By Mary Takach and Kathy Witgert

Analysis of State Regulations and Policies Governing the Operation and Licensure of Retail Clinics

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Portland, Maine Office:
10 Free Street, 2nd Floor
Portland, ME 04101
Phone: [207] 874-6524

Washington, D.C. Office:
1233 20th Street, NW, Suite 303,
Washington, D.C. 20036
Phone: [202] 903-0101

National Academy for State Health Policy
# Table of Contents

**Acknowledgements**  
1

**Introduction**  
2

**Methodology**  
3

**Issues for State Policy Makers to Consider**  
4

- Access to Care ........................................................................................................4
- Costs of Care ..........................................................................................................5
- Quality of Care ......................................................................................................5

**Lessons Learned From Six States’ Approaches**  
10

- New Jersey ........................................................................................................10
- Texas ..................................................................................................................11
- Illinois ...............................................................................................................12
- Florida .................................................................................................................13
- Massachusetts ....................................................................................................15
- California ............................................................................................................16

**Conclusion**  
19

- Access ................................................................................................................19
- Costs .....................................................................................................................19
- Quality of Care ....................................................................................................19
- Corporate Ownership and Organizational Issues ..............................................19

**Appendix A: Retail Clinic Survey Results**  
21

**Notes**  
24
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Introduction

The recent growth of retail clinics across the United States presents opportunities and challenges for states working to address access, costs, and quality issues within their health delivery systems. With more than 1,000 sites in 37 states, the emergence of retail clinics as an alternate provider has shaken up traditional health care models and can no longer be viewed as a passing trend for the following reasons:

- **Retail clinics are accessible.** They are usually found in suburban settings within a drug store, grocery store, or mass merchandise store. They are open during evening and weekend hours, without waits or appointments.

- **Retail clinic services often cost less.** Because clinics are mostly staffed by lower cost providers such as nurse practitioners and have lower overhead costs, prices for services can be substantially less than alternatives such as an emergency room or urgent care center.

- **Retail clinics provide evidence-based care.** They deliver a limited range of services, but all services delivered adhere to established clinical practice guidelines.

Despite these apparent benefits, the growth of retail clinics poses many challenges for states. Many of these challenges are familiar, such as scope of practices issues, corporate practice of medicine laws, and reimbursement policies. But there are other issues for states to consider, including:

- **Retail clinics may fragment patient care.** By delivering services outside a patient’s medical home, primary care providers may not be aware of immunizations provided or reoccurring problems.

- **Retail clinics may provide inappropriate care.** Physician groups worry that limited physician oversight and reliance on computerized treatment protocols may lead to serious problems being missed or the wrong care being delivered.

- **Retail clinics may strain safety net providers.** Some community health centers are concerned that they will have to compete with retail clinics for primary care providers and possibly patients.

This paper explores how states are using their regulatory and licensing tools to promote, structure, or limit the growth of retail clinics. State approaches in these areas differ, as do state interpretations of how existing regulations fit the retail clinic model. While most states are not regulating retail clinics, those that do, provide a variety of approaches that may be useful for those considering future action.
Methodology

We conducted an email survey of 50 states’ and the District of Columbia’s Medicaid and Licensing and Certification agencies using a survey tool that was developed with the help of state officials and national experts. (See Appendix A for survey results). Surveys were returned from 48 Medicaid agencies and 48 Licensing and Certification agencies. The three states that did not return surveys do not have any retail clinics.

Using advice from experts and research from the web, we selected six states – California, Florida, Illinois, Massachusetts, New Jersey, and Texas – to further explore state policies that affect the operation of retail clinics. The six states were selected because their experiences provide interesting lessons for other states. We conducted interviews with stakeholders in each of the states to understand state policies for regulating health services in retail settings. We used interview protocols that were tailored for each stakeholder group. We interviewed representatives of state Medicaid and Licensing and Certification agencies; retail clinics; organizations that represent health care providers including physicians, nurse practitioners, and two state primary care associations; as well as state legislators and/or their staff. Though each state’s response is unique, common themes emerged that might prove useful for states considering how to address the emergence of retail clinics.
While most states are allowing market forces to dictate retail clinic survival, this article describes a variety of regulatory measures taken by states with regard to retail clinics. Many states share views that retail clinics may help improve access to care and control costs. Only one state is collecting data from retail clinics to monitor quality; practitioner and facility licensing, medical home regulations, and consumer feedback are other approaches being used to help monitor the safe delivery of health care.

**Access to Care**

Many states see retail clinics as a way to expand access to care for some populations for some services. For certain populations — such as insured families with children — the suburban locations and expanded hours of retail clinics are seen as a convenience. These patients would likely seek care in a traditional setting if a retail clinic were not available. For the underinsured — those with health insurance but with high deductibles or other out-of-pocket costs — retail clinics may provide an affordable way to receive basic health services. For other groups, retail clinics represent a culturally familiar health care delivery site. For example, MediGo clinics, located in Navarro Pharmacies in Florida, seek to serve Hispanics who are culturally familiar with receiving health services in a pharmacy.

Whether retail clinics can improve access for the underserved depends on several factors, including out-of-pocket costs to the patient, accessibility of the clinics, and availability of needed treatments. Retail clinic operators point out that charges at a retail clinic are lower than at most doctors’ offices, urgent care centers, and certainly emergency rooms. Patients without insurance (who pay for the full cost of each service) may benefit from these lower costs. However, representatives of community health centers in California and Massachusetts contend that since retail clinic services are not provided on a sliding payment scale, the ability of retail clinics to reach the underserved is limited. Although low income, uninsured patients who qualify for these sliding scale fee arrangements may find lower out-of-pocket costs at community health centers, for those that do not qualify, retail clinics may provide lower prices for select services.

Most Medicaid billing systems do not distinguish retail clinics separately from physician offices and so the Point of Sale (POS) would most likely indicate “office” during the claims submission. In many states, practitioners can submit claims for services at retail clinics under their individual provider numbers, but most Medicaid officials interviewed thought it unlikely that Medicaid beneficiaries are seeking services at retail clinics.

In Massachusetts, the Medicaid agency is currently working through technical issues so that they will be able to recognize and therefore reimburse retail clinics – rather than individual practitioners – as Medicaid providers. The retail clinic chain MinuteClinic has been working directly with the state to complete the necessary applications to be enrolled as a MassHealth (Medicaid) provider. Medicaid officials in both Washington and Oregon said they would enroll retail clinics as Medicaid providers, but have received no requests to do so yet. Many retail clinics do not plan to accept Medicaid as payment, mainly citing low reimbursement rates.

A few states indicated in their survey that Medicaid managed care plans include retail clinics in their networks and therefore reimburse for care provided to Medicaid beneficiaries. Some Medicaid managed care networks in Georgia, Kansas, and Tennessee include retail clinics. Arizona indicated that if services are emergent or urgent, then the plans would be obligated to pay for those services at retail clinics. But if the services provided are routine and should have been obtained from the member’s primary care provider,
then the health plan could deny payment for those services. Idaho and Illinois both use primary care case management programs to manage their Medicaid beneficiaries and stated that retail clinics could be used by beneficiaries if prior authorization was received from the primary care provider. Retail clinic operators said prior authorization is a significant hurdle for patients and can significantly deter their use of retail clinics.

A few retail clinics are using novel approaches to increase access to physicians, manage chronic conditions, or reach out to needy populations. For example, Access Clinic in Texas uses telemedicine to facilitate doctor-patient interactions. The Lindora Clinic in California provides 10-week programs to help patients manage obesity-related chronic diseases in addition to providing acute care services. The AtlanticCare system in New Jersey includes both a retail clinic and an after-hours clinic at a Federally Qualified Health Center (FQHC) as an emergency room diversion provider. While these variations are currently the exceptions, they provide potential models to explore as retail clinics become more prevalent throughout the U.S. health care system.

**Costs of Care**
Affordable prices for both consumers and payers make health care services at retail clinics attractive. Retail clinics, which generally charge $40-80 for services, offer price transparency at the door so customers can make informed decisions. Advertising the price of services at retail clinics became an issue for two of the states interviewed for this study. Illinois and Massachusetts both introduced legislation or regulations that restricted the scope of advertising for retail clinics. In each state, the Federal Trade Commission advised against the proposed provisions.5 (See also Table 2, page 13.)

When retail clinics first opened, most of them required cash payments and did not accept any public or private insurance. This has changed dramatically—the share of out-of-pocket costs to consumers using retail clinics fell from 100 percent in 2000 to 15.9 percent in 2007.6 Most retail clinics now accept private insurance, some accept Medicare and a few accept Medicaid. Only one of the retail clinics we interviewed, Take Care Health, is currently accepting Medicaid payments, although not in all the states in which they operate. Other retail clinic operators are currently in negotiations with Medicaid agencies.

For public payers such as Medicaid, state policy makers agreed that emergency room diversion is the most attractive aspect of expanding access to retail clinics. While retail clinics do not provide emergency medical care, they may be helpful in diverting patients with acute but non-emergent conditions from a nearby emergency room and thus reduce the costs of care. One study found the average total cost for a retail clinic episode was $51 less than in the urgent care setting, $55 less than in the physician office, and $279 less than in the emergency department.7 “(The same study cautioned that retail clinics might potentially increase the overall cost of care by either increasing demand from consumers who might ordinarily self-treat, and/or by inappropriately delaying preventive or chronic care that would have been provided during a physician’s office visit.)”8

A New Jersey retail clinic operator described how they have begun to open retail clinics in an effort to more appropriately triage patients. HealthRite’s CEO said that almost everyone who uses HealthRite clinics also accesses other parts of the AtlanticCare system.9 HealthRite believes that such integrated systems are likely to benefit patients, as well as providers and health care systems, by facilitating treatment of all patients in the most appropriate settings.

**Quality of Care**
States have responsibility to protect public health by ensuring the safe delivery of health care. Although
many states monitor patient safety and quality data by requiring health facilities—not practitioners’ offices—to report patient safety data, none collected data from retail clinics, because retail clinics are generally treated like practitioners’ offices. States are monitoring quality of care through licensure of practitioners and health care facilities and consumer complaints. Some physician group stakeholders contend that states should also be monitoring how retail clinics affect medical homes.

**Licensing practitioners**

According to the retail clinic representatives, the most powerful state regulatory tools affecting their operations are the scope of practice regulations that govern nurse practitioners and other non-physician medical personnel. Most retail clinics are staffed by nurse practitioners. For a majority of the states surveyed, the care provided in the retail clinic setting is not subject to oversight by health departments, but by the applicable practitioner licensing authority, for instance, the Board of Nursing.

Eleven states allow nurse practitioners to practice independently without physician oversight, but the majority requires some degree of supervision.\(^{10}\) Some states specify an upper limit on the number of nurse practitioners that a single physician may supervise. Some states also regulate the frequency and proximity of that supervision, requiring the physician to be on site for a certain number of hours or within a certain radius of a nurse practitioner-staffed clinic. (See Table 1 on page 11 for six state comparisons.) These kinds of regulations can greatly affect the cost structure of retail clinics and may affect where retail clinics locate, their staffing, and their hours of operation.

Additionally, regulations that govern the scope of practice for nurse practitioners have a potentially large impact on the services offered by retail clinics. Because nurse practitioners are the primary practitioners in most retail clinic models, any restrictions on their scope of practice will affect how they can provide care in retail settings. Most states allow nurse practitioners to diagnose and treat illnesses, order tests, and prescribe medications following a written clinical protocol or physician collaboration.

Both the Massachusetts Medical Society and the Florida Academy of Family Physicians view the supervision laws as an important aspect of safeguarding the health of the public. In contrast, the Illinois Society for Advanced Practice Nursing feels this kind of supervision is counterproductive, especially in light of the shortage of primary care practitioners. The retail clinic operators similarly view these supervision requirements largely as an unnecessary burden that has no impact on quality. They cite a few small studies that have compared adherence to treatment guidelines in retail clinics with other settings and found retail clinics compare favorably.\(^{11,12}\) They point to adequate quality controls stating nurse practitioners follow protocols imbedded in and prompted by the electronic medical records that all retail clinics employ. In addition:

- All retail clinic operators report a strong internal quality control that includes physicians reviewing charts.
- Take Care Health clinics track and trend HEDIS\(^ {13}\) scores against the national average for streptococcal infections, bronchitis, and upper respiratory infections.
- HealthRite sends all its nurse practitioners to an FQHC “boot camp” where they practice clinical guidelines for 30 days. This “boot camp” provides an intensive orientation at a full-scope primary care facility to expose the nurse practitioners to a wide range of patients and medical conditions. HealthRite conducts a 100 percent file review for the first 90 days of a new employees’ work that tapers to 10 percent at the end of the first year.
- MinuteClinics receive accreditation from the Joint Commission for meeting the ambulatory care standards applicable for services provided in retail settings.\(^ {14}\)
Licensing health care facilities

Health care facilities licensing is a regulatory tool used by states to ensure that basic structural requirements are in place in order to provide safe, quality care. State regulations of the physical space of health care facilities vary. In general, states require hospitals and nursing homes to meet the most stringent facility standards. In a majority of states, retail clinics are treated like private physician offices and therefore, are not subject to regulation.

A few states provide separate regulations for ambulatory, urgent care, and physician offices. These types of regulations may affect the operations of retail clinics, which are located in settings that average between 200 and 500 square feet. In Rhode Island, retail clinics would fall into the current Organized Ambulatory Care category. However, since most clinics cannot meet the privacy and physical environment criteria under this category, there are no retail clinics in Rhode Island.

Massachusetts took a different approach. Retail clinics could not operate under the state’s regulations for licensed clinics without multiple waivers, so the state was prompted to promulgate new regulations. These regulations specifically addressed the physical space standards for retail clinics as well as issues such as continuity of care (see below). Only two other states, Arizona and Florida, are licensing retail clinics. In Florida, some corporate-owned retail clinics are licensed, while those that are owned by a licensed practitioner are not. (See page 9 for more on corporate ownership and organizational issues.) Retail clinics in Arizona are licensed by the Department of Health services under the category of Outpatient Treatment Centers.

Kentucky and New Hampshire are currently in the process of drafting regulations to license retail clinics. Kentucky is proposing licensing regulations for retail clinics under the title “minor care health clinics.” Under these regulations, retail clinics will be allowed to perform only those services that the state defines as “minor health care.” In addition, retail clinics will be prohibited from treating patients younger than 18 months. Both physicians and nurse practitioners at retail clinics will be required to work from established protocols. Physician’s assistants will be permitted to work in the clinics, but a nurse practitioner must be on site during operating hours.

Similarly, New Hampshire plans to license retail clinics. In New Hampshire, they will fall under the category of “outpatient clinics, laboratories, and collection centers.” There are currently no retail clinics operating in New Hampshire.

A few states surveyed have recently begun policy discussions regarding the emergence of retail clinics in their state. Connecticut held a legislative forum in August 2008 to determine whether retail clinics in the state should be regulated. Lawmakers concluded that retail clinics are more akin to a physician’s office rather than a full service clinic, and no action is currently warranted. The Kansas Health Policy Authority has been closely following the growth of retail clinics in their state and the health care industry and consumer response to inform their state policies. In Tennessee, the Board of Nursing and the Board of Medical Examiners plan to discuss retail clinics in a joint meeting within the next year. The groups will discuss applicable rules and regulations for retail clinics.

Medical homes

Are retail clinics medical home wreckers? Physician provider groups tend to think so and believe states should play a larger role in oversight—only Massachusetts has done this. Physician provider groups feel that a retail clinic is a poor substitute for a regular source of comprehensive primary care otherwise known as a medical home. But a recent study found that most people who seek care at retail clinics do not have medical homes. For these patients, physician groups want to make sure that retail clinics are trying to help them make a connection to a regular source of primary care.
For those patients with medical homes, physician groups feel that retail clinics fail to adequately communicate with primary care providers about services delivered and ultimately undermine the doctor/patient or medical home relationship. Compounding this is a perceived lack of follow-up care after a patient’s visit to a retail clinic to find out if the patient is improving and is getting connected with a primary care provider.

In response, a Take Care retail clinic representative stated that within 24 hours of their visit all patients receive a follow-up phone call from the nurse practitioner who provided treatment to check on the patient’s health and treatment status. Clinic operators stated that all patients leave with a copy of their visit record and, if consent is given, a copy is also faxed to their primary care provider’s office. Clinic operators also stressed efforts to help patients find a primary care provider if they did not have one already and some said they keep lists of nearby providers who are accepting new patients.

However, physician provider groups do not feel that these efforts are uniformly followed. For example, the California Academy of Family Physicians members report that patients do not always receive written visit records from retail clinics. With the exception of Massachusetts, states have not been involved in this aspect of regulation. As one state legislative director pointed out, continuity of care is largely up to the individual patient and states may have few appropriate mechanisms to influence what an individual does after they leave any medical provider’s office.

Customer satisfaction

All states interviewed investigate consumer health care complaints on a case-by-case basis, but complaints have not been an issue with regard to retail clinics. National, independent surveys have measured consumer satisfaction with retail clinics in the areas of quality of care, convenience, and costs, with each of these areas receiving ratings of about 90 percent. Our interviews with retail clinic operators revealed the following statistics:

- According to Take Care Health, patient satisfaction data compiled by Gallup reveals overall satisfaction has been about 96 percent.
- HealthRite retail clinics in New Jersey reports consumer satisfaction ranking in the 85th percentile when compared with other urgent care centers.
- According to RediClinic in Texas, 97 percent of their consumers would recommend the clinic to friends and family.

Conflicts of Interest

Our study of six states turned up two areas of concern regarding potential conflicts of interest for retail clinics. First, because retail clinics are very often located within a larger store that includes a pharmacy, some people are concerned that practitioners in the retail clinic will over-prescribe or selectively prescribe both prescription and over-the-counter medications that are for sale at the host store. For instance, CVS recently introduced its Rx Health Savings Pass program, through which customers who enroll receive both discounted generic drugs and discounts on Minute Clinic visits. Retail clinic operators told us that patients are informed that they can purchase their medications at any location of their choosing.

Second, some physician groups feel that alcohol and tobacco products should not be sold in stores that also provide health care. In Illinois, the Illinois Medical Society supported a bill prohibiting retail clinics statewide from operating in stores that sell alcohol and tobacco. The bill was introduced in the Illinois legislature in 2008 but did not pass. A letter of opinion from the Federal Trade Commission criticized components of this bill as anticompetitive and pointed out that cigarettes are already for sale at many drug stores and grocery stores that house a pharmacy. (See Table 2, page 13.)
Corporate ownership and organizational issues

In many states, the regulation of healthcare facilities varies according to both the health care functions performed (hospital, nursing home, outpatient clinic) and the organizational structure of the entity (for-profit, not-for-profit, private). In some states, corporations are expressly prohibited from employing physicians; in other states, this “corporate practice of medicine” rule is derived from multiple sources of law. The corporate practice of medicine is a legal doctrine that generally prohibits anyone who is not a licensed medical provider from “interfering with or influencing the physician’s professional judgment.”21 The doctrine bans for-profit and not-for-profit corporations from directly employing physicians. The intent of this doctrine is to ensure that non-physician entities do not influence treatment decisions so that physicians retain ultimate responsibility over the practice of medicine.22, 23

Because corporate practice of medicine guidelines vary from state to state, legal ownership of retail clinics is an important factor that decides how and if states will regulate those clinics. Thus, retail clinics have adopted various ownership configurations in order to fit into the existing regulatory structures of a given state. For example, New Jersey forbids the corporate practice of medicine, which means physicians are prohibited from being employed by a corporation to provide medical services. In response to this prohibition, one retail clinic operator in New Jersey reorganized two years ago to remove themselves from under a larger corporate umbrella. Today, each retail clinic is independently owned and operated by a physician or group of physicians, even within one retail clinic “chain.” For regulatory purposes, these clinics’ operations are considered the private practice of medicine.24
Lessons Learned From Six States’ Approaches

Few states have developed regulations to govern retail clinics’ organization and operations. Only Massachusetts has written regulations specific to retail clinics. Many state policy makers are waiting for market forces to decide whether retail clinics should stay or go. In the meantime, they will continue their present regulatory roles – as one state legislative director stated, “States can regulate the buildings or the people who work in the buildings.” As retail clinics establish staying power, policy makers may consider other options.

These six states were selected because they provided interesting lessons and approaches for other states to consider. New Jersey was selected because it offered insight into how retail clinics organized to fit in the existing health care system; Texas, because of its nurse practitioner oversight regulations; Illinois, because of recent legislative activity; Florida because of its unique licensure structure; Massachusetts, because of recent regulations to create a separate licensure category for retail clinics; and California, because of its interest in exploring how retail clinics fit into its health delivery system.

New Jersey
Several chains are operating a total of 30 retail clinics in New Jersey. The New Jersey Department of Health and Senior Services regulates ambulatory care facilities with regard to the physical facility and infection control measures, but exempts private physicians’ offices from regulation or licensure in the state. Thus, retail clinics in New Jersey have chosen to organize as private physicians’ offices. The retail clinics use a “closely held physician captive” model in which each clinic location is owned by a physician but all clinics are managed by a larger corporate entity.

Licensing officials we spoke with in the state were unsure whether retail clinics could improve access to care for the underserved, noting that they do not provide free or reduced-cost care. In contrast, retail clinic operators in New Jersey feel the extended hours of the retail clinic model can help meet the needs of underserved or transient residents. One operator of a retail clinic in New Jersey also operates an after-hours clinic at an FQHC: nurse practitioners who provide care at the HealthRite retail clinic are encouraged to also take shifts – for pay – at the FQHC’s after-
hours clinic. The retail clinic provides limited services and does not accept Medicaid, while the after-hours clinic offers a wider array of health services and does accept Medicaid reimbursement.

**Texas**

There are 79 retail clinics run by several operators in Texas. Texas limits the corporate practice of medicine; therefore, for-profit corporations, unless exempted, cannot directly employ physicians. However, other clinicians — including nurse practitioners — can be employed by corporations. Thus, retail clinics in Texas are owned by corporations that directly employ nurse practitioners. The corporations then enter into independent contractor arrangements with physicians who supervise those nurse practitioners.25

Texas tightly regulates the supervision of nurse practitioners by physicians. In addition, these regulations vary according to the regions of the state.26 Generally, for a nurse practitioner to have prescribing authority, a physician must be at the clinic with the nurse practitioner 20 percent of the time. In medically underserved areas, including rural areas, however, this rule is relaxed to one oversight visit by a physician every 10 business days. Retail health clinic operators feel that this requirement increases their costs without improving quality of care. The Coalition for Nurses in Advanced Practice told us that they see these regulations as a significant hindrance.

During the last legislative session in Texas, legislation was introduced to loosen the nurse practitioner oversight regulations.27 The bill did not pass, but a similar bill may be introduced in the 2009 legislature. Lawmakers who support the bill hope that less restrictive regulations might encourage the expansion of retail clinics that could provide convenient sources of care and curb inappropriate use of emergency departments.

| **Table 1. Physician Oversight of Nurse Practitioners in Six States** 28 |
| **State** | **Ratio NP:MD** | **Other Regulations** |
| California | 4:1 | Physician collaboration and written practice protocol required. Physician supervision required for prescriptions. |
| Florida | 4:1 | Physician supervision required. Physician may not supervise more than four offices in addition to the physicians’ primary practice location. |
| Illinois | None stated | Physician collaboration and written practice protocol required. Physician delegation required for prescriptions. Physician must be on-site once per month. |
| Massachusetts | None stated | Physician supervision and written practice protocol required. Physician must review charts once every three months. |
| New Jersey | None stated | Physician collaboration required for prescriptions. Physician must review charts (% not specified). |
| Texas | 3:1 | Physician supervision and written practice protocol required. Physician delegation required for prescriptions. Physician must be on-site 20 percent of the time (less in underserved areas). Physician must review 10 percent of all charts (less in underserved areas). |
None of the Texas retail clinic operators that we spoke to accept Medicaid. The Medicaid agency in Texas told us that clinicians working in retail settings could apply to be Medicaid practitioners using the regular enrollment process. Some Medicaid managed care plans in Texas are exploring the option of including retail clinics in their networks.

**ILLINOIS**

There are 65 retail clinics in Illinois. Retail clinics are considered physician offices and therefore are not licensed or subject to oversight by the Department of Public Health, and are not required to have a Certificate of Need licensure. This may change, according to the Department of Public Health. As the number of retail clinics grows, the state will examine if and how to regulate these clinics so that they fit into the existing service delivery system.

Scope of practice regulations are handled through the Illinois Department of Financial & Professional Regulation. Current state law requires physicians to meet once per month with the nurse practitioners they supervise, but does not specify any duration of time for that meeting. In addition, nurse practitioners must have a written collaborative agreement with a physician to make diagnoses and prescribe treatment and medications. According to the Illinois Society for Advanced Practice Nursing, there is no limit on the nurse practitioner to physician ratio, although there have been attempts by the Medical Society to alter this. The Illinois Society for Advanced Practice Nursing does not want to see new regulatory requirements for retail clinics out of concern that it might spread to more oversight and regulation for other outpatient settings.

Illinois Medicaid has been reimbursing for services at retail clinics, but with a new managed care model underway, this may change. Now, most Medicaid and All Kids beneficiaries who are not enrolled in a voluntary managed care organization will be required to receive health care through Illinois Health Connect. Beneficiaries select a primary care provider who has agreed to provide or coordinate most services their patients need. The Medicaid agency is in the process of finalizing a referral process, but the initial plans were not to pay for services provided by a provider who: (1) is not the primary care provider, or (2) does not have a referral from the primary care provider. Participating primary care providers agree to see (or refer) beneficiaries with urgent non-emergency conditions within 24 hours. When the referral process is finalized, enrolled Medicaid providers who work at a retail clinic may receive payment for services with a referral, and according to Illinois Medicaid, this referral could be backdated a maximum of 14 days. Retail clinic representatives feel that this referral process will result in the loss of their Medicaid and All Kids business.

In response to the increasing trend of retail clinics in the state, the Illinois State Medical Society advocated for the introduction of House Bill 5372 in February 2008. The bill added regulations to “ensure patient safety and adequate follow-up care.” It would have authorized the Department of Public Health to issue a separate application and permit for each retail clinic with exceptions for certain owners (for example, physician-owned or hospital-owned clinics) as well as ban the sale of tobacco and alcohol in facilities that housed retail clinics. Under the bill, inspections would occur within 90 days of application and if approved, a one-year permit would be granted. The Department of Public Health opposed the legislation due to “fiscal problems” and the bill, after some contentious debate, was not passed out of the Rules Committee.

Rep. Elaine Nekritz was approached by CVS shortly after the bill was introduced to write a letter to the Federal Trade Commission (FTC) voicing concerns over what the pharmacy chain perceived to be anti-competitive provisions in HR 5372. The FTC came out strongly against many provisions of the bill (see
inset) and Rep. Nekritz said she found herself receiving emails and calls, mostly supportive, as well as media interest and attention. During an interview with Rep. Nekritz, it was her sense that “the purpose of the bill was to slow the growth of clinics and regulate them to the point that made them no longer viable.” She said she feels there is a role for retail clinics to play in serving underserved populations and feels that these alternate systems of care are worth pursuing.

**FLORIDA**

There are 139 retail clinics in Florida, more than in any other state. Like other states, Florida does not license retail clinics that are owned by licensed health care practitioners – but in Florida retail clinics can be owned by nurse practitioners. Florida has a unique licensure structure for corporate-owned clinics.

### Table 2. Federal Trade Commission Weighs In on Illinois Legislation

The Federal Trade Commission (FTC) is charged with preventing unfair methods of competition and unfair or deceptive acts of practice in or affecting commerce. Although the FTC commended Illinois in its efforts to open new points of access to health care through new models of delivery, concerns were expressed over provisions that may have caused undue burden on retail clinics thereby limiting their ability to compete.

<table>
<thead>
<tr>
<th>Illinois proposal (HB 5372)</th>
<th>FTC comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advertising</strong></td>
<td>Prohibits facility’s ability to advertise comparisons of its fees for available services with the fees of other facilities.</td>
</tr>
<tr>
<td><strong>Clinic operations</strong></td>
<td>A physician may be a medical director of no more than 2 retail clinics.</td>
</tr>
<tr>
<td><strong>Insurance Payments</strong></td>
<td>Retail clinics must be subject to the same co-payment and deductible requirements that are required of others provided for a similar service in a different setting.</td>
</tr>
<tr>
<td><strong>Alcohol and Tobacco sales</strong></td>
<td>Prohibits a clinic being located in any store that has alcohol or tobacco products for sale to the public.</td>
</tr>
</tbody>
</table>
Anti-Fraud Campaign Spurs Regulation of Florida’s Retail Clinics

The regulation of retail clinics in Florida was an inadvertent result of a grand jury investigation of fraud in the automobile personal injury insurance industry. Inappropriate diagnostic testing, inflated charges, and over-utilization of treatments had resulted in soaring costs of auto insurance premiums. In 2003, the legislature passed a law that required health care clinics to be licensed and established the Health Care Clinic Unit within the Bureau of Health Facility Regulation at the Agency for Health Care Administration. The Health Care Clinic Unit is charged with denying, revoking, or suspending licensure of clinics that bill insurance companies for fraudulent claims. According to the Bureau of Health Facility Regulation, retail clinics that are corporately owned are subject to licensure by the state; practitioner-owned clinics are not. The application process for retail clinic licensure includes criminal background checks on chief operating officers, clinic staff, and board members. Licensure is granted for two years and the renewal process consists of field visits and inspections that focus on the “business side” of clinics. Any concerns on the medical side of operations are referred to the state Medical Board.

State Medicaid officials said that Medicaid does not recognize retail clinics in their own right as providers. Claims could be paid to nurse practitioners or physician assistants who submit claims under their own Medicaid provider number, but the agency does not track this data. The advantage for retail clinics to be recognized as a Medicaid provider would be from an accounting perspective— if there was a turnover at their clinics, the cash flow would continue regardless of the change of providers. This kind of change would require the state to change their Medicaid claims processing systems. (Florida Medicaid official)

Florida has also seen changes in its oversight of nurse practitioners and physician assistants, including those who work at retail clinics. In 2006, legislation was signed into law (Safe Supervision Bill) that limits the number of clinic sites where a physician may supervise physician assistants or nurse practitioners to no more than four satellite offices, in addition to their primary place of practice. Medicaid officials have said they are open to the possibility of retail clinics alleviating emergency department crowding and helping with access to care, but feel that the fee schedule may be too low for them to participate.

Florida has also seen changes in its oversight of nurse practitioners and physician assistants, including those who work at retail clinics. In 2006, legislation was signed into law (Safe Supervision Bill) that limits the number of clinic sites where a physician may supervise physician assistants or nurse practitioners to no more than four satellite offices, in addition to their primary place of practice. Medicaid officials have said they are open to the possibility of retail clinics alleviating emergency department crowding and helping with access to care, but feel that the fee schedule may be too low for them to participate.
Massachusetts

The Commonwealth of Massachusetts has undergone an intensive process to fit retail clinics into its health service delivery system that address issues regarding physical space and fragmentation of medical care. When CVS Minute Clinic requested permission to open several retail clinics in 2006, the state realized that its existing clinic regulations did not match the retail clinic model. In order to issue a full clinic license, the state would have needed to grant multiple waivers and would not have had the ability to limit the scope of services offered once a license was granted. As these waivers were being considered, other interested stakeholders began to convey their concerns. It became clear to the state that new regulations were needed in order to address these issues, raised primarily by the medical community.

In response, the Massachusetts Department of Public Health, Bureau of Health Care Safety and Quality developed the “limited service clinic” (LSC) regulations and convened two public hearings at which they received dozens of comments and written testimony from stakeholders, including the Federal Trade Commission. Public health advocates expressed concern regarding tobacco sales, corporate profits, and fragmentation of care, among other issues. Although the legislature was not involved in writing the regulations, many letters of support for the retail clinic model were received from some state legislators and other advocates.

Department of Public Health officials expressed some surprise that the Massachusetts Medical Society cited quality and safety concerns with regard to unsupervised nurse practitioners – especially given the limited scope of services offered at clinics. The input from the Massachusetts Academy of Family Physicians and Massachusetts Medical Society helped shaped regulations that, for the first time in the United States, addressed strengthening retail clinic ties to primary care. CVS Minute Clinic opened its first limited service clinic in Medway, Massachusetts on September 17, 2008 and plans to open several more in the near future.

Safety net issues

The role of retail clinics in providing health care to safety net populations was discussed during the stakeholder interviews. The Massachusetts League of Community Health Centers raised issues of whether the emergence of clinics in areas served by Community Health Centers will impact the Health Profession Shortage Area (HPSA) designation that allows health centers to receive federal assistance to recruit scarce primary care practitioners and other federal grants. With nurse practitioners in short supply in the state, the
Massachusetts League of Community Health Centers also expressed concern about vying for the same scarce practitioners and being unable to compete with probable higher salaries offered by retail clinics.

According to the Department of Public Health, the Commissioner of Health has encouraged community health centers to open limited service clinics. Although some have indicated interest, at the time of this publication, none have done so. Representatives from the Massachusetts League of Community Health Centers said they would want a limited service clinic operated by a community health center to be part of a health center’s cost structure and therefore receive Medicaid cost-based reimbursement encounter rate for FQHCs. Medicaid is expected to pay limited service clinics a rate that reflects their overall lower cost structure and this, according to the Massachusetts League, would not be sufficient to support the health centers’ costs. Cost-based reimbursement allows the health centers to provide comprehensive services for all patients.

Massachusetts Medicaid has also been developing ways to enroll limited service clinics as Medicaid providers. The agency plans to have this process in place in 2009. The Massachusetts League of Community Health Centers expressed concern about the complexity of the Medicaid eligibility and enrollment process and wondered what a retail clinic will do if a patient presents unsure about his or her eligibility. Would the retail clinic direct the patient to the community health center for enrollment or eligibility verification and then have the person return to the retail clinic to receive services? The League felt that the best retail clinic model would be staffed with nurse practitioners and community health workers who can enroll people in coverage, connect them to a primary care doctor, and ensure they get there.

**California**

There are 90 retail clinics currently open in California, operating under different models and offering different types of services; all are exempt from state licensure.

One of the largest is MinuteClinic, with 61 locations in southern California. MinuteClinic provides the typical array of retail clinic services – treatments for common illnesses, chronic disease screening, and vaccination – and in California also provides tuberculosis testing. MinuteClinic accepts some insurance.54

Another retail clinic chain, QuickHealth, operates in nine locations in northern California. QuickHealth is staffed by physicians, in addition to some mid-level practitioners, and therefore can provide a wider scope of acute and chronic care services. QuickHealth does not accept any insurance, but will provide consumers with a receipt that they can submit to their insurers for reimbursement.

The Lindora Clinic has been operating in California for 37 years. With nine locations in RiteAid pharmacies, Lindora Clinics focus on weight loss and chronic disease management while also offering a limited range of acute care services. They do not currently accept insurance, but are negotiating with Blue Cross Blue Shield.

Finally, Sutter Express Care is the retail clinic arm of Sutter Health, a non-profit network of hospitals and physicians in northern California offering the typical scope of retail clinic services. Sutter Express Care clinics accept private health insurance and Medicare, but do not accept Medicaid.

While these four clinic chains are operating successfully using various models of organization and employing varying reimbursement strategies, other retail clinic chains have indicated to the Governor’s office that there are barriers to opening clinics in California. Governor Schwarzenegger’s health care advisor told us the Governor is supportive of the retail clinic model. He believes retail clinics might help curb the rate of growth of health care costs by providing affordable primary care in a more accessible setting, while also alleviating the burden in the state’s over-crowded emergency rooms.
California prohibits the direct employment of physicians by corporations, often called “the corporate practice of medicine.”56 The Medical Board of California interprets this law to also prohibit management services organizations from arranging for or advertising medical services, even where physicians own and operate the business.57 However, retail clinics can organize as a “professional medical corporation” in which only physicians and other licensed professionals own shares.58 The Lindora Clinic retail clinics operate under this model.

Practice Issues for Nurse Practitioners

California allows nurse practitioners to provide health services and order medications under a standard protocol with a physician. California has relatively strict standards for the supervision of nurse practitioners by physicians. The supervisory ratio in California was increased recently, so that one physician may now supervise four nurse practitioners. The Governor’s Office has proposed increasing the ratio further, to 1:6. The Governor’s Office is also studying the issue of nurse practitioner supervision of unlicensed medical assistants.

<table>
<thead>
<tr>
<th>Table 3. Possible State Policy Levers</th>
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</thead>
<tbody>
<tr>
<td><strong>Regulatory Mechanism</strong></td>
</tr>
<tr>
<td>Create a separate regulatory category for retail clinics.</td>
</tr>
<tr>
<td>Provide more options for businesses like retail clinics to comply with corporate practice of medicine restrictions.</td>
</tr>
<tr>
<td>License retail clinics like other licensed health care facilities.</td>
</tr>
<tr>
<td>Streamline oversight of nurse practitioners and physician assistants.</td>
</tr>
<tr>
<td>Impose marketing and advertising restrictions.</td>
</tr>
<tr>
<td>Develop Medicaid reimbursement policies specific to retail clinics.</td>
</tr>
<tr>
<td>Require retail clinics to make referrals to primary care providers.</td>
</tr>
</tbody>
</table>
Access for the Underserved

Many stakeholders in California are cautious about the ability of retail clinics to extend access to those who may not be able to afford or access appropriate care in traditional health settings. The California Primary Care Association would prefer a model that explicitly connects retail clinics to the larger health care delivery system. It favors requirements that retail clinics make referrals to a regular source of care and inform low-income customers about other treatment options, such as community health centers.

A representative of the California Department of Health Care Services, which administers the state's Medicaid program, felt that retail clinics could provide a convenient point of care for Medicaid beneficiaries for acute illnesses, but many Medicaid beneficiaries also have chronic conditions which can not be managed at a retail clinic. Representatives of the California Department of Public Health noted that retail clinics are, so far, locating in metropolitan areas, rather than in underserved, rural portions of California.
Conclusion

Despite the growth of retail clinics in the United States, there has not been a corresponding growth in the number of states regulating clinics. Rather, many states are letting market forces decide the fate of retail clinics, but there have been some exceptions. Most notably, often in response to physician groups, states have increased physician oversight of non-physician practitioners who work at retail clinics.

Access
State policy makers believe that there is a role for retail clinics to play in expanding access to health services. Retail clinics reach some populations for a limited set of conditions and may reduce unnecessary emergency department use. Although it appears that Medicaid beneficiaries have made little use of retail clinics for health care, this could change as states make payment arrangements that recognize retail clinics as Medicaid providers. Continued low reimbursement rates by Medicaid may continue to be a barrier to retail clinics accepting Medicaid as payment. In Massachusetts, the Medicaid agency plans to recognize retail clinics as a separate entity able to submit claims to Medicaid in 2009. In other states, retail clinic operators are discussing payment issues with Medicaid agencies. There are Medicaid managed care plans in some states that allow beneficiaries to seek care at retail clinics.

Costs
State policy makers may consider costs to the state and costs to the consumer when thinking about retail clinics. Consumers who appropriately use retail clinics in lieu of emergency rooms may reduce out-of-pocket costs and possibly overall health system costs. Although, one study cautioned that retail clinics might increase the overall cost of care by increasing demand from consumers who might ordinarily self-treat or who might have delayed preventive care. In addition, out-of-pocket costs for patients without insurance may be higher at retail clinics than at community health centers where services are provided on a sliding scale for certain income levels.

Quality of Care
Licensing health facilities and practitioners gives states the ability to monitor patient safety and health care quality. Most states exempt retail clinics from facility licensure and rely instead on practitioner licensure by the applicable state board for oversight. Massachusetts’ system of licensing retail clinics separately distinguishes retail clinics from private physician offices and from other health care facilities. This allows the state nuanced regulation of retail clinics without regulating other health care practitioners. It has allowed Massachusetts to regulate retail clinics to promote medical homes by requiring them to connect better to primary care providers.

As states require increased oversight of health care practitioners such as nurse practitioners, they will increase the retail clinics’ operating costs and may dissuade some clinic chains from doing business in the state. Physician groups argue that physician supervision of nurse practitioners is necessary to maintain quality and ensure patient safety. Others see it differently: retail clinics use evidenced-based guidelines that deliver appropriate services and ensure that nurse practitioners are operating well within their scope of care.

Corporate Ownership and Organizational Issues
State regulations restricting the corporate practice of medicine may limit the proliferation of retail clin-
ics by requiring physician involvement at each clinic location. However, retail clinics in several states that prohibit the corporate practice of medicine have found other organizational structures that allow them to operate.
### Appendix A: Retail Clinic Survey results

<table>
<thead>
<tr>
<th>State</th>
<th>Number of Retail Clinics, Nov. 2008 (CCA)*</th>
<th>Medicaid Certifies as Distinct Provider Type</th>
<th>State Licenses Retail Clinics</th>
<th>Type of Facility License</th>
<th>Licensing Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>0</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alaska</td>
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<td>no</td>
<td></td>
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<td>Arizona</td>
<td>49</td>
<td>no**</td>
<td>yes</td>
<td>Outpatient treatment center</td>
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<td></td>
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<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>0</td>
<td>no retail clinics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delaware</td>
<td>0</td>
<td>no retail clinics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Florida</td>
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<td>no</td>
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<td>Health care clinic</td>
<td>Agency for Healthcare Administration, Health Care Clinic Unit</td>
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<td>no**</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>no retail clinics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Idaho</td>
<td>0</td>
<td>no retail clinics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illinois</td>
<td>65</td>
<td>no</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indiana</td>
<td>33</td>
<td>no**</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iowa</td>
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<td>no retail clinics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
<td>13</td>
<td>no</td>
<td>in development</td>
<td>Minor health care clinic</td>
<td>Office of Inspector General, Cabinet for Health and Family Services</td>
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<tr>
<td>Louisiana</td>
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<td>no retail clinics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maine</td>
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<td>no retail clinics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maryland</td>
<td>32</td>
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<td>no</td>
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<td></td>
</tr>
<tr>
<td>State</td>
<td>Number of Retail Clinics, Nov. 2008 (CCA)*</td>
<td>Medicaid Certifies as Distinct Provider Type</td>
<td>State Licenses Retail Clinics</td>
<td>Type of Facility License</td>
<td>Licensing Entity</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------</td>
<td>---------------------------------------------</td>
<td>------------------------------</td>
<td>--------------------------------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>7</td>
<td>yes (planned)</td>
<td>yes</td>
<td>Limited services clinic</td>
<td>Department of Public Health</td>
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<td>Michigan</td>
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<td></td>
</tr>
<tr>
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<td>51</td>
<td>no**</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mississippi</td>
<td>0</td>
<td>no retail clinics</td>
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<td></td>
<td></td>
</tr>
<tr>
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<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Montana</td>
<td>0</td>
<td>no retail clinics</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nebraska</td>
<td>0</td>
<td>no retail clinics</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nevada</td>
<td>17</td>
<td>no</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Hampshire</td>
<td>0</td>
<td>no retail clinics</td>
<td>in development</td>
<td>Outpatient clinics, laboratories, and collection stations</td>
<td>Bureau of Health Facilities Administration</td>
</tr>
<tr>
<td>New Jersey</td>
<td>30</td>
<td>no</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Mexico</td>
<td>0</td>
<td>no retail clinics</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New York</td>
<td>7</td>
<td>no</td>
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<td></td>
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</tr>
<tr>
<td>North Carolina</td>
<td>36</td>
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<td>no</td>
<td></td>
<td></td>
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<tr>
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<td>0</td>
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</tr>
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<td>41</td>
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<td>no</td>
<td></td>
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</tr>
<tr>
<td>Rhode Island</td>
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<td>no retail clinics</td>
<td>yes***</td>
<td>Organized ambulatory care setting</td>
<td>Office of Facilities Regulation</td>
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<tr>
<td>Tennessee</td>
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<td>Texas</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vermont</td>
<td>0</td>
<td>no retail clinics</td>
<td>no</td>
<td></td>
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<tr>
<td>Number of Retail Clinics, Nov. 2008 (CCA)*</td>
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<tr>
<td>Virginia</td>
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<td></td>
<td></td>
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<tr>
<td>Washington</td>
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<td>no</td>
<td></td>
<td></td>
</tr>
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<td>West Virginia</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Wisconsin</td>
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<td>no</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wyoming</td>
<td>0 no retail clinics</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

* Number of clinics in each state who are members of the Convenient Care Association, as of November 2008

**Medicaid agencies indicated in their response that one or more Medicaid managed care organizations reimburse for services provided to beneficiaries.

***Although there are currently no retail clinics in Rhode Island, if they were to apply for licensure, they would fall in this category.
Notes

1 Laws, Margaret and Scott, Mary Kate, “The Emergence of Retail-Based Clinics in the United States: Early Observations,” Health Affairs 27 (2008): 1293.
2 Thygeson, Marcus et al., “Use and Costs of Care In Retail Clinics Versus Traditional Care Sites,” Health Affairs 27 (2008): 1287-1288.
5 Massachusetts Department of Public Health proposed regulations to require pre-screening for all advertising for limited service clinics. FTC commented that the proposed pre-screening requirement for all LSC advertising may be overly restrictive and recommended that it be struck. FTC suggested that the Department of Public Health would be on “firmer regulatory ground if it merely prohibits false or misleading advertising.” (FTC letter to LouAnn Stanton, 2007).
7 Thygeson et al., 2008, 1287-1288.
8 Thygeson et al., 2008, 1290.
9 HealthRite clinics in New Jersey are affiliated with the AtlanticCare system through its for-profit arm, AtlantiCare Physician Group.
11 One study looked at visits for one retail clinic operator and found better than 99 percent adherence to clinical guidelines in the care of acute pharyngitis. Woodburn and Smith, “Quality of Care in the Retail Health Care Setting Using National Clinical Guidelines for Acute Pharyngitis,” American Journal of Medical Quality 22 (2007): 457-462. Another found 99.15 percent adherence to clinical guidelines for negative strep tests. [Costello, Daniel, “A Checkup for Retail Medicine” Health Affairs 27(5) 2008.]
13 Healthcare Effectiveness Data and Information Set (HEDIS) is a tool for defining and measuring health plan performance in addition to allowing for comparison to national or state benchmarks.
16 Some of the physical space regulations addressed making sure that toilet facilities are in a convenient location—not necessarily within treatment areas; separate supply closet for cleaning supplies; minimum examination room space of 56 square feet to accommodate wheelchairs, and adequate space for reception and waiting, but not necessarily separate space. Letter to Commissioner John Auerbach and Public Health Council, Dec. 12 2007.
17 Mehrotra et al., 2008, 1276.
24 New Jersey does not regulate private medical practices. The State Board of Medical Examiners in the Division of Consumer Affairs of the Department of Law and Public Safety licenses individual providers. N40 N.J.R. 702(a) January 22, 2008 p.6.
29 In Illinois, Certificate of Need requirements are needed for ambulatory surgery centers and other more complex facilities; facilities performing simpler treatments, such as retail clinics, are exempt from CON requirements.
32 All Kids is a complete healthcare program for every uninsured child in Illinois regardless of medical conditions or income.
42 400.990-400.995, the “Health Care Clinic Act.” Title XXIX Public Health Chapter 400 Nursing Homes and Related Health Care Facilities.
44 http://www.fdhc.state.fl.us/mchq/health_facility_regulations/HealthCareClinic/docs/dec_rpt3.pdf
46 Ibid.
50 Email from the U.S. Department of Health and Human Services Health Resources and Services Administration stated that mid-level practitioners are not counted toward Health Professional Shortage Area designations. Andy Jordan, e-mail message, October 22, 2008.
51 Omnibus Budget Reconciliation Act (OBRA) of 1989, which established the Federally Qualified Health Center (FQHC) reimbursement designation was passed because Congress was concerned that, due to inadequate reimbursement rates, health centers were shifting federal grant funds meant to care for the poor and uninsured to cover the costs of caring for Medicaid and Medicare patients. Health centers and other qualified health clinics receiving the FQHC designation began receiving enhanced Medicaid and Medicare reimbursements for actual costs—including overhead expenses such as mortgage and utilities, regardless if these expenses were covered by other sources. Previously they had received a reimbursement according to a predetermined fee schedule.
