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MINUTE MEDICINE: EXAMINING RETAIL CLINIC LEGAL ISSUES AND LEGISLATIVE CHALLENGES

Aaron Hoffman†

INTRODUCTION

In the back of the local CVS drug store, behind aisles stocked with shampoo, painkillers, soda, and holiday decorations, sits a clinic examination room. The exam room is located next to the pharmacy. The couple of chairs between them do the double duty of seating patients who are waiting to be seen and customers waiting for prescriptions. A small touch screen display outside of the closed door permits those wishing to see the nurse to tap out their name and browse the menu of services that the clinic provides. Services range from pre-summer camp physicals and strep throat tests to diabetes testing and meningitis immunizations. Within fifteen minutes, a patient’s name is called, and he or she is ushered into the exam room set up as a smaller-scale physician’s examination room. When the exam is completed, the patient will leave the exam room with either a prescription for the pharmacy next door or with an answer to his or her medical problem, all without having to wait in an urgent care clinic, or needing a pre-scheduled doctor’s appointment.

By summer 2009, the Convenient Care Association, a trade group for the retail clinic industry, estimated that 1,200 retail-based health clinics operated in the United States.1 With such operations in place, any patient who is eighteen months or older2 can enter a drug store or

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2 A minor must be accompanied by a parent or guardian or present a signed Authorization to Treat form. See MinuteClinic, Authorization to Treat, http://www
supermarket that contains a clinic and can be seen and assisted, usually within fifteen minutes of arrival. Each patient of a retail clinic takes part in what critics and proponents alike agree is a major change in the manner in which Americans receive healthcare. Doctors, nurses, politicians, and patients are closely following the spread of retail clinics. These groups hold diverse views on the retail clinics’ growth, ranging from deeming the clinics as a solution to the crisis of healthcare coverage, to condemning the clinics as the complete undoing of the doctor-patient relationship in America.

The American public has enjoyed an immense increase in consumer power in every area of commerce. No longer are consumers willing to enter a store and rely completely on the salesman to tell them what products to purchase. As the balance of power shifts from salesman to consumer, so too does the balance shift in the U.S. medical community, with patients increasingly demanding more information and more choices when it comes to their healthcare. The idea that a patient is a retail consumer and healthcare is the product has negative implications within the medical community. The medical community has relied historically on its advanced training and position of power to guide patients in making health-related decisions. To say that a patient could enter into a doctor’s office and purchase a strep throat test sounds strange, and yet, as fewer and fewer Americans have access to the traditional primary care provider relationship, shopping becomes a more apt analogy. Accordingly, retail clinics have responded to consumers’ demands for convenience, control, and value throughout the United States.

In 2008, spending on healthcare in the United States represented sixteen percent of gross domestic product at $2.3 trillion. As healthcare costs continue to rise, nearly forty-five million Americans remain

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3 Annie Hsu, Legal Issues Concerning Retail Clinics, HEALTH LAW., June 2008, at 13, 13.
5 Hsu, supra note 3, at 16-17.
7 See generally Rahul K. Parikh, Wal-mart Can Be Good for Your Health, SALON, Feb. 19, 2008, http://www.salon.com/mwt/feature/2008/02/19/retail_health_clinics/index.html (outlining the medical community’s opposition to drop-in clinics and the benefits that these clinics may have).
uninsured and without adequate access to necessary health services. The spread of retail clinics is not a panacea to the healthcare problems facing the United States. It is too early to accurately judge the impact which retail clinics may have on healthcare in the United States, but many groups both for and against, are tracking these clinics' development. Implemented correctly, and controlled appropriately, the increased access to healthcare and preventative focus which retail clinics can provide may help extend healthcare to more Americans when they need it, creating a healthier society. Retail clinics can achieve these goals because of their innovative use of non-physician providers as well as technological and medical innovations. Retail clinic expansion should be guided by targeted legislation meant to ensure patient safety, without destroying the economic advantages which make them successful.

This Note discusses the legal and regulatory issues retail clinics face in conjunction with their rampant expansion within the United States. Section I discusses the historical development of retail clinics as well as the staff composition. Section II analyzes various regulations that have had an effect on both the medical and business aspects of retail clinics. In particular, this Note closely examines the recent amendment to Massachusetts state regulations, which concerns clinic licensure, and the role retail clinics played in crafting the new regulations.

After discussing these regulations, the Note analyzes issues of concern related to retail clinics and recommendations for best approaches to these concerns. Moreover, the discussion focuses on the general opposition to retail clinics from the physician community. In response to the raised opposition, a proposal for specific guidelines as to how retail clinics may address some of the legitimate health concerns these groups express is put forward. Section III recommends regulation seeking to specify physician oversight of the retail clinic staff as well as regulation which ensures sufficient hygiene. The argument is put forward that regulation that simply seeks to make retail clinics economically unviable, such as parking limits, advertising restrictions, and tobacco sales bans should be dismissed. Finally, this Note will discuss the ways in which the development of Electronic Health Records will significantly benefit retail clinics and help to answer some of the major criticism levied against retail clinics.

I. CLINIC OVERVIEW

A. Historical Clinic Development

Advances in medical testing have led to efficient diagnoses of a range of medical problems which can be safely and easily treated with prescription drugs. Medical issues such as strep throat, influenza, and ear and bladder infections, which are relatively common in the population and comparatively easy to diagnose, can be easily treated before they become exacerbated and require more expensive and involved medical care. Many doctors do not have the time to make appointments on short notice to diagnose these conditions when symptoms first emerge. Appointments cost patients both time and money. Indeed patients incur the medical expenses associated with treatment, but patients also incur costs associated with missing work or school. Doctors must hold open time slots for simple diagnoses or else hold extra hours in order to cope with the demand for such services. It was the realization of these issues which led a doctor to invent the first retail clinics.

In 2000, physician Doug Smith remained at his office after-hours on a Friday night to administer a strep test to an acquaintance's son. The acquaintance was concerned about his sick child and could not find any place that would administer the test over the weekend. This incident inspired Dr. Smith to open QuickMedX, the first so-called convenient care clinic in America and the precursor to modern retail clinics. Dr. Smith, along with his acquaintance, businessman Rick Krieger, set about designing a new way of providing medical care. Answering the demand for ready access to low-cost medical care, Smith began by opening three clinics located in drug stores in the Minneapolis-St. Paul area. Smith, together with his business partner, founded QuickMedX to provide "convenient, fast and inex-

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10 See Parikh, supra note 7.
13 Id.
14 Id.
pensive access to basic healthcare to patients without requiring unreasonable office hours for physicians.\footnote{15}

Smith realized that non-physicians, who had prescriptive power, could diagnose and efficiently respond to the demand for such medical services in locations that were more convenient for patients than doctors' offices.\footnote{16} With no appointment necessary, QuickMedX allowed a patient to come in for a twenty-minute exam that could allow the patient either to receive treatment or a prescription for medication.\footnote{17} From its modest start, QuickMedX grew to become MinuteClinic, which is now wholly owned by CVS and is the leader in the retail clinic industry.\footnote{18} With the swipe of a credit card, a consumer at the supermarket can get a strep test administered by a trained medical professional at the first sign of a sore throat and walk out of the supermarket with the appropriate prescription drugs if necessary. From three locations in the Twin Cities to national chains such as MinuteClinic, the retail clinic model has emerged specifically to provide low-cost preventive and early diagnostic care to a broad range of patients.

\textbf{B. Clinic Set-up}

The retail clinic model is fairly straightforward. A small staff of one or two advanced-practice nurses ("APN") holds open office hours to treat certain specifically listed medical issues.\footnote{19} The clinic is normally situated towards the back of the store, near the pharmacy.\footnote{20} Many clinic chains use computerized sign-in systems for check-in.\footnote{21} Customers enter their name and the reason for their visit into a touchscreen display and then are placed on a waiting list. Some locations provide clinic customers with electronic pagers, which allow these customers to shop in the retail store while waiting to be examined.\footnote{22}

\begin{footnotesize}
\textsuperscript{15} As with the development of the Nurse Practitioner and Physician's Assistant, many innovations in the medical field came from doctors seeking ways to decrease the overburdened schedules of primary care physicians. \textit{Id.}
\textsuperscript{16} Champlin, \textit{supra} note 12.
\textsuperscript{17} Walecia Konrad, \textit{A Quick Trip to the Store for Milk and a Throat Swab}, \textsc{N.Y. Times}, Oct. 2, 2009, at B6.
\textsuperscript{19} Konrad, \textit{supra} note 17.
\textsuperscript{21} \textit{Id.}
\textsuperscript{22} Michelle Beaver, \textit{Britain Experiments with Supermarket Clinics}, \textsc{Immediate Care Bus.}, Mar. 3, 2008, http://www.immediatecarebusiness.com/blogs/}

\end{footnotesize}
Most retail clinics consist of one or two small examination rooms with limited medical equipment, a stripped down version of a physician’s examination table, and a computer terminal. Clinic staff must follow rigid protocols that specifically address how each medical issue on the clinic’s menu should be diagnosed and treated. The patient’s information is entered digitally and may be shared between clinics of the same chain and even forwarded to the particular customer’s physician. Indeed, retail clinics’ use of technology and low-cost space makes retail clinics cost efficient.

As is true for urgent care clinics, the majority (sixty-nine percent) of retail clinic patients seek acute care for common ailments. Preventative care, particularly immunizations, makes up the balance of retail clinic business. If a retail clinic is unable to service a patient, the clinic will refer the patient to a physician or to an urgent care clinic for treatment. This referral system allows retail clinics to provide limited medical care and provide the necessary information to those patients who present with issues outside the retail clinic’s scope of care. While retail clinics’ services may seem extremely limited compared with a primary care physician’s services, the focus on prevention evinced by the retail clinics’ scope of care as well as a limited number of easily treatable medical problems allows for a high standard of care as well as quick patient turnover.

C. Advanced Practice Nurses

Typically, when a patient visits a retail clinic that patient is examined by an APN. The APN is either a nurse practitioner (“NP”) or a physician’s assistant (“PA”) who has undergone additional and often specialized training. Such professionals are licensed to provide medication and to make decisions independent of physicians. They are a


Urgent care is defined as walk-in or ambulatory care for primarily for the treatment of injury or illness which requires immediate treatment but is not serious enough to warrant going to an emergency room. Examples include x-ray and setting of broken bones, and the treatment of moderate to severe lacerations. See Urgent Care Ass’n of Am., Urgent Care Definition, http://www.ucaoa.org/docs/UrgentCareDefinition.pdf (last visited May 3, 2010).

Ateev Mehrota et al., Retail Clinics, Primary Care Physicians, and Emergency Departments: A Comparison of Patients’ Visits, 27 HEALTH AFF. 1272, 1276 (2008).

Hsu, supra note 3, at 13.

Ann Ritter & Tine Hansen-Turton, The Primary Care Paradigm Shift: An Overview of the State-Level Legal Framework Governing Nurse Practitioner Prac-
key to retail clinics' successes by providing the medical expertise, clinical training, and cost savings necessary to make a retail clinic economically and medically viable.

Both PAs and NPs, as nursing specialties, were developed in the 1960's with the explosive growth in demand for medical services stemming from the post-war baby boom and an increase in social services subsidizing medical care. Drawing on the success that the military had in training corpsmen to provide basic medical care without the time and expense of physician’s training, two different programs developed independently to capitalize on this innovation. Both the NP and PA programs stress the skills necessary to interact with patients in clinical settings, allowing the nurses to begin the diagnostic process by taking patient histories, administering physical exams, and conducting basic diagnostic tests and treatments. While PAs and NPs are able to examine patients and prescribe medication without the direct consultation of a physician, supervision on some level is required.

The relationship that APNs have with physicians is not currently governed by any fixed guideline or standard. Different states require varying levels of supervision. Many states give APNs prescriptive authority, which is a requirement for APNs who staff retail clinics. Further discussion on supervision and prescription authority will be undertaken in Section II.

D. Statistics on Retail Clinics

The following discussion provides a snapshot of the patients who make up the customers of retail clinics and the reason for their visit. These numbers demonstrate the broad demographic range of retail clinic customers and the basic medical reasons for their visits.

### Characteristics of Patient Visits to Retail Clinics

<table>
<thead>
<tr>
<th>No. of Visits (Millions)</th>
<th>All Patients</th>
<th>Children</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.35</td>
<td>0.36</td>
<td>0.97</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>37.2%</td>
<td>47.3%</td>
<td>33.5%</td>
</tr>
<tr>
<td>Female</td>
<td>62.8%</td>
<td>47.3%</td>
<td>33.5%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2</td>
<td>0.2%</td>
<td>0.8%</td>
<td></td>
</tr>
<tr>
<td>2-5</td>
<td>6.3%</td>
<td>23.5%</td>
<td></td>
</tr>
<tr>
<td>6-17</td>
<td>20.3%</td>
<td>75.7%</td>
<td></td>
</tr>
<tr>
<td>18-44</td>
<td>43%</td>
<td>58.8%</td>
<td></td>
</tr>
<tr>
<td>45-64</td>
<td>22.6%</td>
<td>31%</td>
<td></td>
</tr>
<tr>
<td>&gt;65</td>
<td>7.5%</td>
<td>10.3%</td>
<td></td>
</tr>
<tr>
<td>Primary Source of Payments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out of Pocket</td>
<td>32.9%</td>
<td>29.5%</td>
<td>34.0%</td>
</tr>
<tr>
<td>Insurance (any)</td>
<td>67.1%</td>
<td>70.5%</td>
<td>66.7%</td>
</tr>
<tr>
<td>Patients Reporting Having a PCP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>38.7%</td>
<td>52.9%</td>
<td>33.3%</td>
</tr>
<tr>
<td>No</td>
<td>61.3%</td>
<td>47.1%</td>
<td>66.7%</td>
</tr>
</tbody>
</table>

### Reasons for Visits at Retail Clinics

<table>
<thead>
<tr>
<th>Reason for Visit</th>
<th>All Patients</th>
<th>Children</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Visits (Millions)</td>
<td>1.35</td>
<td>0.36</td>
<td>0.97</td>
</tr>
<tr>
<td>Upper respiratory infection, sinusitis, or bronchitis</td>
<td>27.4%</td>
<td>16.3%</td>
<td>31.6%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>21.2%</td>
<td>35.1%</td>
<td>16.3%</td>
</tr>
<tr>
<td>Immunizations</td>
<td>19.7%</td>
<td>9.4%</td>
<td>24%</td>
</tr>
<tr>
<td>Swimmer’s Ear or ear infection (otitis media or otitis externa)</td>
<td>12.7%</td>
<td>26.1%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>4.6%</td>
<td>6.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Urinary Tract Infections</td>
<td>3.5%</td>
<td>0.4%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Screening lab test or blood pressure check</td>
<td>1.3%</td>
<td>0.8%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Other preventative care</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Other care not included in above categories</td>
<td>8.9%</td>
<td>5.8%</td>
<td>9.7%</td>
</tr>
<tr>
<td>Total, ten most common reasons for visits to clinics</td>
<td>90.3%</td>
<td>93.4%</td>
<td>90.0%</td>
</tr>
</tbody>
</table>

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33 Mehrota et al., supra note 26, at 1277.
34 Id. at 1278.
E. Economic Advantages of Retail Clinics

The retail model of healthcare has proven to be a good investment for its operators and investors. The business model which retail clinics are built on succeeds because of the efficiencies gained from staffing, space requirements, and the limited menu of services provided. With regard to staffing, physicians are expensive; their wages are high and maintaining a doctor’s office is expensive due in part to costs associated with expensive diagnostic equipment and a large staff. Conversely, a retail clinic may only staff one nurse, who provides care at a lower salary than a physician who would provide comparable care. The space that retail clinics occupy is low cost for the retailers because of the small footprint of the clinics. This allows retailers to remove a minimal amount of retail inventory to accommodate the clinic. Finally, limiting the services to a small menu allows the clinic to stock only equipment used to diagnose those maladies. Advertising what services the clinic provides also helps prospective patients to choose when it is appropriate to go to a retail clinic, which in turn decreases the wait and lost revenues associated with having to turn away a patient whose malady is outside the scope of care.

When a patient comes in to see the APN at a retail clinic, the APNs will observe and confirm symptoms and follow protocol to prescribe medication or to provide basic and inexpensive treatment that can be performed within the confines of the medical clinic quickly. Clinics also benefit the retailers in which they are located. For example, they increase prescription volume at the retailer’s pharmacy and also may increase sales of other products sold by the retailer, both through recommendation of over-the-counter medical products and through sales of products unrelated to the customer’s clinic visit that the customer might otherwise not have purchased.

MinuteClinic provides the best example of these efficiencies to date. With locations in twenty-six states, MinuteClinic provides services with an average cost ranging from $25 to $60. MinuteClinic groups its services into six categories: “Minor illness exam,” “Minor Injury exam,” “Skin condition exam,” “Wellness & prevention,” “Health condition monitoring,” and “Vaccinations.”

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36 Margaret Laws & Mary Kate Scott, The Emergence of Retail-Based Clinics in the United States: Early Observations, 27 HEALTH AFF. 1293, 1294 (2008); Hsu, supra note 3, at 15.
37 See MinuteClinic, Services and Costs, http://www.minuteclinic.com/
ness exam includes diagnosis and treatment of allergies, aches, symptoms involving the ear, nose and throat, and urinary tract infections among others. The Wellness and Prevention screening services include pre-camp and college physical exams, cholesterol, diabetes and hypertension screening as well as a "Smoking cessation" session.

"Vaccines," which vary by state, include flu, hepatitis, polio, and measles, mumps, and rubella. Each category of treatment on the website includes a short listing of what to expect during the visit. This information further warns patients what symptoms require care at a more advanced facility.

The treatments and services that MinuteClinic provides are representative of what other major retail clinics provide. Each service provided can be accomplished in a short period of time, with tests that have a high degree of accuracy.

II. REGULATORY ISSUE

A. Massachusetts Limited Service Clinic Regulation

In early 2006, the CVS chain of convenience stores sought approval to expand its MinuteClinic operations into locations in its stores in the state of Massachusetts.

Massachusetts' regulations concerning healthcare facilities proved to be an impediment to all retail clinics that were located in the state because of the strict requirements associated with operating a health clinic. To expand into Massachusetts, CVS sought a waiver that would allow CVS to open retail clinics without having to comply with all state health clinic regulations. The Code of Massachusetts Regulations, 105 § 140.099, provides for waiver of requirements for clinics upon a finding by the Health Commissioner that:

40 For a Minor Illness Exam, MinuteClinic will not treat patients requiring x-rays, patients with wounds to the eyes, groin, or other sensitive areas, or patients presenting with a fever of over 100 degrees. MinuteClinic, Minor Injury Exam, http://www.minuteclinic.com/services/minorinjuryexam/ (last visited May 3, 2010).
(1) compliance would cause undue hardship to the clinic;  
(2) the clinic is in substantial compliance with the spirit of the requirement; and  
(3) the clinic’s non-compliance does not jeopardize the health or safety of its patients and does not limit the clinic’s capacity to give adequate care. . . .

Among other requirements, CVS sought to be excused from providing for: a sink and toilet, a janitor’s closet and cleaning supplies, soiled linen storage room, and a phone service for answering after-hours patient calls. By late 2006, the Massachusetts Department of Public Health sought comment from medical groups in the state on the regulations impacting retail clinics. In January 2008, Massachusetts state health officials had approved sweeping amendments to the regulations which exempted retail clinics from the health clinic regulations from which CVS had sought waiver. Many groups testified to the Massachusetts Department of Health regarding proposed legislation, from Wal-Mart and nursing professional associations, to the Massachusetts Medical Society and other professional physicians groups. Retailers and nursing groups testified in support of these changes while physicians’ groups were strenuously against them.

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43 105 MASS. CODE REGS. 140.099(A) (2009).  
46 105 MASS. CODE REGS. 140.1001 (2010)  
The Massachusetts Department of Public Health found that applying regulations intended for other types of healthcare clinics to retail clinics would involve a constant process of waivers and reviews for each retail clinic location, even in a chain of identical clinics. Instead of granting waivers for each clinic location and significantly delaying the introduction of retail clinics into Massachusetts, the Department of Public Health decided to enact these waivers into the code, thereby allowing clinics that meet the limited service requirements to be regulated by a different set of rules. Massachusetts' codification of these waivers for retail clinics marked a key turning point in the expansion of retail clinics. Massachusetts physician's groups argued the original code was needed in its entirety to ensure patient safety. These advocacy groups argued that the waiver of any of the code's provisions would endanger retail clinic patients. To date, no evidence supports the opponents' claims.

The Massachusetts Medical Society and other physicians' associations object to the organization of a system of medical care predicated on independent treatment, or treatment outside of the doctor-patient relationship. The creation of a doctor-patient relationship, argued Doctor Bruce Auerbach, President of the Massachusetts Medical Society, is necessary to ensure proper treatment. Any health care delivery model that disrupts this relationship should be, in the Society's view, discouraged. Further, an APN may overlook or misdiagnose a patient if the APN does not have access to the patient's medical history. Auerbach argues that highly trained doctors use a patient's history and the physician's personal knowledge of the patient as an aid to physician's diagnostic skills to make the best possible decisions to treat any medical problem. Indeed, patients who see a primary care provider regularly benefit from the familiarity which develops between the doctor and patient. However, not all patients in the United States fit this profile. Retail clinics' availability and

50 See Takach & Witgert, supra note 48.
51 See Potter, supra note 44.
52 See Takach & Witgert, supra note 48.
53 Auerbach, supra note 47.
54 See id.
reduced costs of the preventative testing and treatments should alone merit their existence. To suggest that innovation in the healthcare industry that does not bring about the perfect doctor-patient relationship for every American should be suppressed is illogical and detrimental to the overall health of the United States. Nevertheless, individuals' access to healthcare must be regulated but not to the extent that the regulation hinders access to qualified providers. The general public already experiences the medical care provided by APNs in settings such as radiological imaging centers, nursing homes and hospitals. Retail clinics build on the demonstrated successes of APNs to an innovative new healthcare model.

Opponents of the Massachusetts regulation have garnered particular opposition to the exemption from the requirement that all medical clinic staff have direct access to a sink. Here the opponents to the Massachusetts regulation have a valid concern. With an increase in the rate of hospital-acquired infections, the emphasis on frequent and proper hand-washing has been reasserted to control the spread of infection. These dangers are magnified within clinics as the staff treats a variety of ailments and possibly contagious patients in quick succession. Proper hygiene and sanitation is required to ensure patient safety and to reduce the risk of cross-contamination in all medical settings. The lack of clear guidelines regarding cleanliness in retail clinics is indeed problematic. The regulations simply require hand sanitizer dispensers to be located outside of each examination room at a limited service clinic and to be used after each patient visit. Yet while gel based hand sanitizers can be effective in preventing the spread of infection, manufacturer guidelines recommend hand-washing after multiple hand sanitizer uses to ensure cleanliness.

While creating the plumbing necessary to provide sink and sanitary access to the examination rooms may increase the costs associated with opening a retail clinic, the benefits to patient and provider safety, coupled with personal value to patients in knowing these facilities exist, outweigh the cost. Therefore, state regulation governing retail clinics should not allow exemptions for sanitary facility access regarding sinks and hand washing. The Massachusetts limited service regu-

56 See AUERBACH, supra note 47; see also Roy M. Poses, Will MinuteClinics Be a Wash?, Jan. 10, 2008, http://hcrenewal.blogspot.com/2008/01/will-minuteclinics-be-wash.html (describing the concerns over regulations that only require hand washing facilities adjacent to retail clinics).
58 105 MASS. CODE REGS. 140.1002 (2009).
59 AUERBACH, supra note 47.
lation establishes one possible middle ground for regulation of retail clinics, taking into account input from retail clinic operators, physician groups, and nursing associations, while keeping patient safety at the forefront. The Massachusetts regulations pave the way for further retail clinic expansion in the state while limiting the scope of practice at retail clinics to a level appropriate for their APN staff. With the reservations noted in this section, this Note argues that the Massachusetts regulation can provide an effective model on which other states may base effective regulation of retail clinics.

B. Current and Proposed Legislation

Retail health clinics’ ascendance as a viable healthcare model has resulted in increased legislative scrutiny and a rush of proposed laws, many backed by competing healthcare providers. While this regulation is aimed at protecting patient safety, many proposals seem little more than efforts to curtail the expansion of the retail clinic industry. As with any medical business that treats patients, the organization and ownership structure of the business must be scrutinized with regard to state corporate practice of medicine laws. Along with existing regulations which affect retail clinics, many states legislatures are considering legislation targeted specifically at retail clinics. Proposed regulations to restrict retail clinic expansion have taken two basic avenues: (1) physician supervision requirements for clinic staff; or (2) operating requirements for clinic facilities. Examples of the first category include limiting the number of clinics that one physician may supervise or requiring a clinic to have a physician present for a minimum hours per week. Examples of the second category include prohibitions of the sale of tobacco in the same location as a retail clinic, restriction of advertising, and regulation of restroom facilities. While these prohibitions impose great costs on retail clinics, the customers and patients derive little to no benefit or protection.

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61 FLA. STAT. ANN. § 456.041 (West 2006) (prohibiting physicians from supervising more than one office facility and no more than four nurse practitioners or physician’s assistants); Ill. H.B. 1885 (Proposed 2007) (would limit each supervising physician to two nurse practitioner); SCOTT, supra note 11, at 22; CAUCHI & THANGASAMY, supra note 32.

62 SCOTT, supra note 11, at 12.

63 105 MASS. CODE REGS. 140.099(A) (2009); CAUCHI & THANGASAMY, supra note 32.
tions of such regulation will be discussed below. State legislatures must be cognizant of the impact regulations will have on retail clinics. Patient safety must be the ultimate goal, with restraint of trade and anti-competitive motives kept in check.

1. Corporate Practice of Medicine

Retail clinics also face hurdles in the interpretation of existing state legislation concerning ownership. The doctrine of corporate practice of medicine restricts licensure of corporately owned medical facilities. This doctrine restricts licensing by allowing only an individual person to be licensed as a professional medical provider. The corporate practice doctrine seeks to keep the economic and business incentives of corporations from interfering with the duties of a licensed medical practitioner. Because individuals are tested, certified and held accountable individually, a corporation’s limited liability structure would obfuscate these requirements. For example, corporate officers owe a duty to the corporation, while medical doctors owe a duty to their patients. Indeed, a corporate officer’s fiduciary obligation of maximizing shareholder profit is potentially at odds with a licensed physician’s medical responsibilities. This conflict can be manifested in decisions made by non-physicians involving the cost of different medical procedures or in guidelines for treatments.

However, many states allow for the formation of professional service corporations, also known as medical corporations, if these entities are controlled exclusively by licensed physicians. For example, in California and Tennessee, retail clinics must be set up as a medical corporation, owned by a specific physician. Since states may vary in

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64 See generally Terrell J. Isselhard, Are Health Clinics Operating in Large Retail Stores Violating the Corporate Practice of Medicine?, 110 CHICAGO MED. 44, 45-46 (2007) (Because retail health clinics are located within chain stores that sell pharmaceuticals and other healthcare products, a conflict of interest may exist between the retail clinic that prescribes drugs and recommends healthcare products on the one hand and the store that profits from the sale of those products on the other.).


67 Kaiser & Friedlander, supra note 65, at 55.

68 Id.

69 SCOTT, supra note 11, at 12; see generally CA.gov, Corporate Practice of Medicine, http://www.medbd.ca.gov/licensee/corporate_practice.html (last visited May 3, 2010) (providing guidance on the prohibition against the corporate practice of medicine); Kaj Rozga, Retail Health Clinics: How the Next Innovation in Market-
their allowance for particular corporate structures, clinics, therefore, will need to tailor their operations to coincide with state-specific regulations. A cost indeed results from such tailoring, but clinic operators must bear this cost should the operators wish to expand.

Hospitals and doctors’ offices are owned and run by doctors. The standard retail clinic set-up is owned by a commercial retailer with doctors acting in advisory roles to create the medical protocol. Because of the lack of doctors in the ownership positions, the standard exceptions to corporate practice of medicine law may not apply. Retail clinic owners and operators will need to demonstrate to the courts and to the legislature that all business decisions affecting customers medically are made by licensed physicians.

Some clinics have organized around the corporate practice of medicine limitation. Wal-Mart has addressed this issue by partnering with various health organizations to run their retail clinics. Wal-Mart solely leases the clinic space in their retail outlets and provides marketing and organizational support to the independent clinics. Because Wal-Mart only provides services to the clinic (such as retail space) and does not participate in the medical aspects of the retail clinic, its corporate duties do not intersect with its medical duties. Wal-Mart has argued that licensure regulations that affect retail clinics, such as MinuteClinic, should not be applied to Wal-Mart because of the clinics’ separate nature. While Wal-Mart has taken a different approach to managing retail clinics than other providers, differences in service or in the quality of care provided have yet to been seen or reported. If necessary, in states where corporate practice cases and statutes may preclude the standard retail clinic corporate set-up, clinics may choose to follow the Wal-Mart approach and partner with hospitals and other established medical providers.

2. Supervision Requirements

As previously discussed, retail clinics are staffed by professional nurses who are certified by state or private licensing bodies, and trained extensively in the diagnostic and treatment requirements of the


70 Rozga, *supra* note 69, at 218.

71 HALEY, *supra* note 47.

72 Id. Retailers such as CVS own and operate the retail clinics in their stores. In contrast, in Wal-Mart clinics, a separate corporate entity controls staffing decisions, owns the medical equipment, and supplies treatment guidelines.
services offered by retail clinics. Each chain of retail clinics develops its own menu of services and its own protocols for how each service is to be provided. To design these menus and protocols, the clinics rely on physicians and physician associations' expertise. Beyond the initial creation of such protocols, physicians supervising retail clinics have little interaction day-to-day with clinic patients. The clinics operate under the premise that competent nurses can accurately diagnose a patient and follow the protocol used to treat the diagnosed malady. The substitution of the lower-priced services provided by APNs for the high-cost services of physicians gives retail clinics an economic advantage.

Legislation seeking to impose strict physician supervision requirements on APNs should be scrutinized only as to the extent that the legislation would benefit patients. Because many of the health issues retail clinics serve may be ameliorated through prescription medicines, the ability for APN providers to prescribe medicine is key to the retail clinic's operation. Retail clinics do not operate in states which do not give prescriptive authority to APNs. The states that do allow these nurses to write prescriptions mandate a certain level of physician supervision, either over each activity, or generally over their practice. Proposed legislation to further restrict what an APN may do without supervision has been debated in Florida. Some legislative models allowing “non-physician medical practitioners to prescribe drugs independently” only extend that authority to cover prescription drugs used in the scope of their practice. The physicians

74 Tine Hansen-Turton et. al., Convenient Care Clinics: The Future of Accessible Health Care, 10 DISEASE MGMT. 61, 63 (2007).
75 Id.
76 ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS, RETAIL CLINICS: FACT SHEET (2009), http://www.astho.org/Programs/Access/Primary-Care/Retail-Clinics-Fact-Sheet/.
77 Hsu, supra note 3, at 13.
78 This Note does not suggest that APNs should replace physicians in the American healthcare system. Without the support of physicians, in the form of supervision and protocol development, APNs would not be able to provide the level of service required to keep patients safe and make retail clinics successful.
79 See Susanne J. Phillips, 22nd Annual Legislative Update: Regulatory and Legislative Successes for APNs, 35 NURSE PRAC. 24 (2010).
80 Id.
81 See FLA. STAT. ANN. § 456.041 (West 2009); CAUCHI & THANGASAMY, supra note 32.
82 ILL. ADMIN. CODE tit. 68, § 1305.40(c) (2006). Unlike a physician, who
who create the treatment protocols for retail clinics delegate the prescriptive authority to APNs, allowing the APNs to write prescriptions to treat patients under protocols developed by the physician. This limitation allows physician to have control over what the APN provider may prescribe while still allowing the APN to maintain some measure of independence.

Similarly, legislation such as Illinois House Bill 5372 requires a physician medical director to determine the set of medical services each clinic may provide. The medical director is also limited to overseeing two clinic locations. There seems to be no specific rationale provided as to why a medical director could not adequately provide these services for more than two locations. As with other regulations aimed at retail clinics, the underlying rationale seems to be solely to increase the costs associated with setting up and running retail clinics. It has been argued by physician's advocacy groups that the nursing staff at retail clinics requires supervision in the daily activities of the clinic. To this end, many states have proposed regulation seeking to mandate physician supervision of APN's for a certain number of hours weekly, or for a certain number of medical decisions made by the APNs. It is this Note's position that this restriction furthers neither the health nor safety of clinic patrons and only serves to increase the costs of setting up multiple clinic locations.

APNs who are licensed by state medical boards are already subject to collaboration or supervision requirements that each state has deemed necessary to ensure proper patient care. The supervision requirements have so far not been waived for retail clinic APNs and each chain of retail clinic has organized to ensure compliance with...
these existing requirements. The restrictive legislation enacted or proposed in many states is redundant in its purpose to ensure the proper supervision of these nursing professionals. Excess supervision only serves to increase the costs associated with running a retail clinic, where specifically the relatively less expensive labor of nurses replaces expensive wages of physicians. No basis is provided in proposed legislation for the imposition of higher standards of supervision in the retail setting than are required for similarly licensed nurses in other healthcare settings.91

For the retail clinic industry to function efficiently and safely, there must be appropriate legislation at the state level that mandates the minimum training and licensing requirements of its staff, and ensures that the health services provided are properly created by trained physicians. Overly burdensome legislation hampers the retail clinic’s goals of providing economical healthcare and instead serves only to limit retail clinic’s ability to leverage cost savings.

Efficient legislation of APN supervision requirements would ensure that physicians have a role in creating a rigidly defined set of treatments for retail clinics. Physicians would have to take into account state laws, and differing community needs in creating guidelines. By ensuring that local physicians have input in what services local retail clinics provide, retail clinic chains can tailor their services, within the APNs scope of practice, to a given community’s needs. Limiting physicians to a certain number of retail clinic locations that they can help set up does not serve this goal. Accordingly, each clinic operator should choose how to integrate local physicians into their own healthcare process. Clinics may seek to cater to a community’s needs and involve more local physicians or may seek to offer a broader and more universal treatment menu, with less local physician input. Beyond requiring physicians to develop the treatment guidelines, regulation on this subject should be limited.

Physician oversight of APNs at retail clinics serves as an added safety measure on the care provided by the APNs beyond the educational and licensing requirements of the nursing staff. However, this type of oversight is not prophylactic and would only catch issues after the fact. To ensure quality care, retail clinics rely on the training and licensing of the APNs, with oversight acting as a check to make sure the services are up to the proper standards. While not all states specify the maximum number of APNs that a physician may oversee, those that do generally will cap at four per physician. Many states do not further define what oversight entails. Regulations include wording

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91 Letter from Ohlhausen et al., supra note 60, at 7.
such as supervision, delegation, and collaboration. However phrased, oversight limits must ensure that a supervising physician has adequate time to review patient charts to ensure that the clinic APNs are following the treatment guidelines. In order to accomplish this oversight some retail clinic operators have implemented their own requirements, such as requiring that newly hired APNs have their patients’ charts reviewed by physicians one hundred percent of the time, decreasing after a period down to a minimum of ten percent of patient charts reviewed by physicians. This review procedure can serves as a model for state regulation making the amount of oversight required variable, decreasing as the tenure and experience of the APN increases.

3. Operation Restrictions

Beyond restrictions on staffing and supervision, many states have considered legislation that directly impacts the ability of clinics to be housed within retail outlets. A common legislative initiative is to restrict the sale of cigarettes and tobacco products in establishments that provided medical services. This initiative is specifically aimed at retail clinics whose locations are within convenience stores and supermarkets that sell tobacco products. While the government has a significant interest in decreasing the use of tobacco products by citizens for the promotion of health and welfare, how that interest is served in relation to retail clinics is unclear. Tobacco products make up a lucrative revenue stream for retailers and one of the major economic advantages of retail clinics is the inexpensive availability of space within convenience stores and supermarkets, located near and convenient to the customer base. Selling tobacco products in the vicinity of a health facility does nothing to give the impression of safety to cigarettes or cigars.

There has also been proposed legislation to ban or limit advertising of the medical services and the fees charged by the retail clinics. However, the Federal Trade Commission ("FTC"), in its examination of the proposed legislation, determined that the advertising provisions appeared “likely to raise the costs of operating [retail clinics] and to delay or suppress their truthful and non-misleading advertising.”

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92 See TAKACH & WITGERT, supra note 48, at 4.
93 A survey of current state oversight requirements is reproduced in Appendix A.
95 Letter from Ohlhausen et al., supra note 60, at 10.
96 105 MASS. CODE REGS. 140.1001(I)(2) (2010).
97 Letter from Ohlhausen et al., supra note 60.
The FTC further found that such restrictions are baseless when applicable only to retail clinics and no other medical service provider.\textsuperscript{98} While protecting consumers from false or misleading advertisements is important, most states already have laws that serve such a purpose.\textsuperscript{99} Specific legislation aimed solely at retail clinics is redundant and increases the economic burden on the specific industry without increasing public welfare.\textsuperscript{100} Clinics rely on consumers to self identify their medical issues and to decide if a clinic provides the services they need.\textsuperscript{101} Advertising allows clinics to widely and efficiently disseminate this information. Evidence suggests that the vast majority of clinic customers is very good at this type of diagnosis and rate it as a positive aspect of the retail clinic experience.\textsuperscript{102}

4. Proposed Legislation

State legislatures successful regulation of retail clinics with the goal of protecting patients and allowing for the efficient delivery of health service is by no means an easy task. Retail clinics would not benefit from an expansion and redefinition of the role of their APN health providers. Clinics economically employ these licensed professionals within their statutory scope of practice to provide basic diagnoses and treatments to patients quickly and safely. To this end, regulation seeking to impose onerous supervision requirements does not increase patient safety beyond current levels and only serves to increase the costs associated with the retail clinic business.

Additionally, the previously discussed and laudable goal of promoting a strong doctor-patient relationship is not served by excessive supervision requirements. Instead, legislation and government assistance in the implementation of communication avenues such as electronic health records will facilitate communications between retail clinics and primary care doctors. This model is exemplified by the Cleveland Clinic, which has partnered with MinuteClinic to provide

\textsuperscript{98} Id. at 7.
\textsuperscript{99} See, e.g., Ohio Rev. Code Ann. § 1345.02 (West 2009).
\textsuperscript{100} Advertising for professional services has often been a contentious issue with legislatures and courts balancing the right of consumers to information with the goal of protecting those consumers from misleading information in these vulnerable settings. See Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976) (striking down restrictions on individual pharmacies advertising prescription drug prices because commercial speech is constitutionally protected under the First Amendment); see, e.g., Terry Calvani et al., Attorney Advertising and Competition at the Bar, 41 Vand. L. Rev. 761, 779-81 (1988) (discussing the results a survey regarding the advertising of optometrists).
\textsuperscript{101} Letter from Ohlhausen et al., supra note 60.
\textsuperscript{102} Id.
physician oversight and to fully integrate the MinuteClinic locations into the hospital’s electronic health records system. Such integration allows patients whose primary care physician is affiliated with the hospital to immediately access notes and tests taken at the retail clinic locations and incorporate these notes into a patient’s medical file for future reference. The partnership between retail clinics and local hospitals serves to effectively integrate the retail clinics into the local medical community by allowing retail clinics to access patient medical records and physician expertise already in place within the community. In this way the retail clinic serves as a collaborator in providing community health rather than a competitor of standard primary care providers. For these reasons, this Note strongly supports and recommends the establishment of retail clinics and their collaboration with regional hospitals.

This Note further proposes an APN supervision model based on the ready availability of off-site physician consultation for APNs combined with periodic physician review of patient charts following the visit in order to determine if the APN has complied with the treatment protocols and guidelines. The corporate owners of retail clinics must provide the physician employees and advisors autonomy in which to create and supervise the protocols and treatment guidelines. A board of controlling physicians within each corporation should actively work with physicians associations and state medical groups in the development of the guidelines and protocols. In this way, retail clinics can avoid charges of corporate practice of medicine if the medical decisions are made only by those licensed to practice medicine.

State supervision regulations should mandate that a retail clinic’s supervising physicians must ensure that APNs comply with all applicable standards of care. While this would expose the physicians to liability for actions of the subordinate APNs, it would also ensure active and diligent participation of physician supervisors in the safe operation of the retail clinic. This situation would be very similar to the liability that physicians experience from their staff in a doctor’s office or hospital. The State Board of Medical Examiners of Tennessee is illustrative. Specifically, this board established supervision requirements that ensure a sufficient level of patient care while not overburdening clinic operators. Physicians are required to ex-

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104 See Clinical Supervision Requirements, TENN. COMP. R. & REGS.
amine twenty percent of patient files and must review any file if a patient requests.\textsuperscript{105}

A supervision regime should also increase physician supervision of new-hire APNs to ensure reliability and an appropriate level of medical education before tapering down to a lower percentage of supervised decisions. In order to counter any conflict of interest, physician supervisors who work with individual retail clinics should not have management ties to the clinic or to the retail stores’ business operations. To ensure that a patient who presents with symptoms outside of the treatment scope is adequately cared for, referral guidelines linking retail clinics and local physicians should be put in place.

A list of available physicians for consultation should be provided by local doctors who rotate through on-call periods during the retail clinics operating hours. APNs should be able to consult with the doctors if they needed assistance or at the request of the patient.\textsuperscript{106} The APN would be able to electronically transmit a patient’s charts or test results to the physician if necessary. This process serves two purposes: to provide assistance to APNs and to initiate doctor-patient contact for those patients whose needs cannot be met at the retail clinic. The retail clinic industry, like other healthcare providers, should not escape the scrutiny of regulation meant to ensure patient safety. However, the combination of a decreasing requirement of physician supervision based on APN experience and local physicians providing on-call support satisfies patient safety concerns while also ensuring the viability of retail clinics.\textsuperscript{107}


\textsuperscript{106} To discourage every patient from asking the APN to consult a physician, an extra fee may be assesses and the patient would be required to return at a later time when the physician can see them.

\textsuperscript{107} This Note does not cover the regulator issues of the Stark Act and various state anti-kickback issues. Any retail clinic operation must be cognizant of the provisions of the federal Stark Act and state regulation which seek to separate corporate profit-making influence from medical decision making. A thorough discussion of these regulator issues may be found in Dan McGuire and Mac Schneider’s survey of healthcare fraud. \textit{See generally} Dan McGuire & Mac Schneider, \textit{Health Care Fraud}, 44 \textit{Am. Crim. L. Rev.} 633 (2007).
The major difference between a retail clinic and a doctor’s office is the extent to which APNs are used for diagnosis and treatment of patients. Because these APNs have not had the extensive training and schooling of physicians, their compensation is lower compared with physicians even though they complete many of the same medical procedures as physicians. There are obvious situations in which the advanced training of a physician is required to ensure proper care, but for the limited care provided by retail clinics, APNs provide commensurate care as physicians. Unlike the traditional nursing role which places the nurse in a “completely dependent” position to the physician, advanced-practice nursing has expanded the role of nurses to cover independent decisions on many medical procedures. As the role has expanded, a universally defined scope of practice has not emerged to provide a boundary for the nursing profession. State medical and nursing boards codify a scope of practice guidelines and limits on prescriptive authority. The Texas Standards of Nursing Practice require APNs to accept only those nursing assignments that take into consideration patient safety and, “are commensurate with the nurse’s educational preparation, experience, knowledge, and physical and emotional ability.” A defined scope of practice is beneficial in determining the standard of care against which an advanced practice nurse should be measured. In medical malpractice cases, unlike other negligence cases, the practitioner is held to a higher standard than that of a reasonable person. Physicians are held to a standard of “what comparable physicians in the same or similar community, exercising reasonable care, would have done in like circumstances.” Because health providers are measured against other providers in their profession, each set of providers, whether doctor, nurse, or other specialist, establishes its own standards for the group.

108 Mary O. Mundinger et al., Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A Randomized Trial, 283 JAMA 59, 64 (2000).
110 Id. at 343.
111 See, e.g., Standards of Nursing Practice, 22 TEX. ADMIN. CODE § 217.11 (West 2009).
112 § 217.11(T).
113 Phyllis Coleman & Ronald A. Shellow, Extending Physician’s Standard of Care to Non-Physician Prescribers: The Rx for Protecting Patients, 35 IDAHO L. REV 37, 75 (1998).
114 Id. at 76.
115 Id.
of one profession delegate medical tasks to providers in a different group and mistakes are made, tension arises when a court must determine the correct standard against which that provider may be judged. Should an APN be held to the standard of a physician, or measured against other competent APNs? Without a clearly defined scope of practice, APNs and the physicians who supervise them are less able to create effective guidelines which ensure patient safety and which minimize provider liability.

The California Supreme Court, in Fein v. Permanente Medical Group, held that an APN who missed the signs of a heart attack should be held to the standard of what a reasonable, prudent APN would have done in a similar situation. In Fein, the plaintiff, after experiencing worsening chest pains over the course of several days, was examined by a NP employed by the defendant medical group. In consultation with a supervising physician the NP diagnosed plaintiff’s chest pain as a muscle spasm and sent him home with medicine prescribed for that diagnosis. When the pain worsened, the plaintiff sought further medical care, and after two trips to an emergency room, was correctly diagnosed as having had a heart attack. Jury instructions given at the trial court contained the following passage as to what standard of care the original APN who examined the plaintiff should be held to: “The standard of care required of a nurse practitioner is that of a physician and surgeon . . . when the nurse practitioner is examining a patient or making a diagnosis.”

The California Supreme Court found that California legislation on the topic of guidelines for registered nurses did not reserve “examination” and “diagnosis” of patients to physicians, and therefore, when those tasks were delegated did not require the providers who were delegated these responsibilities to be held to a physician’s standard.

The Ohio case Berdyck v. Shinde further clarifies the standard of care to which a nurse acting under the guidelines of a physician must be held. In this case a hospital nurse did not recognize the symptoms of prenatal distress in her pregnant patient. The court in Berdyck affirmed the lower court’s finding that summary judgment for the defendant hospital was precluded in this case. The court found

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116 See id. at 78.  
118 Id.  
119 Id. at 673.  
120 Id. at 674.  
121 613 N.E.2d 1014 (Ohio 1993).  
122 Id. at 1022.  
123 Id. at 1024.
that even while the nurse was acting under the direction of the attending physician, the standard of care appropriate to judge her actions was that of a nurse exercising, "reasonable care" in the possession of "a standard minimum of special knowledge and ability for persons in their callings." In this ruling, the doctor reserves the right of diagnosis to physicians and only judges the APN on how they follow the guidelines provided by the physician and their medical training. Applied in the retail clinic context liability would turn on whether the APN acted reasonably in relation to other APNs similarly employed. Further scrutiny would also fall on the treatment guidelines and if those were reasonably created by the physician. These dual levels of scrutiny increase liability for retail clinics but also allow each medical professional to be judged at a level appropriate to their position and education.

The APN profession has vigorously and successfully argued for the broadening of nurses' roles into the sphere previously reserved only for physicians. Underlying this argument is the claim that APNs can provide the same level of care as physicians when comparing similar procedures performed by both groups. While making this argument in an amicus brief in Fein, the California Coalition of Nurse Practitioners ("CCNP") also asserted that APNs should not be held to a physician's standard of care when judging malpractice. Nursing advocates argue that holding APNs to the same level as physicians would be impossible and would destroy the APN profession. The CCNP concedes that "[APNs] simply do not possess the 'learning and skill' of physicians" even as they admit that both are required "to take the same action or observe the same things."

The separately codified standards of care for different medical provider groups do not pose a problem for all types of medical care. Both doctors and nurses can perform standard medical procedures and can diagnose basic ailments. The standard of a reasonable doctor and the standard of a reasonable APN while technically separate standards, require the same performance for basic diagnostic procedures

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124 Id. at 1023.
125 Id.
126 Id. at 673-74, n.5 (providing background on the California legislation which governs nursing: "It is the legislative intent also to recognize the existence of overlapping functions within organized health care systems . . .").
127 Coleman & Shellow, supra note 113, at 79 ("[The California Coalition of Nurse Practitioners] support different standards while asserting that a separate standard of care for nurse practitioners would not create a lower level of care.").
128 Id.
such as those employed in retail clinics.\textsuperscript{129} As discussed previously, retail clinics generally operate with physician-created guidelines for each ailment that they diagnose. The fact that patients are satisfied with care received by APNs is uncontested.\textsuperscript{130} The areas of medical care for which patients have a clear preference for APNs are those relating to "length of consultation, reassurance about symptoms, and information with coping with disease, and attention to impact of disease on daily life."\textsuperscript{131} Generally though, when standard patient visits are compared, "[t]here were no significant differences in the scores between nurse practitioners and physicians for any of the satisfaction factors after the first visit."\textsuperscript{132}

While this data may demonstrate that retail clinics employing APNs are a good business model, in the eyes of patient-consumers, satisfaction after a visit does not capture whether the visit was successful medically. The treatment guidelines created by physicians and implemented by APNs at retail clinics create a less autonomous environment and limit the APNs' exposure to liability with strict adherence to these guidelines. The guidelines have been cited as a negative aspect of retail clinics in that the guidelines are not as thorough a diagnostic tool as those employed by physicians. This claim has been refuted when simple treatment practices such as those used by retail clinics are studied.\textsuperscript{133} Recent reports have found egregious overtreatment with antibiotics for patients presenting to health providers with acute pharyngitis (sore throat). Up to seventy percent of adults who sought treatments for pharyngitis were prescribed antibiotic treatment, even though only five percent to ten percent of pharyngitis in a representative adult population should be treated with antibiotics.\textsuperscript{134} Overtreatment with antibiotics is harmful both medically and fiscally because it contributes to increasing antibiotic resistance in infections and expands the number of costly and useless medical treatments which must be paid for at one level or another.\textsuperscript{135} In contrast, a recent study found evidence to suggest that the use of clinical treatment guidelines

\textsuperscript{129} For example, both APNs and physicians would be expected to provide the same level of care and expertise in taking a patient's temperature or checking pupil dilation.

\textsuperscript{130} Miranda G. Laurant et al., \textit{An Overview of Patients Preference for, and Satisfaction with, Care Provided by General Practitioners and Nurse Practitioners,} 17 J. CLINICAL NURSING 2690, 2695 (2008).

\textsuperscript{131} \textit{Id.}

\textsuperscript{132} Mary O. Mundinger et al., \textit{Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A Randomized Trial,} 283 JAMA 59, 64 (2000).

\textsuperscript{133} \textit{Id.}

\textsuperscript{134} \textit{Id.} at 457.

\textsuperscript{135} \textit{Id.} at 460.
increases the standard of care regardless of the provider. The study of treatment for acute pharyngitis at retail clinics has suggested that the use of "clinic guidelines" produces "exceptionally high-quality care" when compared to treatment at other primary care settings.\textsuperscript{136}

While scope of practice issues provide some uncertainty for the liability of the APN staff of retail clinics, this uncertainty does not detract from APNs' demonstrated effectiveness regarding primary care. In the context of the care provided in a retail clinic, it would seem that the standard of care applied to APNs following the standardized protocols should be that of a reasonably prudent APN. The general public can still expect high levels of care without holding APNs to a standard above what their training and skill would suggest. When matched with supervising physicians and integrated into a local medical community, retail clinics increase access to healthcare and support through their referral network to primary care providers rather than competing with physicians.

\section*{IV. ELECTRONIC HEALTH RECORDS}

The success of retail clinics in treating ailments such as acute pharyngitis stems in part from the use of electronic health records ("EHR") combined with computerized clinical treatment guidelines in the diagnosis and treatment of patients.\textsuperscript{137} The computerized system used by most clinics contains "standardized . . . clinical history questions and physical examination elements developed by the [Institute for Clinical Systems Improvement]."\textsuperscript{138} The use of EHRs plays a significant role in the success of retail clinics. The increased focus on EHRs will allow retail clinic expansion to increase with even higher standards of patient care and community integration.\textsuperscript{139}

Many of the criticisms leveled against retail clinics, can be addressed with the strong implementation of EHRs combined with integrated clinical guidelines. This Note does not go in-depth into the unique legal issues which must be addressed before widespread implementation of EHRs may be made feasible.\textsuperscript{140} Instead this Note

\begin{flushleft}
\textsuperscript{137} See id. at 458.
\textsuperscript{138} Id.
\textsuperscript{139} Julie A. Muroff, \textit{Retail Health Care: "Taking Stock" of State Responsibilities}, 30 \textit{J. Leg. Med.} 151, 156 (2009)
\textsuperscript{140} But see Sharona Hoffman \\ & Andy Podgurski, \textit{Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems}, 22 \textit{Harvard J.L. \\ & Tech.} 104 (2008); see also Steve Lohr, \textit{Taking Innovation Beyond the 'Aha,'} N.Y.
examines the effects that EHRs will have on the retail clinic industry. EHRs’ have the ability to bring retail clinics and primary care providers together while lessening the extent retail clinics may disrupt prior doctor-patient relationships and further facilitate the creation of new doctor-patient relationships for customers who lack a primary care provider.

A major cost associated with healthcare transactions is the cost of recordkeeping and the difficulty in sharing patient records between different health providers. Many retail clinics will fax patient records from a visit to the patient’s primary care provider, but there is little standardization in the industry. The development of EHRs has been mired in controversy even as President Obama has called for billions of dollars of stimulus money to be put towards EHR implementation. Members of the medical community, including hospital administrators, doctors, and retail representatives, have pushed for the adoption of EHRs to lower costs and increase patient safety.

Despite the strong support of the medical community, members of Congress have cautioned that a quick push to digitize patient records must be matched with increased privacy safeguards. Both the inadvertent theft and the deliberate sale of these records are feared if patient medical information becomes as ubiquitous online as consumer credit reports.

Proposed and adopted regulation mandates that health charts from a patient’s visit must be provided to each patient and forwarded to the patient’s primary care physician, if they have one. Standardized EHRs would improve a patient’s ability to send their health records from one medical provider to another. Further, a secure online database of patient EHRs would allow different chains of retail clinics to screen patients to prevent abuse such as doctor shopping. Doctor shopping can consist of repeated visits to healthcare providers to obtain prescription drugs for personal use stemming from addiction, or for illegal resale. The EHR system would flag patients who exhibit

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Times, Mar. 1, 2009, at BU3 (discussing proposed federal legislation incentivizing the use of computerized medical records).

141 Patient records may be transferred to a physician at the request of the patient, or if the retail clinic has referred the patient to a specialist.


143 Robert Pear, Privacy Issue Complicates Push to Link Medical Data, N.Y. TIMES, Jan. 18, 2009, at A16.

144 Id.

145 Id. at A16-17.

signs of doctor shopping and prevent this abuse.\textsuperscript{147} EHRs would also allow the APNs to see a patient’s medical history and more readily identify symptoms that may suggest chronic illnesses.

The development and implementation of EHRs throughout the medical field would significantly further the retail clinic industry’s ability to serve as an additional healthcare source to those who lack primary care providers. Full EHR implementation will require significant investment and cooperation by many different healthcare providers. By creating continuity of information, EHRs provide the retail clinic APN with a more in-depth patient history without the time and expense needed to obtain the information anew from each patient at each visit. EHRs would also minimize the disruptiveness of retail clinics to the traditional doctor-patient relationship by allowing the information gathered and treatments provided at retail clinics to be seamlessly integrated with patient health records compiled by the patient’s primary care provider. This Note does not posit that EHRs are critical to the retail clinic industry but seeks to point out that the costs associated with the disruptive innovation of the retail clinic should be borne until such time as EHRs can help integrate the retail clinic industry into the medical market in the United States. As EHR development continues, spurred in large part by retail clinic operators themselves,\textsuperscript{148} retail clinics will grow to provide invaluable medical services working in partnership, not opposition, to physicians. Once EHRs become fully integrated into the U.S. healthcare system, many of the issues which opponents of retail clinics cite, such as overprescription, doctor shopping, and the standard of care provided in the absence of prior patient histories will become moot.

CONCLUSION

Still in their infancy, retail clinics have begun to change the way Americans receive medical care. This Note has provided background on the development of retail clinics and the legal and medical issues that must be addressed for this healthcare model to thrive. The use of advanced practice nurses provides the foundation for competent and successful patient care. Legislation giving these nurses limited independence coupled with a defined scope of practice will ensure patient safety and clinic viability. Further focus on electronic health records will bring retail clinics more fully into the medical community, integrating them with primary care providers. With the right mix of legis-

\textsuperscript{147} \textup{Auerbach, supra note 47.}

lation, voluntary industry action, physician support, and cost-effective services, retail clinics can expand as a successful business model, and a safe medical provider in the continuing struggle to address the healthcare needs of all.

**APPENDIX A**

**Physicians Oversight of Nurse Practitioners**

<table>
<thead>
<tr>
<th>State</th>
<th>Ratio (APN:MD)</th>
<th>Other Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>4:1</td>
<td>- Physician supervision required</td>
</tr>
<tr>
<td>Florida</td>
<td>4:1</td>
<td>- Physician may not supervise more than four offices in addition to the physician's primary practice location</td>
</tr>
<tr>
<td>Illinois</td>
<td>Not Stated</td>
<td>- Physician delegation required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Physician must be on-site once per month</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Not Stated</td>
<td>- Physician supervision required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Physician must review charts once every three months</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Not Stated</td>
<td>- Physician collaboration required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Physician must review charts (percentage or frequency not specified)</td>
</tr>
<tr>
<td>Texas</td>
<td>3:1</td>
<td>- Physician delegation required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Physician must be on-site 20 percent of the time (less in underserved areas)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Physician must review 10 percent of all charts (less in underserved areas)</td>
</tr>
</tbody>
</table>

149 Takach & Witgert, supra note 48, at 2.