacy protection than HIPAA does.

### ***State Considerations***

With respect to state laws impacting retail clinics, one example of the great variation among states is the level of autonomy afforded nurse practitioners and other non-physician practitioners pursuant to scope-of-practice regulations. Some states allow nurse practitioners and physician assistants to operate autonomously without physician oversight, for example, while other states require some degree of physician supervision or collaboration. Furthermore, some states require a physician to act as a medical director of a retail health clinic, but not all states require that the medical director be physically present at the clinic. Based on scope-of-practice laws alone, it is easy to see how the variation in state laws presents a challenge to chain retailers looking to establish clinics in multiple states.

Licensure requirements for retail clinics also vary from state-to-state. Some states (e.g., Florida) require retail clinics to be licensed as health care entities, while other states (e.g., California) exempt retail clinics from licensure.<sup>11</sup> Additionally, states have differing corporate practice of medicine laws, which generally impose restrictions on the ability of for-profit and not-for-profit corporations to directly employ physicians. Thus, the ownership structure of a retailer operating retail clinics in multiple states may impact whether that retailer’s clinics are able to operate in a particular state.<sup>12</sup>

Furthermore, some states have fee-splitting prohibitions, which prohibit licensed medical professionals from splitting professional fees with other individuals or entities in exchange for referrals. Thus, another important consideration is whether a particular arrangement in place at a retail clinic implicates a fee-splitting prohibition. Lease arrangements and management contracts should be carefully considered in this context, particularly if the management company is paid a percentage of revenue based on productivity of the retail clinic.

### ***Conclusion***

---

<sup>11</sup> Hofstra and Perling, Retail Clinics in Healthcare Webinar, *supra*.

<sup>12</sup> CHCF, Issue Brief, Retail Clinics, *supra*, at p. 7.

These are just some of the considerations and legal implications surrounding retail health clinics. Retail health clinics continue to proliferate and expand the services they offer, as consumer-patient demand for easier access to health care and lower health costs increases. Retailers looking to establish clinics within the retail space, or physicians who may be employed by or contracted with retail health clinics or who have an ownership interest in a retail health clinic should be aware of these issues before entering into any arrangements with or making any referrals to the clinic. An experienced health care attorney can help navigate the legal and regulatory landscape and help to avoid any potential pitfalls related to arrangements with retail health clinics.