



Retail Clinics: Six State Approaches to Regulation and Licensing

Introduction

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

- **Retail clinics are accessible.** They are usually located within suburban drug, grocery, or mass merchandise stores, and are open evenings and weekends without an appointment or wait.
- **Retail clinic services often cost less.** Because they are staffed mostly by nurse practitioners rather than physicians and have lower total overhead, their prices are often below those of other types of providers such as emergency rooms or urgent care centers.²
- **Retail clinics offer evidence-based care.** Their limited range of services normally adheres to established clinical practice guidelines.³

Despite these apparent benefits, retail clinics pose a number of challenges for state policymakers and regulatory agencies working to improve access, cost, and quality within their health delivery systems. The challenges identified by stakeholders during the course of research for this report coalesce within five issues:

1. **Patient safety and quality of care.** There is concern from some stakeholders that insufficient state regulation or physician oversight at retail clinics may lead to inappropriate care delivery.
2. **Access for the underserved.** Despite their generally lower charges, the payment structures of retail clinics may exclude underserved populations who are eligible for sliding scale fees in other settings. There is also concern among some that retail clinics may negatively affect the viability of safety-net clinics.
3. **Care fragmentation.** Care at retail clinics may interfere with the continuity of care a patient receives through a medical home.
4. **Conflict of interest.** Because retail clinics are often located in a facility with a pharmacy, there is concern that the clinics will influence patients to buy medications and other items at that facility.
5. **Corporate ownership and organizational issues.** Because corporate practice of medicine laws vary from state to state, legal ownership of retail clinics influences whether and how states regulate those clinics.

This issue brief explores how six states—California, Florida, Illinois, Massachusetts, New Jersey, and Texas—are using regulation and licensure to promote, structure, or limit the operation of retail clinics. These six states were selected because their recent experiences may provide instructive lessons for other states. The states' approaches to the clinics vary, as do interpretations of how existing regulations fit the retail clinic model. Only one state, Massachusetts, has written new regulations expressly for retail

clinics. Among the steps being taken or considered by these states are:

- Creating a separate regulatory category for retail clinics;
- Licensing retail clinics as they do other health care facilities;
- Altering oversight requirements regarding nurse practitioners and physician assistants;
- Imposing or loosening marketing and advertising restrictions;
- Developing Medicaid policies to facilitate clinic participation; and
- Requiring clinics to make referrals to primary care providers.

The project's researchers conducted interviews with stakeholders in each of the six states concerning the state's regulation of health services in retail settings. The researchers 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; and state legislators and/or their staff. Interview protocols were tailored for each stakeholder group. This report addresses some common themes that emerged, as well as each state's unique response to the emergence of retail clinics.

Issues for State Policymakers

Retail clinics present a series of interrelated considerations for state policymakers and regulators. States may want to consider how regulation of retail clinics might affect patient safety, quality of care, access to medical care for the underserved, continuity of care and medical homes, and potential conflicts of interest regarding the delivery of care. States should also be aware that existing laws and regulations regarding corporate practice of medicine may affect the proliferation of retail clinics.

Patient Safety and Quality of Care

States have a responsibility to protect public health by ensuring the safe delivery of health care. States can use their regulatory powers to protect and enhance the quality of patient care at health care facilities.

Regulation of Clinics Through Facility Licensing

The licensing of health care facilities is a regulatory tool that states can use to help ensure that basic structural requirements are in place to provide safe, quality care. Of the six states discussed in this report, only Massachusetts directly licenses retail clinics as a separate type of health care facility. State regulation of other health care facilities varies: For example, states require hospitals and nursing homes to meet the most stringent facility standards; some states provide separate regulations for ambulatory and urgent care clinics.

Applying regulations intended for other types of facilities to retail clinics may adversely affect clinic operations. Massachusetts found that, without multiple waivers of minimum standards, retail clinics could not operate under the state's existing regulations for licensed clinics, including physical space requirements (retail clinics are located in settings that average between 200 and 500 square feet).⁴ This prompted the state to promulgate regulations specifically to address physical space standards for retail clinics (as well as issues such as continuity of care; see below).⁵

Conversely, physician offices, the rubric under which retail clinics operate in most states, usually are not regulated with regard to their physical space. In most states, retail clinics formally organize themselves as physician offices, and thus are not subject to state facility regulation.

Provider Regulation

According to retail clinic representatives, the state regulatory tools most strongly 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. Eleven states allow nurse practitioners to practice independently, without physician oversight, but all others require some degree of supervision.⁶ 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 for a six-state comparison.) These kinds of regulations can greatly affect the cost structure of retail clinics and may influence where these 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 that retail clinics offer. Most states allow nurse practitioners to diagnose and treat illnesses, order tests, and prescribe medications following a written clinical protocol or physician collaboration, but they also place limits on these practices. Because nurse practitioners are the primary providers in most retail clinics, restrictions on their scope of practice affect the care provided in retail settings.

Both physician groups interviewed in this study consider the supervision laws to be an important aspect of safeguarding public health. In contrast, the nursing organization interviewed sees this kind of supervision as counterproductive, especially in light of the shortage of primary care providers. Retail clinic operators share the nurses' views and find the supervision requirements largely an unnecessary burden with no impact on quality of care. 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.⁷ They also point out that nurse practitioners follow protocols embedded in and prompted by the electronic medical records that all retail clinics employ. In addition, all retail clinic operators contacted in this study report strong internal quality control that includes physician review of charts.

State Systems for Monitoring Patient Safety

Many states monitor patient safety and quality of care by requiring health facilities, though not physicians or other private provider offices, to report patient safety data. However, only Massachusetts collects data from retail clinics. States are able to indirectly monitor quality of care at retail clinics through licensure of providers

Table 1. Physician Oversight of Nurse Practitioners in Six States

	RATIO (NP:MD)	OTHER REGULATIONS
California	4:1	<ul style="list-style-type: none"> Physician supervision required.
Florida	4:1	<ul style="list-style-type: none"> Physician may not supervise more than four offices in addition to the physician's primary practice location.
Illinois	None stated	<ul style="list-style-type: none"> Physician delegation required. Physician must be on-site once per month.
Massachusetts	None stated	<ul style="list-style-type: none"> Physician supervision required. Physician must review charts once every three months.
New Jersey	None stated	<ul style="list-style-type: none"> Physician collaboration required. Physician must review charts (percentage or frequency not specified).
Texas	3:1	<ul style="list-style-type: none"> Physician delegation required. 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).

Source: Adapted from *State-By-State Guide to Regulations Regarding Physician and Nurse Practitioner Practice*. Convenient Care Association, 2008.

Retail Clinics Report Internal Quality Controls

Some retail clinic operators find that regulations limiting nurse practitioner scope of practice are unnecessarily strict. In support of their position that the clinics themselves provide sufficient quality control, several clinics reviewed in this study cite specific examples of internal training, supervision, and tracking of quality of care:

- Take Care Health clinics track and trend Healthcare Effectiveness Data and Information Set (HEDIS)* scores against the national average for streptococcal infections, bronchitis, and upper respiratory infections.
- HealthRite clinics send all their nurse practitioners to a Federally Qualified Health Center (FQHC) “boot camp” where they practice clinical guidelines for 30 days. This provides intensive orientation at a full-scope primary care facility, exposing 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 employee’s work; this tapers to 10 percent by the end of the first year.
- MinuteClinic receives accreditation from the Joint Commission for meeting the ambulatory care standards applicable to services provided in retail settings.†

*The Healthcare Effectiveness Data and Information Set (HEDIS) is a tool for defining and measuring health plan performance with comparison to national or state benchmarks.

†Source: Khoury, Nicole. “MinuteClinic Receives JCAHO Accreditation.” MinuteClinic press release, Sept. 20, 2006 (www.minuteclinic.com/documents/press-releases/minute_clinic_receives_jcaho_accreditation.pdf).

and consumer complaints. But some physician groups contend that states should also monitor how retail clinics are affecting matters such as continuity of care.

States investigate consumer health care complaints on a case-by-case basis but do not compile data specifically with regard to retail clinics. Anecdotally, this study’s interviews with state officials revealed few complaints about retail clinics. Independent national surveys regarding retail clinics have rated consumer satisfaction in the areas of quality of care, convenience, and cost each at about 90 percent.⁸ Interviews with retail clinic operators

in this study also revealed the following measures of consumer satisfaction:

- According to Take Care Health, patient satisfaction data compiled by Gallup reveals overall satisfaction with care at its clinics has been about 96 percent.
- HealthRite retail clinic system 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 its consumers would recommend the clinic to friends and family.

Access for the Underserved

In addition to adding convenience for insured patients, retail clinics may expand access to limited types of care for some populations. For the underinsured—those with health insurance but with high deductibles or other high out-of-pocket costs—retail clinics may provide an affordable way to receive some basic health services. For other groups, retail clinics represent a culturally familiar health care delivery site where they may be more likely to seek care. For example, MediGo clinics in Navarro Pharmacies in Florida seek to serve Hispanic patients who are culturally familiar with receiving health services in a pharmacy.⁹

Whether retail clinics can improve access for the underserved depends on several factors, including accessibility of the clinics, Medicaid participation, and out-of-pocket costs to patients. To date, many retail clinics are located in suburban or metropolitan areas, rather than in rural areas where there is limited access to primary care providers.

Medicaid Participation by Retail Clinics

When retail clinics first began operating, most of them did not accept any public or private insurance, requiring immediate cash payment instead. This has changed dramatically: Consumers’ share of out-of-pocket costs for retail clinics fell from 100 percent in 2000 to 15.9

Costs at Retail Clinics Versus Community Health Centers

With regard to access for the underserved, retail clinic providers note that charges at their clinics are lower than at most doctors' offices, urgent care centers, and certainly emergency rooms. Uninsured patients may benefit from these lower out-of-pocket costs. In particular, patients who do not qualify for sliding scale fees at community health centers may find lower prices for certain services at retail clinics. However, representatives of community health centers in California and Massachusetts contend that low-income, uninsured patients who do qualify for sliding scale fee arrangements may find that their out-of-pocket costs are lower at community health centers than at retail clinics.

percent in 2007,¹⁰ with most retail clinics now accepting private insurance and some accepting Medicare. Only a very few, however, accept Medicaid: Just one of the six retail clinics interviewed for this study, Take Care Health, currently accepts Medicaid payments, and not in all the states where it operates. Other retail clinic operators are in negotiations with state Medicaid agencies.

From the standpoint of public payers such as Medicaid, retail clinics offer the significant attraction of diversion from other, more expensive settings, especially the emergency room. One study found that 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.¹¹ (The same study cautioned, however, that retail clinics might potentially increase the overall cost of care by increasing demand from consumers who might ordinarily self-treat or might delay preventive care.¹²) Although retail clinics do not provide emergency care, they may divert patients with acute non-emergency conditions from going to an emergency room, thus substantially reducing the costs of care.

Medicaid-enrolled practitioners who provide care in retail clinics can submit claims for services delivered

there. However, Medicaid officials in the six study states believe it is unlikely that many Medicaid beneficiaries are receiving services at retail clinics. (Actual figures are not available because most Medicaid billing systems do not distinguish retail clinics from physician offices.) Retail clinics in most states simply do not accept Medicaid patients; the reason often cited is low Medicaid reimbursement rates. And in Illinois, a newly introduced managed care model for Medicaid enrollees may make retail clinic use impractical (this issue is included in the wider discussion of Illinois policies in the state-by-state section later in this report).

In Massachusetts, the Medicaid agency is developing the technical capability to recognize and therefore directly reimburse retail clinics rather than requiring individual providers to seek reimbursement. MinuteClinic has been working directly with the state to become a Medicaid provider. The advantage for retail clinics to be recognized as a Medicaid provider would be from an accounting perspective: When there is turnover at their clinics, cash flow would continue regardless of the change of providers.

Price Advertising

Low costs for both consumers and payers is a large part of what makes retail clinics attractive. A related element of retail clinics pricing is transparency: Prices are commonly advertised, both at the door and in other advertising forms, so that customers can make informed decisions. Price advertising by retail clinics was debated in two of the states researched for this study. Both Illinois and Massachusetts introduced legislation or regulations that would have restricted the scope of advertising by retail clinics. In each state, the Federal Trade Commission (FTC) advised against the proposed provisions.¹³ (See the discussion of various FTC positions regarding retail clinics in the Illinois part of the state-by-state section, later in this report.)

Care Fragmentation

Some physician provider groups argue that retail clinics are sometimes medical home-wreckers and assert that states should play a larger role in their oversight. The physicians believe that a retail clinic is a poor substitute for a medical home, a patient's regular source of comprehensive primary care. A recent study found that most people who seek care at retail clinics do not have a medical home.¹⁴ Physician groups would like to see retail clinics help these patients make a connection to a regular source of primary care.

For those patients who do have a medical home, physician groups are concerned that retail clinics do not communicate well with primary care providers about services delivered, and thus ultimately undermine the doctor/patient or medical home relationship. Compounding this is a perceived lack of follow-up care following a patient's visit to a retail clinic. Clinic operators emphasize that clinics provide all patients with a copy of their visit record and, if consent is given, also fax a copy to their primary care provider's office. Clinic operators also stress their efforts to help patients find a primary care provider if they do not have one; some clinics report that they keep lists of nearby providers who are accepting new patients. Physician provider groups, however, do not feel that these efforts are uniformly followed.

Policymakers who share these physician concerns might consider developing regulations that promote retail clinic efforts to assist patients in follow-up and continuity of care. With the exception of Massachusetts, none of the states in this study has developed this type of regulation. As one state legislative director noted, states may have few appropriate mechanisms to influence what individuals do after they leave any medical provider's office, and continuity of care remains largely up to the individual patient.

Conflicts of Interest

This study examined concerns raised in some states about potential conflicts of interest regarding retail clinics. Because retail clinics are often located within a store that includes a pharmacy, there is concern that retail clinic providers might overprescribe or selectively prescribe both prescription and over-the-counter medications that are for sale at the host store. For example, CVS pharmacy recently introduced its Rx Health Savings Pass program by which customers who enroll receive both discounted generic drugs and discounts on visits to MinuteClinics, which are located within CVS facilities.¹⁵ Retail clinic operators, however, report that clinic patients are informed that they can purchase their medications at any location of their choosing.

Alcohol and Tobacco Sales at Retail Clinic Locations

Some stakeholders believe that alcohol and tobacco products should not be sold in stores that also provide health care. In Illinois, the state medical society supported a bill prohibiting retail clinics statewide from operating in stores that sell alcohol and tobacco. 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 drugstores and grocery stores that house a pharmacy.* The Illinois bill was introduced in the state legislature in 2008 but was not enacted into law.

*Source: Federal Trade Commission letter to Elaine Nekritz, May 29, 2008.

Corporate Ownership and Organizational Issues

The "corporate practice of medicine" is a legal doctrine that seeks to prohibit anyone who is not a licensed medical provider from "interfering with or influencing the physician's professional judgment."¹⁶ Corporate practice of medicine laws ban for-profit and not-for-profit corporations alike from directly employing physicians. The intent of this doctrine is to ensure that physicians, rather than corporate employers, retain ultimate responsibility over the practice of medicine.^{17,18} In some

states, corporations are expressly prohibited by law from employing physicians; in other states, a corporate practice of medicine rule is derived from multiple sources of law.

Because corporate practice of medicine rules vary from state to state, the ownership structure of a particular retail clinic system may determine whether that system’s clinics are able to operate in a given state. Thus, retail clinics have adopted various ownership configurations to fit into a state’s existing regulatory structures. For example, in response to New Jersey’s corporate practice of medicine laws, one retail clinic operator reorganized two years ago to remove its clinics from under a corporate umbrella. Today, each retail clinic in this system is independently owned and operated by a physician or group of physicians—thus, for regulatory purposes, each clinic is considered a private practice of medicine,¹⁹ even though they all remain within one retail clinic “chain.”

Lessons Learned from Six States’ Approaches

Few states directly regulate retail clinics’ organization and operations. Only Massachusetts has written regulations specific to retail clinics. Many states are allowing market forces to dictate retail clinic survival within their present

regulatory structures. As retail clinics establish staying power, policymakers may consider other options.

The six states in this study were selected because of the lessons and approaches they offer for consideration by other states. Texas was selected because of its attention to nurse practitioner oversight regulations; Illinois because of recent legislative activity; Florida because of its unique licensure structure; New Jersey because of how its retail clinics reorganized to fit into the existing regulatory system; 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.

Texas

There are 79 retail clinics managed by several operators in Texas.²⁰ Under Texas law, for-profit corporations, unless exempted, cannot directly employ physicians. However, corporations may directly employ other clinicians, including nurse practitioners. Thus, corporation-owned retail clinics directly employ nurse practitioners and enter into independent contractor arrangements with physicians who supervise those nurse practitioners.²¹

Table 2. Potential State Policy Levers

REGULATORY MECHANISM	IMPACT	EXAMPLE
Create a separate regulatory category for retail clinics.	Regulations for retail clinics could be written as broadly or narrowly as needed to accomplish state policy goals.	Massachusetts
Provide options for retail clinics to comply with corporate practice of medicine restrictions.	Retail clinics could more easily develop ownership structures that comply with state laws.	New Jersey Texas
License retail clinics like other licensed health care facilities.	Facility standards, such as size and sanitation requirements, would apply.	Florida
Loosen or streamline oversight of nurse practitioners and physician assistants.	Nurse practitioners and physician assistants would require less physician supervision, making it easier and less costly to operate retail clinics.	Illinois New Jersey
Impose marketing and advertising restrictions.	Retail clinics could not advertise comparative pricing or connections to larger health care systems.	Illinois New Jersey
Develop Medicaid reimbursement policies specific to retail clinics.	Retail clinics could be directly reimbursed by state Medicaid program at rates set specifically for retail clinics.	Massachusetts (in progress)
Require retail clinics to make referrals to primary care providers.	Continuity of care could be facilitated by improving connections of retail clinics to the existing health care system.	Massachusetts

Texas' requirements for physician supervision of nurse practitioners are strict relative to other states and vary in different regions of the state.²² 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 regions, often rural areas, this rule is relaxed to one physician oversight visit every 10 business days. Retail health clinic operators in Texas believe that this requirement increases their costs without improving quality of care. The Coalition for Nurses in Advanced Practice also sees these regulations as a significant hindrance.

Texas lawmakers introduced a bill in 2007 to loosen the nurse practitioner oversight regulations.²³ Lawmakers who supported the bill hoped that less restrictive regulations would encourage the expansion of retail clinics that could provide convenient sites of care and curb unnecessary use of emergency departments. The bill did not pass, but a similar bill may be introduced in 2009.

None of the Texas retail clinic operators interviewed for this study accepts Medicaid, though some Medicaid managed care plans in Texas are exploring the option of including retail clinics in their networks. The Texas Medicaid agency reported that individual providers working in retail settings could participate in Medicaid through the regular enrollment process.

Illinois

Illinois presents an instructive example of potentially complex relations between Medicaid and retail clinics, and also demonstrates how efforts to regulate clinics might run into opposition from the Federal Trade Commission (FTC).

There are approximately 55 retail clinics in Illinois.²⁴ The clinics are considered physician offices and therefore are not licensed or subject to oversight by the Department of Public Health, and do not require certificate of need licensure.²⁵ According to the state's public health

department, however, this may change: As the number of retail clinics grows, the state will examine whether and how to regulate them so that they fit into the existing service delivery system.

Scope of practice regulations that apply to clinicians at retail clinics are handled through the Illinois Department of Financial and 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.²⁶ In addition, nurse practitioners must have a written collaborative agreement with a physician in order to make diagnoses and prescribe treatment and medications.²⁷ 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 state's medical society to alter this.

With regard to Medicaid, individual providers at retail clinics have been reimbursed for care of Medicaid patients. But a new state program, requiring that Medicaid-covered services be delivered through managed care, may eliminate most retail clinic treatment of Medicaid patients. Under the new mandate, most Medicaid beneficiaries (as well as uninsured children under the All Kids program²⁸) who are not enrolled in a managed care organization must receive health care through Illinois Health Connect.²⁹ This is a managed care program in which beneficiaries select a primary care provider who provides or coordinates most patient services. The purpose of this program is to align Medicaid policies with medical home principles. The state's Medicaid agency is finalizing a referral process, but initial plans are to pay for services only from the primary care provider or a clinician with a referral from the primary care provider.³⁰ (According to Illinois Medicaid, the referral could be backdated up to 14 days, which would allow primary care physicians to approve care at a retail clinic after the fact.) Retail clinic representatives in Illinois

believe that this referral process will result in the loss of their Medicaid and All Kids business.

In response to the increasing number of retail clinics in the state, the Illinois State Medical Society advocated for the introduction in February 2008 of House Bill 5372, the stated purpose of which was to “ensure patient safety and adequate follow-up care.”³¹ The new law would have authorized the Department of Public Health to issue a separate permit for each individual retail clinic, with exceptions for certain owners (for example, physician-owned or hospital-owned clinics). Inspections would have occurred after 90 days from the application date, and if approved, a one-year permit would have been granted. The bill also would have banned the sale of tobacco and alcohol in facilities that housed retail clinics.³² The Department of Public Health opposed the legislation due to “fiscal problems” and the bill was not passed out of the Rules Committee.

Shortly after House Bill 5372 was introduced, the CVS pharmacy company approached Rep. Elaine Nekritz, asking her to voice concerns to the FTC over what CVS perceived to be anticompetitive provisions in the bill. She communicated CVS’s concerns to the FTC, which came out strongly against many provisions of the bill (see below). During an interview with Rep. Nekritz by this study’s researchers, she expressed 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 that these alternative systems of care are worth pursuing.

Florida

Florida has 139 retail clinics, more than any other state. Although Florida allows nurse practitioners to own retail clinics, the state requires that they be closely supervised by physicians. Florida has recently tightened physician

Federal Trade Commission Concerns Regarding Illinois Retail Clinics Legislation

The FTC is charged with preventing unfair methods of competition and unfair or deceptive acts of practice in or affecting commerce.* With regard to Illinois’ proposed House Bill 5372, the FTC expressed concerns over provisions that might cause undue burdens on retail clinics, thereby limiting their ability to compete. These concerns are summarized below.

	AREA OF CONCERN	FTC COMMENTS
Advertising	Prohibition on clinics advertising comparison of their fees for available services with the fees of other facilities.	May prohibit or impede consumer access to truthful and non-misleading information about prices for basic medical services.
Clinic Operations	Restriction that physicians may be medical director of no more than two retail clinics. [†]	Undue and costly limitation; could give larger institutional health providers an unfair advantage if they use existing physician staff to fill this role; supervisory requirements for advanced practice nurses would be different in this setting than in other settings. [‡]
Insurance Payments	Subjecting retail clinics to the same copayment and deductible requirements as other providers for a similar service in a different setting.	This “non-discrimination provision” restricts the ability of third-party payers to negotiate favorable terms and to manage costs for health services.
Alcohol and Tobacco Sales	Prohibition against a clinic being located in any store that has alcohol or tobacco products for sale to the public.	Restriction could limit the supply of retail clinics or significantly raise clinics’ costs and prices; no similar prohibition exists for other health care facilities offering the same services or staffing, or for pharmacies and pharmacy services.

Sources:
 *Federal Trade Commission Act, 15 U.S.C., §45 (2007).
 †Illinois HB 5372 (2008).
 ‡Federal Trade Commission. Letter to Elaine Nekritz, May 29, 2008.

oversight of nurse practitioners and physician assistants, including those who work at retail clinics. In 2006, the Safe Supervision bill was enacted, limiting 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 the physician's primary place of practice.³³

Florida also has a unique licensure structure for corporate-owned clinics (60 MinuteClinics and 36 Little Clinics, for example, have this license).³⁴ This was a secondary consequence of an anti-fraud campaign regarding the automobile personal injury insurance industry, in which inappropriate diagnostic testing, inflated charges, and overutilization of treatments had resulted in soaring costs. In 2003, the legislature passed a law that required non-provider-owned 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.³⁵ The Health Care Clinic Unit is charged with denying, revoking, or suspending licensure of clinics that bill insurance companies for fraudulent claims.³⁶ A corporate-owned clinic must pay a \$2,000 two-year license fee, which is payable again at renewal or change of ownership. Applicants must provide evidence of sufficient assets, credit, and projected revenue to cover liabilities and expenses for the first 12 months of operation.³⁷ The renewal process consists of field visits and inspections that focus on the “business side” of clinics; concerns regarding actual care are referred to the state medical board.

Florida's Medicaid agency does not recognize retail clinics as a separate type of provider. As in other states, Medicaid reimburses practitioners who submit claims under their own Medicaid provider numbers, but the agency does not track this data. Nor has Florida Medicaid queried managed care organizations to see if they are paying claims from providers at retail clinics. (A spokesperson from WellCare, the state's largest Medicaid managed care plan, said its organization is not.)

New Jersey

New Jersey provides an example of retail clinics—several chains operate a total of 28 clinics—legally organizing in such a way that they are exempt from state regulation of their facilities.³⁸ The state's Department of Health and Senior Services regulates ambulatory care clinics with regard to the physical facility and infection control measures, but exempts private physicians' offices from regulation or licensure. Thus, retail clinics in New Jersey have chosen to organize as private physicians' offices, using a “closely held physician captive” model in which each clinic location is owned by an independent physician and staffed by nurse practitioners, but with all clinics managed by a larger corporate entity. The management services include hiring staff and billing patients and insurance companies.

The HealthRite clinics provide an example of how this model works. These clinics were originally organized as part of the non-profit AtlantiCare health system. However, this arrangement conflicted with New Jersey corporate practice of medicine laws, so in 2006 HealthRite restructured. HealthRite clinics are now independently owned by physicians in the for-profit AtlantiCare Physician Group. HealthRite has a management contract with AtlantiCare to provide billing and other services for the clinics. State regulations prohibit HealthRite from advertising its affiliation with the AtlantiCare hospital system, but the two entities link to one another's Web sites. HealthRite's CEO reports that almost everyone who uses HealthRite retail clinics also accesses other parts of the AtlantiCare system. He believes that integrated models of care will benefit both patients and health systems by facilitating treatment of all patients in the most appropriate settings. Both the HealthRite retail clinics and its after-hours clinic at an FQHC (see below) may help divert patients from AtlantiCare hospitals' emergency departments.

Expanding Care to the Underserved

One New Jersey retail clinic chain also operates an after-hours clinic at a federally qualified health center. Nurse practitioners who provide care at the HealthRite retail clinic site are encouraged to also work paid shifts at the FQHC's after-hours clinic. The retail clinic provides only limited services and does not accept Medicaid. However, the after-hours clinic offers a wider array of health services and accepts Medicaid reimbursement.

Massachusetts

Massachusetts is the only state in this study that has promulgated extensive regulations specifically intended to fit retail clinics into its health service delivery system, to limit the scope of services that clinics may offer, and to address the issue of fragmentation of medical care.

Limited Service Clinics

The Massachusetts regulations establish what they refer to as limited service clinics (LSCs). The state's Department of Public Health provides a full-time nurse practitioner to review all clinic policies and procedures in order to verify compliance with the regulations, including site visits to verify that construction and operations are consistent with submitted plans. These clinic regulations include:

- LSCs must make referrals to primary care practitioners, including physicians, nurse practitioners, and community health centers;
- Clinics must maintain rosters of primary care providers who are accepting new patients;
- Clinics must develop a process to identify and limit, if necessary, the number of their repeat encounters with individual patients;
- With patient consent, LSCs are to provide a record of each clinic visit to the patient's primary care practitioner; and
- Clinics must provide a toll-free number that will enable a caller to speak with a live practitioner during off-hours.

Extensive Stakeholder and Public Input Led to New Clinic Regulations

When CVS MinuteClinic requested permission to open several retail clinics in 2006, the Commonwealth of Massachusetts realized that its existing clinic regulations did not match the retail clinic model. The retail clinic would have needed a full clinic license, which would have required multiple waivers and left the state without the ability to limit the scope of services offered. As these waivers were being considered, other interested stakeholders began to convey their concerns. It became clear to the state that new regulations needed to be promulgated in order to address multiple issues, raised primarily by the medical community.

The Department of Public Health's Bureau of Health Care Safety and Quality developed proposed LSC regulations and convened two public hearings at which they received comments from stakeholders (including the FTC) and advocates. Although the legislature was not directly involved in writing the regulations, many letters of support for the retail clinic model were received from state representatives. Public health advocates expressed concern regarding tobacco sales, corporate profits, and fragmentation of care, among other issues. The Massachusetts Medical Society cited quality and safety concerns with regard to supervision of nurse practitioners. Input from the Massachusetts Academy of Family Physicians and the Massachusetts Medical Society helped shape regulations that, for the first time by any state, addressed strengthening retail clinic ties to primary care. Following the implementation of these regulations, CVS MinuteClinic opened its first LSC, in Medway, Massachusetts on September 17, 2008, and plans to open several more in the near future.*

*Source: "MinuteClinic Opens First Retail Clinic in Massachusetts Inside CVS/pharmacy Store." Press release, September 17, 2008 (www.reuters.com/article/pressrelease/idUS116475+17-sep-2008+prn20080917).

Safety Net Issues

The role of retail clinics in providing health care to safety-net populations was discussed during interviews for this study. The Massachusetts League of Community Health Centers was concerned that the emergence of retail clinics in an area served by community health centers might affect that area's Health Profession Shortage Area (HPSA)

designation, which triggers federal assistance to recruit scarce primary care practitioners and other federal grants to health centers.³⁹ With nurse practitioners in short supply in the state, the league also expressed concern about health centers vying with retail clinics for the same scarce practitioners and being unable to compete with the higher salaries likely to be offered by retail providers.

According to the Department of Public Health, the commissioner of health has encouraged health centers to open their own LSCs. Representatives from the league stated that they would want an LSC operated by a community health center to be part of its cost structure and therefore receive Medicaid cost-based reimbursement encounter rates for FQHCs.⁴⁰ Medicaid is expected to pay LSCs a rate that reflects their overall lower cost structure but this, according to the league, would not be sufficient to support a health center's costs. Cost-based reimbursement would allow a community health center to cover services for all patients regardless of their ability to pay, and to provide comprehensive services. The decision about whether an LSC would qualify for FQHC cost-based reimbursement, however, ultimately would be made at the federal rather than state level. At the time of this report, some health centers have indicated interest in opening LSCs but none has done so.

Medicaid and Limited Service Clinics

Massachusetts Medicaid has been developing ways to enroll LSCs as Medicaid providers; the agency plans to have this process in place in 2009. The state League of Community Health Centers expressed concern about LSC staff dealing with the complicated Medicaid eligibility and enrollment process and wondered what a clinic would do if a patient presents unsure about his or her eligibility. Would the LSC direct a patient to a community health center for Medicaid enrollment or eligibility verification and then have the person return to the LSC to receive care? The league felt that the best model would have retail clinics staffed with community health workers who, together with nurse practitioners,

can enroll people in Medicaid, connect them to a primary care doctor, and help ensure that they get there.

California

Four clinic chains are operating successfully in California, using various organizational models and reimbursement strategies. During interviews for this study, the governor's health care adviser indicated that the current state administration is supportive of the retail clinic model. The governor, it was reported, believes that retail clinics might help curb the growth of health care costs by providing affordable primary care in an accessible setting, while also alleviating the burden in the state's overcrowded emergency rooms.

Patient Safety and Quality of Care

Some clinics in California, such as primary care clinics, specialty surgery clinics, and birth centers, are licensed by the state while others, including those owned by individual physicians, groups of physicians, or hospital systems, are exempt from licensure.⁴¹ Retail clinics are exempt.

California allows nurse practitioners to provide health services and order medications under a standard protocol, if under the supervision of a physician. Nurse practitioners may diagnose conditions, order tests and drugs, and refer patients to other providers, according to specific written protocols developed jointly with supervising physicians. This scope of practice falls approximately in the middle of what other U.S. states allow.⁴² However, 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 up to four nurse practitioners. The governor has proposed increasing the ratio further, to one physician supervising up to six nurse practitioners. Some provider organizations have expressed concerns about this proposed expansion. The governor's office is also studying the issue of nurse practitioner supervision of unlicensed medical assistants.

The California Retail Clinic Landscape

There are more than 80 retail clinics in California, operating under various models and offering different types of services.*

- One of the largest clinic chains is MinuteClinic, with 61 locations in Southern California. MinuteClinic in California provides the typical array of retail clinic services—treatments for common illnesses, chronic disease screening, vaccinations—and provides tuberculosis testing. MinuteClinic accepts some insurance.[†]
- The QuickHealth retail clinic chain operates in nine locations in Northern California. QuickHealth is staffed by physicians as well as some mid-level practitioners, and therefore provides a wider scope of acute and chronic care services. QuickHealth does not accept any type of insurance, but provides consumers with a receipt they can submit to their insurers for reimbursement.[‡]
- Lindora Clinics has been operating in California since 1971. With nine locations in Rite Aid pharmacies, Lindora Clinics focus on weight loss and chronic disease management plus a limited range of acute care services. They do not currently accept insurance, but are negotiating with Blue Cross/Blue Shield.
- 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 care. Sutter Express Care clinics accept private health insurance and Medicare, but not Medicaid.**

Sources:

**Merchant Medicine*. April 1, 2008.

†MinuteClinic. "Locations" (www.minuteclinic.com/en/USA/CA/Clinics.aspx) and "Treatment and Cost at MinuteClinic" (www.minuteclinic.com/en/USA/Treatment-and-Cost.aspx).

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**Sutter Express Care (www.sutterexpresscare.com).

Access for the Underserved

Many stakeholders in California are cautious about the ability of retail clinics to extend access to those who are underserved in traditional health care settings. Retail clinics in California do not currently accept Medicaid. A representative of the California Department of Health Care Services, which administers the state's Medicaid program, noted that while retail clinics might provide

a convenient point of acute care for Medicaid patients, many Medicaid beneficiaries have chronic conditions that are not managed at retail clinics. Also, representatives of the California Department of Public Health noted that, for the most part, retail clinics have been locating in metropolitan areas in the state rather than in rural areas, which have a high proportion of the underserved.

Care Fragmentation

The California Primary Care Association would prefer that retail clinics be explicitly connected to the larger health care delivery system. It favors regulations that require retail clinics to refer patients to a regular source of care, such as a community health center, and to inform low-income patients about other treatment options. The California Academy of Family Physicians similarly worries about continuity of care between retail clinics and primary care providers.

Corporate Ownership and Organizational Issues

California's corporate practice of medicine laws⁴³ prohibit not only the direct employment of physicians by corporations but also management services organizations arranging for or advertising medical services, even where physicians own and operate the business.⁴⁴ However, retail clinics are permitted to organize as a "professional medical corporation" — the Lindora Clinic operates under this model — in which only physicians and other licensed professionals own shares.⁴⁵

Conclusion

Most policymakers in the six states of this study believe there is a role for retail clinics in expanding access to health services and an opportunity to lower medical care costs through reductions in unnecessary emergency department visits.

Patient Safety and Quality of Care

Direct licensing of health care facilities and providers gives states the ability to monitor and enhance patient safety and health care quality. Most states exempt private

physician offices from licensure and rely instead on individual provider licensing to assure quality of care in these settings. Massachusetts has taken the step of licensing retail clinics separately, distinguishing them from private physician offices and other health care facilities. This allows the state to tailor regulations to retail clinics without affecting other health care providers.

States also have decisions to make about the extent of oversight and scope of practice for health care providers, especially nurse practitioners, as they relate to retail clinics. Greater practice restrictions can increase retail clinics' operating costs and may dissuade or limit some clinic chains' business in the state. With regard to stakeholders on these issues, physician groups tend to argue that relatively stringent physician supervision of nurse practitioners is necessary to maintain quality and ensure patient safety. Nurse associations and clinic chains, on the other hand, tend to see things differently: They claim that retail clinics' use of evidence-based guidelines ensures the delivery of appropriate care and that nurse practitioners at these clinics are operating well within their scope of practice.

Access for the Underserved

The ability of retail clinics to reach the underserved is a function of several factors, including geography, services provided, cost, and payment structure. One of these elements is the willingness of clinics to accept Medicaid payments. To date, it appears that few Medicaid beneficiaries use retail clinics. But this could change if states make payment arrangements that recognize retail clinics as direct Medicaid providers. In Massachusetts, the Medicaid agency plans to recognize retail clinics as separate entities; they should be able to submit Medicaid claims sometime in 2009. In Illinois and Florida, retail clinic operators are discussing payment issues with Medicaid agencies. There are also Medicaid managed care plans in some states that allow beneficiaries to seek care at retail clinics. Low reimbursement rates may continue

to be a barrier to retail clinics accepting Medicaid as payment.

State policymakers may consider costs to the state as well as to consumers when thinking about support for retail clinics. Consumers who appropriately use retail clinics in lieu of emergency rooms may reduce their out-of-pocket costs at the same time they reduce a health system's overall costs. One study cautioned, however, 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 care. In addition, out-of-pocket costs for patients without insurance may be higher if they receive services at a retail clinic rather than at a community health center where services are provided on a sliding scale for certain income levels.

Care Fragmentation

There is concern that retail clinics would create or exacerbate fragmentation of care by deterring regular primary care or by not coordinating care with a patient's primary care provider. As part of its direct regulation of retail clinics, Massachusetts discourages care fragmentation and promotes medical homes by requiring retail clinics to connect systematically to primary care providers.

Conflicts of Interest

As retail clinics have proliferated, some physician groups have become concerned that the model encourages overuse of medications sold at retail clinic host stores. Other stakeholders have objected to retail clinics being located in stores that also sell tobacco or alcohol. Policymakers who wish to limit sales or advertising at retail clinics should be aware that the Federal Trade Commission has advised against regulations that are anticompetitive.

Corporate Ownership and Organizational Issues

State regulations restricting the corporate practice of medicine may limit the proliferation of retail clinics 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. States that desire to promote retail clinic growth may wish to clarify which organizational structures are legally permitted.

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ABOUT THE FOUNDATION

The California HealthCare Foundation is an independent philanthropy committed to improving the way health care is delivered and financed in California. By promoting innovations in care and broader access to information, our goal is to ensure that all Californians can get the care they need, when they need it, at a price they can afford. For more information, visit www.chcf.org.

ACKNOWLEDGMENTS

The authors wish to thank the California HealthCare Foundation for its support of this project.

This report benefited greatly from the thoughtful input of Neva Kaye, Senior Program Director of NASHP, and from the research assistance of Chris Cantrell of NASHP.

Our deepest thanks go to the following people, who gave generously of their time and expertise during background interviews and subsequent review of the draft of this document:

California: Kathleen Billingsley, Gina Henning, Cheryl Munir, Anna Ramirez, and Belinda Whitsett, Department of Public Health; Richard Figueroa, Office of Governor Arnold Schwarzenegger; Elia Gallardo, California Primary Care Association; Sandra Newman, California Academy of Family Physicians; Stan Rosenstein, Medicaid.

Florida: Brady Augustine and Michael Bolin, Medicaid; Christa Calamas, Florida House of Representatives Healthcare Council staff; Tad Fisher, Florida Academy of Family Physicians; Jeff Gregg, Bureau of Health Facility Regulation, Agency for Health Care Administration.

Illinois: Bill Bell, Department of Public Health; Peter Kale, Illinois Society for Advanced Practice Nursing; Rep. Elaine Nekritz; Steve Saunders, Medicaid.

Massachusetts: Paul Dreyer, Massachusetts Department of Public Health; Patricia Edraos, Massachusetts League of Community Health Centers; Caroline Fisher, Office of Sen. Richard Moore; Bill Ryder, Massachusetts Medical Society; Bill Schmidt, Medicaid.

New Jersey: John Calabria, Department of Health and Senior Services.

Texas: Judy Devore and Garry Walsh, Medicaid; Matthew Miller, Office of Rep. Rob Orr; Nance Stearman, Department of State Health Services; Lynda Woolbert, Texas Coalition for Nurses in Advanced Practice.

Retail Clinic Representatives: Web Golinkin, RediClinic; Cynthia Graff, Lindora Clinics; Lisa Loscalzo, The Little Clinic; Don Parker, AtlantiCare HealthRite; Caroline Ridgway, Convenient Care Association; Sandy Ryan, Take Care Health Systems.

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