

## EASY ACCESS, QUALITY CARE: The Role for Retail Health Clinics in New York

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Beginning in 2014, the Patient Protection and Affordable Care Act, signed into law in March 2010, is expected to significantly extend health-insurance coverage in New York by increasing Medicaid enrollment and offering federal subsidies for the purchase of private health insurance. However, there is no guarantee that the newly insured will be able to access the health-care system in a timely fashion as new demand for services outstrips physician supply.

After a similar insurance expansion in 2006, Massachusetts patients had to wait longer for physicians' office visits, and hospitals noted a surge in emergency-room use. This suggests that New York policymakers should look for new ways to expand access to health-care services well in advance of full health-reform implementation.

In this study, we examine whether retail health clinics (also called "convenient care clinics") have a role in alleviating pressure on overcrowded physicians' offices and reducing inappropriate emergency-room use, thereby lowering overall health-care costs.

Published research and interviews we conducted suggest that retail clinics have the skills and organization to serve as convenient and cost-effective providers of basic health-care services, provided that certain troublesome and unnecessary regulatory barriers are lowered or removed. In particular, research suggests that:

- Retail clinics offer readily accessible, high-quality care for a relatively limited set of basic health-care ailments ranging from minor skin infections to sore throats and earaches. For the services they offer, quality appears to be at least equal to—and, in some cases, superior to—that offered by other types of providers.
- Total costs (to insurers and patients) of care at retail clinics appear to be significantly lower than those incurred by other types of providers such as physicians' offices, urgent-care centers, and emergency rooms. Much of the lower cost can be attributed to the lower overhead associated with their retail location and widespread use of less expensive "mid-level" practitioners such as nurse-practitioners to provide care.
- A significant percentage of emergency-room visits could be safely and effectively redirected to retail clinics, saving millions of dollars annually.
- Patients are seeking care at retail clinics for appropriate conditions, and the availability of retail clinics does not seem to be increasing the utilization of such clinics for unnecessary care.
- Patient satisfaction with the care that they obtain at retail clinics is very high.

Finally, retail clinics may be able to help reduce Medicaid patients' utilization of emergency rooms for minor ailments, although this would require retail clinics as well as Medicaid officials to create reimbursement and enrollment procedures that encourage appropriate retail-clinic use. Previous reports have suggested that expanding retail-clinic utilization in New York could reduce health-care costs by \$350 million between 2011 and 2020.

There are currently fewer than twenty physician-owned health centers operating in New York State in retail stores such as Duane Reade and CVS, and they appear to be expanding slowly. Retail-clinic availability in New York State is also much lower than in other states with retail-clinic access. As of December 2010, New York ranked among the four lowest states in retail-clinic incidence per 100,000 residents, with just 0.1 clinics per 100,000 population, or 75 percent below the median for all states with retail clinics.

Among more affluent urban and suburban areas as well, New York is "undersupplied" with retail clinics. Although New York's Metropolitan Statistical Area (MSA) is the nation's largest by population, it ranks at the bottom of the thirty

largest MSAs in retail-clinic incidence, with just 0.1 retail clinics per 100,000 population, or more than 80 percent below the median.

Several regulatory barriers keep retail clinics from locating or expanding their operations in New York State:

- *Certificate of need*: The state requires health-care providers to obtain certificate-of-need (CON) approval before opening or expanding health-care facilities, including what are currently called Article 28 diagnostic and treatment centers—a provision that affects retail-clinic operators. CON approval can increase the cost structure for potential retail-clinic operators to a prohibitive degree. The time and uncertainty involved in seeking regulatory approval can also deter health systems that are considering opening new clinics in retail stores in the state.
- *Prohibitions on the corporate practice of medicine (CPOM)*: New York State currently prohibits retail-clinic operators from employing even nurse-practitioners and other mid-level practitioners upon whom the cost savings associated with the model depend.
- *Collaborative-practice agreements (CPAs)*: The requirement that nurse-practitioners engage physicians to conduct quarterly chart reviews can make the state less attractive than states that offer nurse-practitioners complete practice autonomy. The cap on the number of nurse-practitioners who can be monitored by a single physician can also drive up costs for clinic operators, which must hire additional physicians to provide oversight.

Many states do not require any additional regulation or licensure beyond that required of the providers who treat patients there. New York's regulations go well beyond this, either prohibiting or making it much more difficult for certain types of retail clinics to operate.

Ideally, legislators would repeal costly regulations that inhibit retail-clinic entry and expansion in New York. However, repeal appears unlikely. A second-best, but still effective, option would be to create a specialized licensure process for retail clinics that would streamline regulation of one or more retail-clinic models and allow corporations that operate retail clinics to employ providers directly, as dialysis treatment centers now do. Nurse-practitioners could also be allowed to practice outside of a collaborative-practice agreement, as nurse-midwives may do. Massachusetts enacted a similar set of reforms in 2008.

These reforms could focus on maintaining basic standards of consumer protection while leveling the playing field between physician-owned clinics and clinic operators that employ nurse-practitioners. An open-door policy toward retail clinics of all kinds would help ensure that federally mandated reforms not only expand insurance coverage but also improve patient access to cost-effective care.

## ABOUT THE AUTHOR

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# EASY ACCESS, QUALITY CARE: THE ROLE FOR RETAIL HEALTH CLINICS IN NEW YORK

Paul Howard

## INTRODUCTION AND OVERVIEW

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act into law. Beginning in 2014, the legislation is expected to extend health-insurance coverage to approximately 32 million previously uninsured Americans through a combination of Medicaid program expansion and federal subsidies for the purchase of private health insurance<sup>1</sup> on newly created state health-insurance exchanges.<sup>2</sup> In New York, one report projects that nearly half (1.2 million) of the state's 2.6 million uninsured residents will acquire coverage.<sup>3</sup> Hundreds of thousands of New Yorkers eligible but not enrolled in the state's Medicaid program will also be able to obtain automatic coverage on the exchange.

Even before reform was enacted, policymakers and medical groups recognized that an increasing shortage of primary-care physicians was threatening patients' ability to access primary care in a timely manner.<sup>4</sup> The complex and varied reasons for the shortage include: stagnation or decline in the size of reimbursements by private and public insurers; much more generous reimbursements for specialists, which medical school graduates therefore seek to become; and the rising demands of an aging population for care.

The shortage of primary-care physicians may threaten the ability of the Affordable Care Act to achieve some of its central goals, such as reducing overall health-care costs by relying on primary-care providers to promote disease prevention and manage chronic disease through the medical home concept.<sup>5</sup> The lack of access to primary care may also force newly insured patients to delay care or seek it in more expensive places, such as hospital emergency rooms.

The collateral effects of similar reforms enacted by Massachusetts in 2006 suggest that these concerns are not unfounded.<sup>6</sup> The expansion of insurance there seems to have exacerbated existing physician shortages and increased patients' wait times to see

primary-care physicians and certain specialists.<sup>7</sup> In July 2010, Massachusetts released data showing that use of emergency rooms in the state increased by nearly 10 percent from 2004 to 2008, disappointing hopes that broader insurance coverage would reduce it. The same report noted that "expanded coverage may have contributed to the rise in emergency-room visits, as newly insured residents entered the health-care system and could not find a primary-care doctor or get a last-minute appointment with their physician."<sup>8</sup> Although the Affordable Care Act contains a number of provisions designed to encourage physicians to enter primary care, experts continue to predict a national shortage of physicians in coming years.<sup>9</sup>

### The BlueCross/BlueShield Perspective in Minnesota

BlueCross and BlueShield (BCBS) of Minnesota contracted with MinuteClinic, a retail-clinic chain, in 2003 to provide in-network services to its members, the first partnership of its kind in the nation. Since then, tens of thousands of Minnesotans have visited retail clinics, enjoying very high levels of satisfaction with the range of services, quality of care, and cost savings that they provide. BCBS continues to reimburse MinuteClinic, as well as Target Clinics and several other operators.

Having discovered that costs are lower when patients choose clinics for treatment of minor ailments, BCBS has waived clinic co-payments, making the cost to the patient of a clinic visit cheaper than a visit to a primary-care physician. Indeed, clinics have become so popular that BCBS frequently receives requests, either directly from members or through their agents, to add retail clinics. As for the quality of care, it is equal to that offered by traditional medical offices.<sup>10</sup>

Before admitting a clinic to its network, the plan determines whether its members have a need for the service in the clinic's area. If there is in fact a need, the plan reviews the applicant's license and board certification, including its Drug Enforcement Administration registration and the status of its medical malpractice insurance. The plan also checks to see whether any sanctions have been lodged against the provider. After all these requirements have been met, a standard contract can be offered. (Full details of the credentialing process are available at [www.bluecrossmn.com](http://www.bluecrossmn.com).)

The clinics are particularly useful for filling gaps in care, especially on nights and weekends. Before the advent of retail clinics, members had only a couple of choices: delay care; or utilize an emergency room (ER) or urgent-care center.

As long as the member shares his primary-care provider's contact information with the retail-clinic operator, the retail clinic will forward to the provider information obtained during the member's visit, minimizing possible disruptions in care continuity. Increasingly, traditional providers have been recognizing the value of retail clinics; some, such as the Mayo Clinic, have even opened their own. The Minnesota market seems to recognize the ability of both models to serve a particular niche.

Among the scholars, retail-clinic operators, and policymakers with whom we spoke for this study, there was broad agreement about the importance of developing additional venues where patients could access primary-care services. Access problems are probably going to worsen over the next several years as a result of the federal health-reform law. Without convenient alternatives,<sup>10</sup> more people will seek nonemergency, even routine, treatment at emergency rooms, the most expensive venue for such care. Retail clinics could become just such a convenient alternative, at least for treatment of certain common health problems.

The benefits that health clinics offer may not be limited to what goes on inside them. They may also have a salutary impact on other types of providers.<sup>12</sup> Their emphasis on convenience and customer satisfaction could encourage other providers to be more flexible in scheduling appointments. These providers might also develop more intensive ways of using nonphysicians on staff. And by following evidence-based protocols, which have proved to produce superior medical outcomes, they would be establishing a benchmark that other providers might feel obliged to meet. Finally, by assuming the treatment of minor illnesses, they could increase the efficiency of the overall health-care system by allowing more highly trained providers to devote their skills to treating patients with complex ailments.

These improvements are likely to result in significant cost savings. Indeed, a 2010 report on reducing health-care costs in New York State found that expanding access to retail clinics could reduce the health-care spending of public and private payers by \$350 million in 2011–20.<sup>13</sup>

New York, like other states, will have to find new ways to meet the surge in demand precipitated by the advent of federally mandated universal insurance coverage. The states must as well contain costs in an expensive health-care system that relies heavily on hospital and emergency-room care. Part of this challenge could be met by expanding access to basic primary-care services in nontraditional settings such as retail health clinics.

## PART I: RETAIL CLINICS—THE BASICS

### Structure and Function

Christensen, Grossman, and Hwang (2009) describe retail clinics as a disruptive innovation that gives consumers a “more convenient and affordable way to access basic health-care services, which are based on evidence-based protocols.” The model assumes a store setting (although some clinics do operate as “stand-alone” facilities in malls or other retail areas), most often a pharmacy outlet in which “mid-level” providers like nurse-practitioners or physicians’ assistants provide treatment. No appointments are required, and the vast majority of retail-clinic encounters are concluded in twenty minutes or less.

With lower wages and overhead than physicians’ offices, urgent-care<sup>14</sup> clinics, or emergency rooms, retail clinics appear to realize substantial economies by providing a limited menu of basic services, including treatment of basic ear, throat, urinary-tract, and skin infections; physicals (for work and school); and immunizations. Basic wellness or screening services (for chronic conditions such as diabetes and high cholesterol) are also routinely available at retail clinics.

The relatively narrow range of their repertoire of services enables them to provide superior care. Patients who are suffering from more complex, medically challenging problems receive referrals. With those services they do offer, clinics strictly follow treatment protocols, unlike much of American medicine. As a result, they do as well as, or better than, other providers in delivering care.

One scholar with whom we spoke said that she believed that retail clinics can play an important role in two areas of what we might call “basic health care”: immunizations and blood-pressure checks, which should be made more widely available; and acute care for basic health problems such as common infections, which a broad assortment of conveniently located clinics would be in a position to address immediately.

Retail operators and their advocates suggest that the model can also improve access to basic health care for the uninsured, the underserved, and even, perhaps, Medicaid recipients. Diversion of these patients from emergency rooms, to which they frequently turn, could save private insurers and the government considerable sums.<sup>15</sup> Some health-care experts and clinic operators further argue that retail clinics could handle the routine screening and monitoring of patients with basic chronic illness. Doing so would promote compliance with treatment regimens and help prevent diseases from going untreated, which usually results in high-cost health-care encounters.<sup>16</sup>

#### Retail Clinics in the U.S.: Where Are They Located?

Pharmacy	73 percent
Grocery Store	15 percent
Mass Merchandiser	7 percent
Other	4 percent
Source: Rudavsky et al. (2009)	

## History and Current Market Structure

Two basic questions regarding any potential health-care innovation are: Is it financially sustainable? And is it replicable? When the first retail clinics opened in 2000, they did not accept insurance, relying entirely on out-of-pocket payments. Today, the vast majority of clinics do accept insurance, and they depend on it financially. Rudavsky et al. (2009) report that almost all retail clinics accept private insurance (97 percent) or Medicare fee-for-service reimbursement (93 percent). Far fewer (60 percent) accept Medicaid, which does not appear to be a significant source of revenue for them. Mehrotra et al. (2008), however, found that out-of-pocket payments remain a significant (30 percent) source of revenue.

Like many promising new business models, retail clinics went through a period of rapid expansion and investor optimism, which was followed by retrenchment and more cautious growth. Rudavsky et al. (2009) report that in its first five years, the industry added only twenty-nine clinics; then growth accelerated rapidly, with the industry increasing its number of outlets more than tenfold between 2006 and 2008. This trend reversed in 2009, with the industry closing about 5 percent of its outlets. However, growth is expected to revive as the overall economy revives.<sup>17</sup> As of July 2010, thirty-eight different operators ran 1,177 retail clinics in the United States. Three large operators (CVS/MinuteClinic, Walgreens/Take Care, and the Little Clinic) comprise about 80 percent of the market.<sup>18</sup> Nationally, through the first six months of the 2010, forty-one clinics opened and fifty-two closed, continuing the downsizing trend. New York currently hosts fifteen total retail clinics, seven hosted by MinuteClinic but owned and operated by Kimberly J. Henderson, MD, and eight hosted by Duane Reade (DR) but owned and operated by DR Walk-In Medical Care.<sup>19</sup>

At the height of the retail-clinic boom, analysts as well as operators predicted the rapid establishment of several thousand retail outlets nationwide. The current rate of growth does not support their optimistic outlook, but there are signs that the industry is poised for a resurgence.<sup>20</sup> One industry consultant noted that the present contraction represents nothing more than the consolidation and restructuring of a maturing industry. A retail-clinic operator we interviewed for this study confirmed that site selection has only recently become sophisticated, giving operators and investors more confidence that newly opened locations will be self-sustaining. Scholars and industry analysts agree that individual clinics require significant daily traffic flow to break even, which is harder to achieve outside the peak winter cold and flu season.<sup>21</sup>

### Retail Clinic Industry Overview

Initially operated by small, independent companies, the majority of retail clinics are now “fully owned subsidiaries” of Fortune 50 corporations. CVS (MinuteClinic), Walgreens (Take Care), and Target (Target Clinic) operate 73 percent of all U.S. clinics (Rudavsky et al., 2009).

The entry of major corporations into the retail-clinic market helped initiate a period of rapid retail-clinic expansion from 2006 to 2009. As a result of their presence, the market has a stronger financial base.

As a result, several smaller firms—which are typically less well capitalized and thus more vulnerable to short-term fluctuations in revenues—have closed, and some of the larger operators have scaled back their operations. For instance, the Kroger Grocery chain recently reduced the number of its Little Clinic outlets from 147 to 117.<sup>22</sup> Wal-Mart, after experimenting with several retail-clinic strategies, announced that it would henceforth expand only in partnership with local health-care systems; as a result, several small regional chains closed the clinics that they operated in Wal-Mart stores.<sup>23</sup>

However, the period of retrenchment may be ending. CVS/MinuteClinic, the industry leader, with 500 clinics operating in twenty-five states, recently announced that it expects to double the number of its MinuteClinics over the next five years,<sup>24</sup> partly in response to the aging of the U.S. population and partly in the expectation that health-care reform will increase demand from newly insured patients for basic health-care services.<sup>25</sup> Another industry leader, Walgreens, the owner of 350 Take Care Clinics in nineteen states, recently purchased New York-based Duane Reade and may be considering expanding its retail-clinic operations.

The Deloitte Center for Health Solutions (2009b) projects 10-15 percent growth in retail clinics in 2010-12, and over 30 percent growth by 2014. Indeed, the scholars, operators, and policymakers we interviewed for this study were nearly unanimous in their belief that pressures on primary-care access will increase after the full implementation of the Affordable Care Act in 2014 and that retail clinics may help reduce these pressures as well as overcrowding in hospital emergency rooms. (As we noted earlier, Massachusetts's experience with health-care reform suggests that the increase in insurance coverage may also increase the use of emergency rooms and lengthen wait times for primary-care visits.<sup>26</sup> Indeed, Massachusetts created a special regulatory pathway for retail clinics in 2008 in part to improve access for consumers with minor health problems.)<sup>27</sup>

Increasing numbers of physicians' groups and health systems have endorsed the concept in the strongest

possible way—by going into business with retail-clinic operators or opening their own clinics. Hospitals, health systems, and physicians' groups account for over half of all operators, according to a RAND study, although they account for only 10-12 percent of all clinics, according to 2008 estimates.<sup>28</sup> Retail clinics benefit from the brand recognition and its associations with quality offered by well-established health systems such as Geisinger and the Mayo Clinic.<sup>29</sup> For instance, Wal-Mart has begun co-branding in-store clinics with trusted local health systems.<sup>30</sup>

The clinic model is also expanding outside of the retail space and adapting new models to reach the underserved. In 2009, the consulting firm Mercer reported that 10 percent of the 345 employers surveyed were considering opening primary-care clinics on premises. Lowe's has already done so under the auspices of Careworks, the Geisinger Health System clinic brand.<sup>31</sup> Also, several Federally Qualified Health Centers (FQHCs) and community health centers have expressed interest in opening clinics in retail areas or in retail stores to expand access for underserved populations.<sup>32</sup> Wal-Mart has also expressed interest in hosting (on a landlord-tenant basis) local community health centers to offer retail-clinic services to its customers.

The Affordable Care Act calls for a substantial increase in funding for FQHCs, and it is expected that the universal coverage it mandates will increase demand at community health centers and thus revenue. Scott (2010) estimates that the number of community health centers could double over the next five years. To meet the need for a rapid increase in capacity and generally expand access, some community health centers are looking into opening satellite offices in retail locations, where they would offer a streamlined menu of services.

Scott (2010) also surveyed several health centers that were either considering expanding into retail settings or had expanded into such settings, reporting that two community health centers that did adopt the retail-clinic model were able to redirect about 2,000 visits from emergency rooms to their retail clinics, achieving savings of about \$3 million over six to eight months of operation.<sup>33</sup>

In sum, although the industry is experiencing the same recessionary stresses as the broader economy, increased demand due to health-care reform and the entry of new operators suggest that the retail-clinic market is poised for new growth once the economy improves.

## Geographical Distribution of Retail Clinics

The geographical distribution of retail clinics appears to be the product of a number of complex variables, including state regulations dictating the scope of practice of mid-level providers (and the degree of oversight, if any, that physicians must exercise); the prohibition of the corporate practice of medicine (CPOM), which prevents clinics from placing caregivers, including nurse-practitioners, on payroll; varying licensing standards; the varying supply of mid-level practitioners; the relative availability of insurance reimbursement for retail-clinic services; and the existing level of access to primary care and its rate of utilization.

The uneven distribution of such clinics nationwide suggests a wide variety of legal, regulatory, and economic circumstances on the ground. Rudavsky et al. (2009) estimate that as of August 2008, forty-two operators were running 982 clinics in thirty-three states.<sup>34</sup> Of these, 43 percent were located in the South and 31 percent in the Midwest. Nearly half (44 percent) were located in just five states: Florida, California, Texas, Minnesota, and Illinois. Sixteen states and the District of Columbia had no clinics. (But see on p. 18 the table, “Retail Clinic Presence by State,” in which HealthCare 311, using a different methodology, identifies only five states as lacking clinics in December 2010, twenty-eight months after the Rudavsky survey was conducted.) Nearly 90 percent of clinics were located in urban areas. Rudavsky et al. also estimate that 11 percent of the U.S. population lives within a five-minute drive of a retail clinic and that 29 percent lives within a ten-minute drive.

When they are considering entering a new market, retail-clinic operators report, they first look at state regulations likely to have an impact on their clinics.

Retail clinics are a low-margin business, and the costs that regulations impose could deter even the largest operators from entering a state or expanding their operations there. A regulatory issue that tests the very viability of the clinic model is the scope of practice that the various states delineate for nurse-practitioners and physicians’ assistants. One representative of a leading national retail-clinic chain we spoke with said that her company’s interest in developing a “national footprint” has been thwarted by some states’ narrow delineation of the scope of practice permitted such practitioners. States can also substantially add to the cost structure of retail clinics by capping the number of nurse-practitioners that may be monitored by a single physician under collaborative-practice agreements (CPAs)<sup>35</sup> and by requiring physicians, as Texas does to some extent, to be physically present at least part of the time when collaborating nurse-practitioners are providing care.

The strictest CPOM states preclude corporations even from employing physicians’ assistants and other mid-level practitioners. New York and California are two of the strictest. Other rules (which we will discuss in our section on state regulations) can require what are termed “clinics” to meet construction requirements going well beyond basic health or fire-code standards or to exclude from the menu of services available to patients even procedures for which nurse-practitioners have been trained and licensed. Both types of regulation can drive up operating costs and make it impossible for clinics to turn a profit.<sup>36</sup>

Clearly, the cumulative costs of regulation affect the feasibility of doing business in a given state or expanding operations there. But some regulations are greater impediments than others. Firms such as Wal-Mart that serve simply as clinics’ landlords worry that the local health systems that would be their lessees may not be able to obtain certificate-of-need (CON) approval for new retail clinics, or may be able to do so only after a long, onerous, and expensive process that proves to be not worth pursuing. Retail-clinic owner/operators worry about CPOM and scope-of-practice rules affecting nurse-practitioners, on whose availability the economic

viability of the model depends. In New York, as we will discuss later, retail-based clinics (or “health centers”) that are operated by physician-owned professional corporations (and thus classified as physicians’ offices) do not face any special regulatory requirements or barriers.

## Concerns and Questions

Retail clinics first appeared only eleven years ago. Consequently, peer-reviewed studies of the phenomenon are relatively few in number, making sweeping judgments about their quality and their potential effect on the overall health-care system difficult to form.<sup>37</sup> This has not prevented some physicians’ associations from expressing concern that the very attributes that make retail clinics attractive to consumers (particularly their retail setting and reliance on mid-level practitioners) may:

- Reduce the quality of care
- Disrupt the physician-patient relationship, a result of which could be limiting opportunities to provide preventive services
- Induce unnecessary care (such as the overprescribing of antibiotics)
- Reduce the financial sustainability of primary-care medical practices

Indeed, some researchers have cautioned that the very convenience of retail clinics may actually induce an increase in the number of medical visits for ailments that do not require medical treatment, adding costs to an already expensive system.

Perhaps the most serious concern is how (or whether) retail clinics fit into one of the central goals of U.S. health-care reform: creating and implementing a comprehensive, integrated framework for health-care delivery. These would be centered on Accountable Care Organizations (ACOs) that direct “bundled” health-care payments to the most efficient and effective providers. One of the most frequent criticisms of the current U.S. health-care system is that it is severely fragmented, with relatively little communication among providers or accountability for patients’ care, particularly of serious chronic conditions. Policymakers and providers may genuinely wonder whether re-

tail clinics’ provision of episodic treatment will only increase fragmentation and frustrate reformers’ efforts to improve continuity and comprehensiveness of care.

The following section presents an overview of several key studies in the academic literature that examine questions relating to concerns about retail clinics’ impact on health-care costs and quality. It also discusses important limitations of the existing research and areas for further exploration.

## Retail Clinics: Literature Review

### A. Whom Do They Serve?

Research indicates that retail-clinic users are different in some significant respects from users of other primary-care providers. Mehrotra et al. (2008) compared details of 1.3 million visits to retail clinics in 2000-2007 with national data on visits to primary-care physicians and emergency departments. This study found that retail-clinic users were disproportionately young: 43 percent of them were between the ages of eighteen and forty-four, while only 23 percent of the patients of primary-care physicians belonged to that age group. Retail-clinic users were more likely to lack a regular relationship with a primary-care physician: only 39 percent had one, as compared with 80 percent of patients nationally who identified a usual source of care.

Drawing on administrative claims data for 2004-07 from a large national insurer that reimbursed charges of retail clinics that were in-network providers,<sup>38</sup> Parente and Town (2009) found that users of retail clinics were younger than nonusers and in better health. They were also more likely to be female and living in less affluent zip codes in proximity to a clinic.

Some supporters of retail clinics have argued that the clinics would make medical care more available to low-income or other underserved populations. As yet, however, retail clinics appear to be less common in areas with such populations than they are in other areas. Rudavsky and Mehrotra (2010) reported that while 21 percent of the overall U.S. population resides in a designated health-professional-shortage

area (HPSA), only 12.5 percent of retail clinics were located in one. The authors also note that “compared with other urban residents, the population that lives within a 5-minute retail clinic catchment area has a higher median household income ... is better educated ... [and] is less likely to live below the poverty line.”<sup>39</sup> Distributions by gender, age, and number of uninsured match the general pattern for urban residents.

In short, Rudavsky and Mehrotra report there is little evidence that retail clinics are “preferentially” located in areas with underserved populations. This is to be expected, since “retail clinics are most commonly run by for-profit companies who want to reach as broad a segment of the whole population as possible.... [P]rimary care physicians’ offices are [also] often preferentially located in higher-income areas.”<sup>40</sup> Urban areas also tend to offer the economic advantage of heavy foot traffic. Yet the greatest need for new primary-care options lies in rural areas, with their low population densities.

In contrast to Rudavsky and Mehrotra, who analyze the communities surrounding retail clinics, Tu and Cohen (2008) analyze a survey of retail-clinic *users* and find some support for the thesis that retail clinics may expand access for low-income and minority populations. They theorize that retail clinics benefit “the uninsured and those with high-deductible health plans who must shoulder the full cost of care out-of-pocket.... [C]linics could represent a more affordable, accessible option than the alternatives, especially hospital emergency departments.”<sup>41</sup> Also, lower-income residents with less flexible work arrangements could benefit from retail clinics’ longer hours and walk-in policies.

Tu and Cohen report that about a third of clinic users were uninsured and that such users utilized the clinic at a higher rate than other groups. Underserved populations as well relied on retail clinics at greater rates than other groups. Families that reported “not getting or delaying needed medical care at some point in the previous 12 months were almost 2.5 times as likely to have used retail clinics as families without such problems.”<sup>42</sup> In addition, “minorities,

especially Hispanic consumers, were more likely to use retail clinics than white consumers.”<sup>43</sup> Retail-clinic users reported convenient hours and location, flexible scheduling, and low cost as major reasons for using retail clinics. More than one in three users cited the lack of a usual source of care as a reason for choosing a retail clinic over other care options, such as an emergency room. Tu and Cohen warn: “If the growth of retail clinics falters, underserved groups already facing access pressures may suffer from the loss of alternate sources of care more than the rest of the population.”<sup>44</sup>

Overall, the research suggests that, like primary-care physicians’ offices, retail clinics tend to be located in affluent neighborhoods. However, it also suggests that for low-income and minority users of retail clinics that operate in their neighborhoods or nearby, retail clinics are an important and affordable care option. One scholar we interviewed who has studied retail-clinic access among the underserved says that there are a significant number of retail clinics in underserved areas but many more in “more affluent” areas. Still, he noted, studies have found that a “fair number” of the uninsured rely on the clinics for basic health services. He also recommends testing the model of FQHCs located in retail stores as a way of expanding access for the underserved.

Retail-clinic operators have reported that low Medicaid reimbursements<sup>45</sup> and the difficulty in becoming registered Medicaid providers act as disincentives for serving as many Medicaid recipients as they might otherwise serve. There is also some evidence that Medicaid’s requirement of a primary-care physician’s prior approval of visits to another provider prevents some beneficiaries with immediate medical needs from visiting participating retail clinics, out of unwillingness or inability to pay out of pocket.<sup>46</sup>

The research literature and interviews we conducted for this project suggest a number of other factors that may be constraining the use of retail clinics by Medicaid recipients or others living in underserved areas:<sup>47</sup> for-profit firms’ location in more affluent urban and suburban areas; low Medicaid reimbursement rates (and slow reimbursement when claims are sub-

## RAND Retail-Clinic Snapshot

RAND researchers have published the most extensive empirical analyses of the retail-clinic industry. In a 2010 synopsis of eight RAND Corporation studies on retail clinics published in peer-reviewed journals (*Health Care on Aisle 7*), RAND reported that nearly 90 percent of retail-clinic visits were for “ten simple acute conditions and preventive care: upper respiratory infections, sinusitis, bronchitis, sore throat, immunizations, inner ear infections, swimmer’s ear, conjunctivitis, urinary tract infections, and screen blood tests. The same conditions account for 18 percent of visits to primary care physician offices and 12 percent of [emergency department] visits.”

Although the RAND research did not examine the impact of retail clinics on existing physician-patient relationships, it found notable that, “in multiple studies, the majority of retail clinic patients did not have a regular provider, so there was no relationship to disrupt.... The profiles of [emergency department] and retail clinic users were similar, and ... it is possible that retail clinics could be a substitute site of care for some patients who now seek care in [emergency departments].”<sup>49</sup> These served a population that lacked regular access to health care, treated a limited number of conditions for less cost than physicians’ offices or emergency departments charged, and had comparable quality scores, according to metrics developed by RAND.

However, RAND found little evidence that the clinics improved access to care for the medically underserved. It also found that clinics tended to be located in more affluent urban areas. While data showed that one in four patients at retail clinics utilized an emergency room when a retail clinic wasn’t available, clinics’ limited scope of practice and low fees for minor treatments suggest that their overall impact on overall U.S. health-care spending would be modest “at best.”

mitted); and complex Medicaid provider enrollment procedures. However, community health centers, including FQHCs, which serve underserved communities, are actively considering expanding services into the retail environment.<sup>48</sup> Operators we interviewed that did not currently accept Medicaid indicated that they remain very interested in developing partnerships with state Medicaid programs, and would participate in pilot programs offering ways of reducing undue reliance on emergency rooms if they led to more generous reimbursements.

### B. Are Retail-Clinic Users Satisfied with Their Experience?

Patient satisfaction with retail clinics appears to be very high. Hunter et al. (2009) report that 96 percent of patients were satisfied or very satisfied with their care; 96 percent also report waiting “not at all” or “less” than they had expected. A 2008 Harris Interactive/*Wall Street Journal* online poll asked, “Overall, how satisfied were you with your or your family member’s experience using an on-site health clinic in a pharmacy or retail chain?” Nearly 90 percent of respondents indicated they were very or somewhat satisfied with the quality

of care; 86 percent were satisfied with the cost; 93 percent with the convenience; and 88 percent thought that clinics had “qualified staff to provide care.”

In a small study, Wang et al. (2010) conducted interviews with sixty-one patients at six retail clinics operated by two different companies (Sutter Express and Quick Care) in California. The top three reasons patients gave for using retail clinics were: short travel distance from home or work (77 percent), reasonable pricing (69 percent), and fast service (62 percent). Interestingly, 36 percent gave as their reason dissatisfaction with other providers such as primary-care physicians and emergency departments. Wang recounts, “One theme of the patient narratives was a ‘triage’ decision by the patient, taking into account the severity of their symptoms, their insurance status, and ability to pay for health care. This was illustrated in the idea that for appropriate minor conditions, retail clinics seemed a superior choice to urgent care centers or the [emergency department] ... [or] provided a reassuring alternative to the wait-and-see approach of self-care because they could now ‘get a health care professional’s opinion.’”<sup>50</sup>

If a retail clinic was not an option, patients' next strategy was to see a physician when they could (38 percent), or "wait and see" whether their condition resolved itself (30 percent). Emergency care (26 percent) and urgent care (18 percent) were the next alternatives. The uninsured were much more likely than the insured to seek care at an emergency department.

Overall, Wang et al. found patient satisfaction to be as high as that found in self-reported surveys conducted by retail-clinic operators and in direct consumer surveys. They conclude that "our study lends credence to the potential for retail clinics to serve as a mechanism to deter unnecessary [emergency department] visits and thereby help alleviate [emergency department] overcrowding.... With many public health facilities and safety net hospitals facing budgetary constraints, retail clinics may offer a market-based solution to provide health care at a price that is sensitive to patients' willingness and ability to pay."<sup>51</sup>

### C. Metrics of Quality and Cost

One of the most serious concerns about retail clinics is that they might have a negative effect on the quality of patient care. A second concern is that in the pursuit of profit, they may prescribe too many pills or provide unneeded care. Physicians, in particular, have expressed concern that the addition of a new mode of service may further fragment care.

Researchers have tried to determine whether retail clinics offer more cost-effective care than other providers do. At first glance, retail clinics' fees appear to be significantly lower than those charged by other providers for the same services. Prices are clearly listed and range from \$50 to \$75, with the majority priced around \$60. Appointments with physicians can range from \$55 to \$250.<sup>52</sup> As we discussed earlier, retail clinics have gone from being a "cash only" business to one increasingly covered by the benefits packages of employers, 42 percent of whom offered these packages in 2009, according to the National Business Group on Health.<sup>53</sup> Co-pays are roughly what they are for visits to physicians' offices, and some insurers waive these fees entirely.

### ***Clinical Guidelines, Quality of Care, and Preventive Care***

Woodburn et al. (2007) examined 57,331 MinuteClinic visits for adherence to clinical guidelines for the treatment of acute pharyngitis (sore throat). Nurse-practitioner and physician-assistant staff at MinuteClinics seeing patients who received a negative result from the rapid strep test adhered to such guidelines in 99.05 percent of cases and did not dispense antibiotics, while 99.75 percent of patients with a positive rapid strep test received an "appropriate antibiotic prescription."

By way of comparison, Woodburn cites one national survey finding that 70 percent of adults presenting with pharyngitis were inappropriately prescribed an antibiotic. Woodburn et al. conclude that "clinical support tools built into an [electronic medical record] and practitioner staff training related to adhering to nationally established, clinical practice guidelines" were responsible for MinuteClinic's very high rates of appropriate care management.<sup>54</sup> An earlier (2006) study from the Minnesota Community Measurement Health Care Quality Report gave MinuteClinic a 100 percent rating for the treatment of pediatric sore throats; for the sixty other providers rated in the report, "ranging from large medical groups to Minnesota pediatric practices," the average score was 81.9 percent.<sup>55</sup>

In one of two studies we reviewed that rely on HealthPartners data in Minnesota, Mehrotra et al. (2009) compared the treatment at MinuteClinic of three common acute conditions (ear infections, sore throats, and urinary-tract infections) as to cost of care, quality of care, and rates of preventive care delivered following treatment in physicians' offices, urgent-care clinics, and emergency departments. The three conditions selected for study account for nearly half of all retail-clinic visits nationally. Evidence-based treatments have been developed for all three conditions.

For their study, Mehrotra and his colleagues collected claims for 2005–06 from HealthPartners, aggregating the initial encounter, any and all follow-up, testing, and prescriptions into a single episode.

Costs included co-payments. Cases were matched according to condition, age, sex, co-morbidity, and income (averaged for the census tract of residence). Determination of the extent of preventive care provided depended on how many of the following services a patient received on an initial visit or within three months:

- Vaccination
- Mammogram
- Pap smear
- Colon-cancer screening
- Cholesterol testing

Mehrotra et al. found savings comparable in size with those found in an earlier study by Thygeson (2008), which we discuss below. Total costs (including patient co-payments) of episodes at retail clinics (\$110) were significantly lower than their counterparts at physicians' offices (\$166) and urgent-care centers (\$156) and much lower than they were at emergency departments (\$570). Mehrotra and colleagues note that the differences primarily reflected the providers' cost of evaluating and managing the patients' care. Unlike Thygeson (who theorized that there might be a small increase in follow-up treatments), they found that every type of treatment venue generated roughly the same number of follow-up visits, with the exception of emergency departments, which showed significantly higher follow-up rates.

Quality scores were similar for retail clinics, physicians' offices, and urgent-care centers, but lower for emergency departments. Mehrotra et al. note that "for most measures, quality scores of retail clinics were equal to or higher than those of other care settings." The sole exception was the smaller proportion of urine cultures performed for high-risk patients at retail clinics.

Roughly the same proportion of patients received preventive care at their initial visit or within three months at retail clinics, physicians' offices, and urgent-care facilities. Emergency departments, not surprisingly, posted lower rates of preventive-care services.<sup>56</sup> Another concern expressed about retail clinics—the risk of their disrupting patient-physician

relationships—does not find a basis in the literature. Many retail-clinic users report that they don't have a usual source of care, or thus any relationship to disrupt. Although evidence on the impact of retail clinics on preventive-care services received by patients who use retail clinics is limited, none of it indicates that they are responsible for a decrease in such care. (Scholars we consulted confirmed that, according to the available data, treatment at retail clinics had no impact on the likelihood of receiving preventive care.)

Mehrotra et al. conclude that the availability of retail clinics for the treatment of mild illnesses is likely to lead to efficient "self-triage"<sup>57</sup> by patients, bringing about a better allocation of health-care resources.

### ***Retail-Clinic Costs Compared with Costs of Other Providers***

There seems to be broad agreement that retail clinics are low-cost providers. Thygeson et al. (2008) examined the claims database of HealthPartners, a non-profit insurer, on retail-clinic use and costs over four twelve-month study periods from November 2002 to October 2006 (MinuteClinic became a provider available to members in 2003). Thygeson reported that requests by many large employers for data on the use, cost, and quality of MinuteClinic services precipitated the study.

The researchers identified five conditions of interest (conjunctivitis; otitis media; minor throat infections, including tonsillitis, adenoiditis, and pharyngitis; acute sinusitis; and infections of the lower genitourinary system) for the study periods, beginning twelve months prior to MinuteClinic's inclusion in the HealthPartners network of providers and including the three subsequent twelve-month periods, from which those above age two who were covered by private insurance suffered.

Researchers found that total costs of care were lower at retail clinics. On average, the cost was \$51 less at MinuteClinic than it was at an urgent-care facility; \$55 less than at a primary-care physician's office; and \$279 less than it was in an emergency department.

Supporting the findings of other researchers, Thygeson et al. found that retail-clinic users were in better initial health than recipients of treatment rendered by other types of providers but concluded that this did not account for the significant difference in cost between retail clinics and the others.<sup>58</sup> They also reported a slight (2 percent) increase in follow-up treatments from episodes initiated at a MinuteClinic location but noted that the increase could also be due to the appropriate referral of more complex ailments to more qualified providers.

Parente and Town (2009) tried to find out whether retail clinics induce patients to seek care unnecessarily. In a review of claims data from United Health, Parente and Town estimate that, even after adjusting for the possibility that retail clinics attract patients in better overall health than other providers do, “retail clinic utilization significantly reduces medical care expenditures” by plan members who used them and that their availability did not induce plan members to seek treatment more often than they had before such clinics were available.<sup>59</sup>

Corroborating other studies’ findings, Parente and Town found that, for conditions commonly treated at retail clinics, total costs of care were 75 percent (\$153) less than costs incurred at physicians’ offices, and 119 percent (\$295) less than costs incurred within emergency departments or urgent-care settings. Nor were these savings dissipated in other ways. For example, the authors did not find any evidence that patients who used retail clinics increased their reliance on emergency departments thereafter or were admitted to hospitals more often. While some physicians’ groups have expressed fear that continuity of care of chronically ill patients who relied on health clinics for treatment of acute episodes would be disrupted, Parente and Town could discern no impact that clinics had on “cost, hospital admission probability or the likelihood of emergency department use” by this group.<sup>60</sup>

Finally, extrapolating from United Health data, Parente and Town suggest a cumulative consumer benefit<sup>61</sup> of \$449 million, or 0.04 percent of total private health-care spending, from the introduction and spread of retail clinics—a relatively modest sum. Similarly, a RAND report on Massachusetts retail clinics found

that they would reduce total expenditures on health care in that state by 1 percent.<sup>62</sup>

## Limitations of Existing Research

A number of important limitations apply to the research conducted thus far. Several studies are small or focus on only one provider (such as MinuteClinic) or one state (Minnesota). Others focus on a narrow range of treated conditions (such as sore throats). Despite researchers’ best efforts to compare apples with apples, so to speak, it is possible that patients who seek care outside of retail clinics are significantly different—and perhaps sicker—in ways that are difficult to measure but that add costs and make the services of retail clinics only *look* less expensive. There is little evidence that the availability of retail clinics generates unnecessary office visits, but only one study that we are aware of directly addresses this issue. There is also little evidence of the impact (financial or otherwise) that retail clinics are having on other care providers, such as primary-care physicians—and thus no way to buttress or refute the concern that retail clinics are diverting revenue on which they depend. These are all subjects that warrant additional research.

In conclusion, the evidence on retail clinics is generally positive but narrow. It is nonetheless sufficient to support the conclusion that clinics are providing high-quality care and that inordinate numbers of follow-up visits to other kinds of providers are not being made. There is also sufficient evidence to conclude that retail clinics probably have a self-limiting<sup>63</sup> role in improving the cost, quality, and convenience of American health care.

In particular:

- Services offered by retail clinics for treating a limited set of uncomplicated conditions are of high quality and at least equal to services offered by other types of providers.
- Total costs (to insurers and patients) of such clinics are significantly lower than those incurred at other types of venues, such as physicians’ offices, urgent-care centers, and emergency rooms.

- Patients seem to be directing themselves (“self-triage”) to retail clinics for the appropriate conditions, and the availability of retail clinics does not seem to be bringing about unneeded care.
- Patient satisfaction with the care they obtain at retail clinics is very high.
- Clinics may free up physicians to devote more attention and higher levels of skill to patients with more serious complaints.
- The entry of retail clinics into new markets and their expansion there can be deterred by the cost of compliance with states’ rules.

Clinics’ validity having been demonstrated, the next section will examine:

- The regulatory environment for retail clinics nationally
- The regulatory environment in New York State, including the extent of oversight of nurse-practitioners, legal restrictions on their scope of practice, and prohibition of the corporate practice of medicine
- The number and type of retail-clinic services currently offered in New York State
- Challenges to primary-care access, particularly for Medicaid recipients and the underserved in New York, including inappropriate ER use.

In the final section, we will suggest reforms and pilot projects that we would hope would result in improved access to high-quality retail-clinic services in New York for underserved and other populations and would help reduce the overall costs of health care.

## PART II: RETAIL CLINICS IN THE NATION AND IN NEW YORK

### States’ Responses to Retail Clinics

Most states where retail clinics operate have less cumbersome regulatory environments than New York’s. Takach and Witgert (2009) conducted a fifty-state examination of states’ exercise of their regulatory and licensing authority to “promote, structure, or limit the growth of retail clinics.” The os-

tensible purpose of such oversight is to protect continuity and quality of care and the economics of other forms of care delivery.

Most states regulate retail clinics only indirectly, by licensing nurse-practitioners and physicians’ assistants to perform only certain tasks and procedures. A majority of states classify retail clinics as medical offices. Doing so allows them to operate under the same auspices as physicians’ offices, without any further regulatory requirements. Takach and Witgert indicate that a handful of states regulate outpatient care, including “ambulatory, urgent care, and physician offices,” which state regulators may interpret to include retail clinics. For instance, Arizona licenses retail clinics as outpatient treatment centers, and Rhode Island licenses them as ambulatory-care offices. Florida does not license clinics owned by licensed health-care providers but does license clinics owned by corporations. A number of other states are considering adopting new laws or regulations to cover retail clinics directly.<sup>64</sup> Massachusetts did so after policymakers and regulators determined that retail clinics could not operate in the state “without multiple waivers.” (See the text box on page 14 for further highlights of Takach and Witgert’s survey.)

Several themes emerge when New York is compared with other states having retail clinics.

- Many states have more inviting regulatory environments than New York’s. In particular, they tend to regulate retail clinics indirectly, through their licensing powers over nurse-practitioners and their assignment of a supervisory role to physicians.
- New York effectively discourages retail-clinic operators from entering the New York market or expanding their operations there. CPOM regulations, an onerous and time-consuming CON process, and CPAs banish some retail-clinic models and add heavily to the cost structure of others. All this is especially true for retail operators that earn low margins.<sup>65</sup>
- Retail clinics have shown, however, that they are able to adapt to a number of different regulatory environments, even to New York’s, to

## Highlights of Six-State Survey

Of the fifty states in their 2009 survey, Takach and Witgert looked into the regulatory approaches of six (California, Florida, Illinois, Massachusetts, New Jersey, and Texas). Among their findings:

- *California*: The state does not license retail clinics but does prohibit the corporate practice of medicine, in the strict sense of the term. However, the several different retail-clinic models operating in the state include professional medical corporations in which “only physicians and other licensed professionals [may] own shares.” The state also has “relatively strict” standards for the supervision of nurse-practitioners by physicians, although those standards have been loosened recently.
- *Florida*: The state does not license provider facilities unless they are owned by corporations, and it permits retail clinics to be owned by nurse-practitioners. Corporate licenses are granted for two years, and the renewal process consists of site visits and review of the clinics’ business operations. Florida limits the number of nurse-practitioners who can be supervised by a single physician to four. The state Medicaid program does not recognize retail clinics as a provider type. Retail-based nurse-practitioners or physician assistants could submit claims under their own Medicaid provider number, but the state Medicaid agency does not track these data.
- *Illinois*: Retail clinics are deemed physicians’ offices and treated accordingly (e.g., they are not subject to CON licensure). The legislature considered but rejected regulating retail clinics per se. The relationship between a physician and the nurse-practitioner staff at the clinics is governed by a collaborative-practice agreement and state laws requiring physicians to meet once a month with the nurse-practitioners under their supervision.
- *Massachusetts*: In 2009, the state created a separate regulatory structure for what it calls “limited service clinics.” There are regulations governing referral of patients to primary-care practitioners (including physicians, nurse-practitioners, and community health centers) and the number of repeat visits by patients. The state, with the patient’s consent, requires the clinic to notify the primary-care provider of the retail-clinic visit.
- *New Jersey*: In order to comply with the regulations that apply to ambulatory-care facilities (and to comply with CPOM regulations), physicians are the owners of retail clinics in this state and staff them with nurse-practitioners. The physicians, in turn, can contract with health systems or retail-clinic operators for “management services” such as billing and other administrative tasks.
- *Texas*: Corporations there cannot directly employ physicians, although they can directly employ nurse-practitioners and retain physicians as independent contractors to perform oversight. Although retail clinics are not directly regulated, state regulations require at least one physician to supervise no more than four nurse-practitioners, and the physician must be physically present 10 percent of the time, although this standard is relaxed in medically underserved areas of the state, where physicians are required to visit every ten business days.

a limited extent. Reforms would likely increase the number of clinics serving the state.

inflation in health-care costs. Many would also benefit from better prevention and surveillance.

We now turn to health-care delivery in New York.

### Challenges in New York State

Many communities and regions in New York State suffer from a lack of access to health care; excessive and inappropriate emergency room (ER) use; and

One of the most frequently given reasons—in New York<sup>66</sup> and nationally—for the overutilization of ERs is the lack of access to primary care. Weinick et al. (2010a) report that Americans frequently seek “nonemergency care at hospital departments, because of long wait times for appointments, limited after-hours care at physician offices, and other barriers to access.”<sup>67</sup> The

authors estimate that 13.7 percent of all emergency-department visits could be handled by a retail clinic, saving hundreds of millions of dollars annually.

The precise incidence of inappropriate ER use in New York is unknown. However, several reports suggest that the problem is significant. A 2010 report from Excellus BlueCross/BlueShield, a New York-based health plan, claims that there were more than 640,000 unnecessary ER visits in 2008 in the forty-three counties constituting upstate New York—or 44 percent of all ER visits in that region. This included more than 20,000 visits for sore throat and more than 22,000 visits for ear infections, two ailments that retail clinics routinely treat.

Excellus estimates that shifting even a small percentage of inappropriate ER visits to physicians' offices would save millions of dollars annually. A 5 percent reduction, it estimates, would save up to \$8.6 million. A complete redirection to proper treatment venues of health problems inappropriately treated at upstate ERs—an unlikely development, partly on account of current constraints on the supply of physicians' offices—could generate \$117–\$172.3 million in annual savings.

The problem appears to be acute downstate as well: a 2006 study focusing on New York City estimated that “two out of every five emergency room visits—over 1 million visits citywide—are for conditions that can or should have been prevented or treated in primary care settings.”<sup>68</sup>

The leader of a local nonprofit research organization that studies and promotes health-services reform in New York cautioned that broadening the availability of primary care doesn't necessarily lead to markedly lower ER use. The quality and comprehensiveness of care available at ERs draws many patients who believe that they have urgent or severe health problems. New York has been actively moving Medicaid recipients who are neither elderly nor disabled into Medicaid Managed Care plans, but it is not yet clear whether doing so is reducing inappropriate ER use.

A Medicaid official we spoke with agreed that there may be long-standing patterns of inappropriate ER

use. Also, until recently, the Medicaid program was paying more for ER visits than for visits to primary-care clinics located in the same facility, discouraging hospitals from redirecting patients there. Recent Medicaid reforms attempt to link the size of payments to providers to the complexity of services provided to patients. Still, ER usage by participants in both traditional Medicaid and the Medicaid Managed Care plans remains high, and it is too soon to tell what effect, if any, those reforms are having on ER utilization. Creating better incentives for providers is probably not enough; it will also be necessary to teach recipients that ERs are not the best places to receive primary care.

Medicaid does not currently cover visits to retail clinics as such, but it will reimburse for services performed by enrolled nurse-practitioners working in them. According to the Medicaid official we spoke with, this is not yet happening much or at all, to the best of his knowledge.

New York residents see a need for more accessible health-care options. At a 2007 forum on retail clinics in New York, CVS/MinuteClinic<sup>69</sup> announced the findings of a survey that it commissioned:

- 36 percent of New York City residents and 32 percent of state residents overall have gone to the ER for a common illness because they could not get an appointment with a primary-care physician.
- 23 percent of both state and city residents have had to wait two or more days to be treated by a doctor for a common illness.
- 35 percent of city residents and 32 percent of state residents have put off seeking care for themselves or a family member for a common illness in order to avoid taking time off from work.
- 67 percent of city residents and 63 percent of state residents are concerned that ER physicians are spending too much time treating minor medical issues.
- 77 percent of city residents and 73 percent of state residents say that they would be interested in using the services of a retail clinic in their community.

Low-income communities appear to have more limited access to primary care than other communities and thus rely more heavily on ERs. A September 2007 report from the Office of the New York City Comptroller found that city neighborhoods belonging to the poorest sextile had the fewest primary-care physicians per 100,000 residents—just 73.7—while the most affluent neighborhoods had 197.9. The comptroller's report made a number of recommendations to improve less affluent residents' access to primary care, including opening "health clinics in drug stores, supermarkets, and 'big box' stores" located in their communities.<sup>70</sup>

Another possible role for retail clinics in New York is administering vaccinations. According to a RAND 2010 survey, nearly one in five (17 percent) U.S. adults who received an influenza vaccine in 2009 received it at a retail store, including retail clinics, pharmacies, and grocery stores.<sup>71</sup> Lee et al. (2009), in a national panel survey exploring the utilization of alternative (nontraditional) sites for influenza vaccination, found that about 9 percent of vaccinated adults received their vaccination at a retail store. The authors also found that patients vaccinated in this kind of environment were more likely to be older, nonwhite, and classified as at high risk of contracting influenza. The authors conclude that "alternative locations address some population segments not captured by the traditional health care system."<sup>72</sup>

In October 2009, the New York City Department of Health reported that the immunization rates of the group at highest risk for influenza, adults aged sixty-five and older, averaged about 57 percent. This finding is well below the national target rate of 90 percent, and an expansion of retail clinics would probably help close this gap.<sup>73</sup>

## The Regulatory Environment for Retail Clinics in New York

The regulatory hurdles for retail clinics in New York vary depending on the type of operator, but the overall environment is expensive and burdensome, replete with barriers to both the entry and the expansion of lower-cost health-care services. The following

emerged from our discussions with scholars and retail-clinic operators as some of the most significant regulatory burdens on the New York market.

### ***The Prohibition against the Corporate Practice of Medicine***

The CPOM prohibition in New York creates an uneven playing field for retail-clinic operators, preventing those that directly employ nurse-practitioners from competing with physician-operated facilities in retail stores offering many of the same types of services.<sup>74</sup>

Although almost all states have some type of prohibition on the corporate practice of medicine, New York has strong statutory language that has been strictly interpreted by the courts. New York's education law (Sec. 6522)<sup>75</sup> limits the practice of medicine to "natural persons." In practice, with a few exceptions,<sup>76</sup> the prohibition means that a "general business corporation (as opposed to a hospital corporation or a professional corporation) may not employ licensed professionals such as doctors, nurses, physician assistants, etc., to provide medical services."<sup>77</sup>

Consequently, a walk-in clinic "must be owned and operated either by a licensed facility such as a hospital or a diagnostic and treatment center, or by a properly licensed professional or group of licensed professionals practicing in a professional corporation or partnership."<sup>78</sup> Both nurse-practitioners and physicians can form such professional groups among themselves and then lease space and acquire administrative support services from a retail store or other administrative services provider at fair-market rates. State law prohibits fee-splitting, while a federal statute known as the Stark Law prohibits such professional groups from paying kickbacks to the parties that refer Medicare and Medicaid patients to them.<sup>79</sup> Although they are permitted, we are not aware of any nurse-practitioner-operated retail clinics in New York State.<sup>80</sup>

The operators we spoke with were split on the effects of the CPOM. The president of one firm that had operated several clinics in Manhattan until 2007 reported that it was able to comply with the

## The Prohibition on the Corporate Practice of Medicine

In a discussion of New York's prohibition, one expert on New York State health law we spoke with noted that many other states, including Illinois, Pennsylvania, and California, have similar restrictions. Historically, these prohibitions date back to the late nineteenth century, when physicians were employed by railroads and forestry and mining concerns. Organized medicine strenuously objected, claiming that these corporations would try to influence the professional judgment of the physicians whom they employed. For over a hundred years, physicians' groups and medical societies have been very protective of their franchises.

The prohibition is designed to protect physician autonomy (a legitimate concern, then and now), but certain kinds of practices or enterprises, often in health-related fields, escape the prohibition. For example, New York pharmacies that have pharmacists on their payroll don't have to be owned by pharmacists. Eyeglass retailers may employ optometrists. Moreover, private corporations can and do employ licensed professionals. Private schools often employ nurses, and department stores often employ physicians to perform employee physicals, run employee health programs, and treat employees who get sick or injured on the job. These exceptions are permitted because these employers are not holding themselves out to the general public as offering medical treatment or services. Retail or walk-in clinics also raise interesting CPOM issues. In New York, a supermarket or drugstore may not directly employ a nurse or physician's assistant to staff a walk-in clinic; it may only lease space to them. Hospitals in New York have not, for the most part, gone into operating retail clinics because to do so would require them to build, equip, and staff them according to New York's rigid requirements (under Article 28 of the Public Health Law) for off-site health clinics, an often expensive undertaking that would demand more extensive facilities than retail clinics typically utilize for their limited menu of services.

state's CPOM law by entering into a management-of-services agreement with a physician who was the owner of record of clinics in three Duane Reade stores. However, the payments that had to be made under this arrangement rendered the economics of such clinics less robust than those of outlets operated in less regulated states, in which such "workarounds" were unnecessary. The operator added that it would have been impossible for the chain in New York, with multiple physician owners, to attain a level of standardization that assures the efficient delivery of consistently high-quality care.

Numerous studies confirm the importance of consistency and standardization in health-services delivery. They have found that many primary-care providers often do not follow even widely accepted evidence-based protocols and that practice variation among them can produce large differences in outcomes and costs. Clinic operators contend that other assurances of quality care are available that do not reduce competition or bring about the usual result—higher fees for patients. Nurse-practitioners, for example, all have master's degrees and make sure to keep their activities within the scope of their licenses.

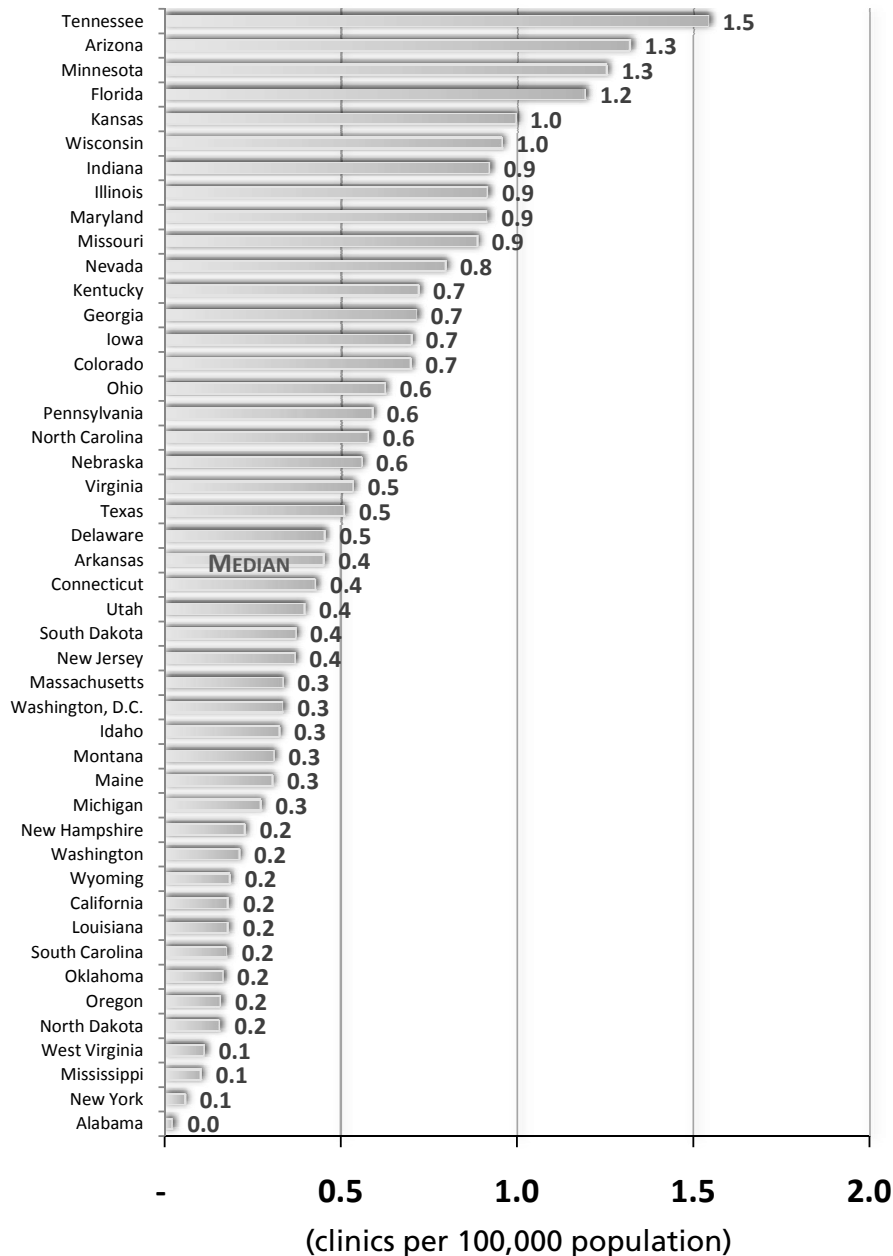
Retail-clinic operators also employ quality-control mechanisms that are built directly in to their systems and processes. For instance, outside of New York, clinic operators contract with collaborating physicians who regularly review nurse-practitioners' charts and make themselves available to the company's clinicians as necessary; however, they are not employed on-site or involved in the ownership of the facilities. The operator indicated that he would consider returning to New York if the regulatory environment improved.

Both Duane Reade (with eight stores in Manhattan) and CVS/MinuteClinic<sup>81</sup> (with seven stores in Westchester and on Staten Island and Long Island) host physician-owned medical centers<sup>82</sup> in retail stores in New York State in a landlord-tenant relationship.

We spoke to the president of a physician-owned firm that manages on-site consumer health centers and provides such services to physician-directed Duane Reade clinics in New York about how the Duane Reade model works; we also spoke with a representative of Duane Reade's hospital-system partner, Continuum Health Partners, about how its current referral model operates.

## Retail Clinic Presence by State

Table 1 shows the incidence of retail clinics per 100,000 population in the forty-six states that had them in December 2010.<sup>83</sup> The median concentration is 0.4 retail clinics per 100,000 population. Among northeastern states, only Pennsylvania had more than the median (0.6 clinics per 100,000 population). New York ranks among the four lowest states (the others being West Virginia, Mississippi, and Alabama), with just 0.1 clinics per 100,000 population, or 75 percent below the median. A number of complex business, economic, and regulatory factors are responsible for New York State's low ranking.



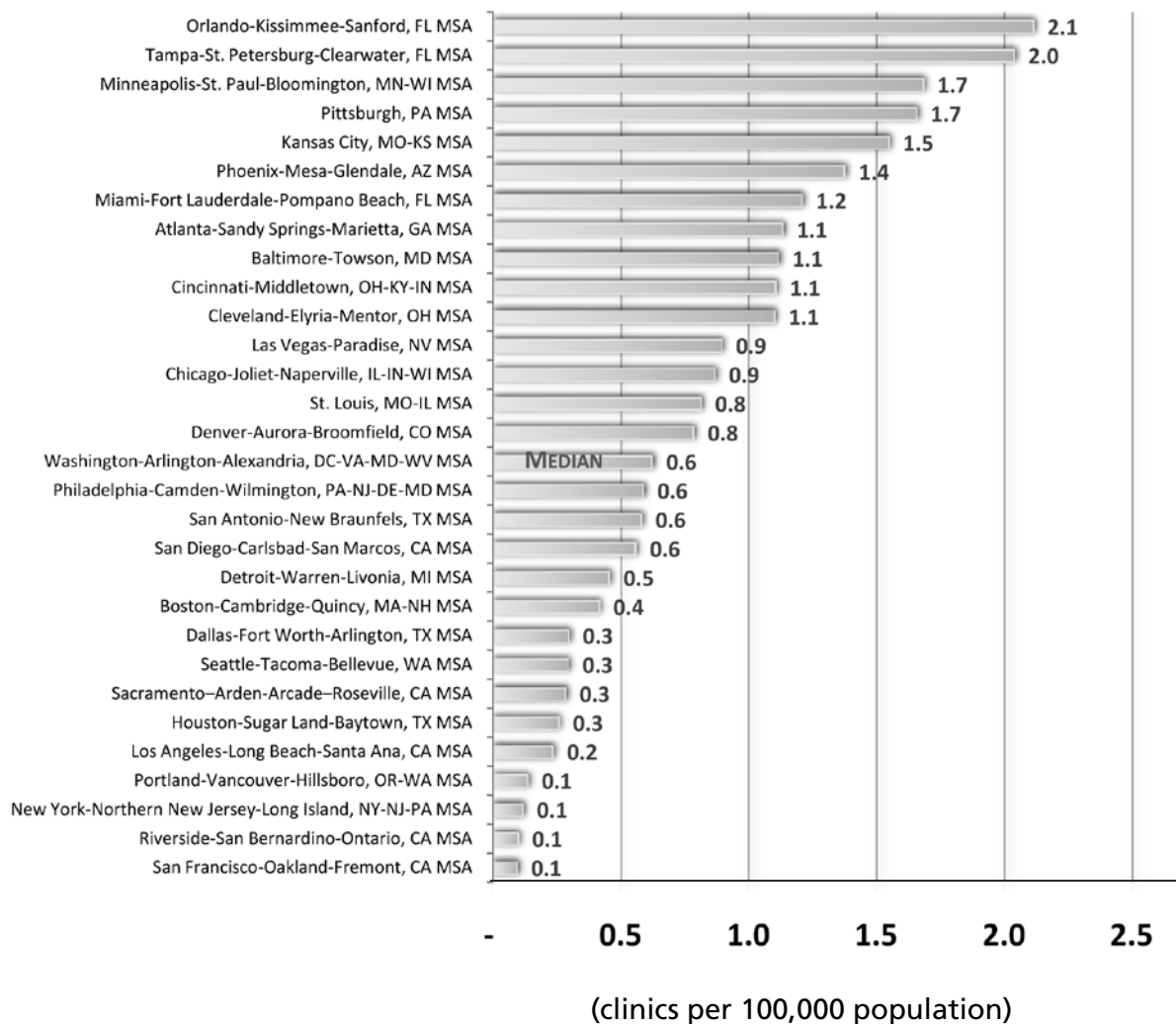
Source: Healthcare 311, December 2010

Note: In the five states whose names do not appear in the chart—Alaska, Hawaii, New Mexico, Rhode Island, Vermont—there is no record of any firm identifying itself as owning or operating a retail clinic. Such clinics do operate in Alabama, the last named state, but they serve fewer than 0.1 residents per 100,000 population.

## Retail Clinic Presence in 30 Largest Urban Areas

This table depicts the presence of retail clinics in the thirty largest Metropolitan Statistical Areas (MSAs), as defined by the U.S. Office of Management and Budget. MSAs encompass an urban core and its surrounding communities. The concentration of retail health clinics within these densely populated areas may be a better measure of the practical access to such facilities than their distribution by population across an entire state, the subject of the facing table.

The two MSAs with the highest concentration of clinics by population are both located in Florida. In Pennsylvania, the northeastern state with the highest concentration of clinics, Pittsburgh is the MSA with the highest incidence. The median MSA is 0.6 clinics per 100,000 population. Although the New York-New Jersey-Long Island, NY-NJ-PA MSA is the largest in population, its position more than 80 percent below the median lands it at the bottom of this table. It should be noted, however, that densely populated areas with low rankings, like the New York MSA, may afford greater practical access than clinics located in higher-ranked but less densely populated areas. Even these areas are likely to benefit from a further influx of clinics.



Source: Healthcare 311, December 2010

New York Walk-In Medical Group, MD, PC<sup>85</sup> took over the Duane Reade operations in Manhattan after the previous operator withdrew, and it has operated there exclusively for the last several years. Recently, the firm announced plans for expansion into the other four boroughs and beyond. The management-services operator we spoke with suggested that the physician-centered model offered an improvement over the basic retail-clinic model. First, Duane Reade health centers, by integrating themselves into a health-care system that includes a network of specialists and hospitals, avoid disruption or fragmentation of care.<sup>86</sup> To improve integration, New York Walk-In Medical Group credentialed their physicians at Continuum hospitals. There appear to be two aspects of service provision: emergency care rendered at hospitals, which patients access by dialing 911; and urgent care, which is rendered at Duane Reade centers because it does not require the services of a hospital. In the case of other symptoms that might indicate a serious underlying medical condition, New York Walk-In Medical Group can make referrals to specialists within the Continuum network or some other system.

Using an electronic health record (EHR), Duane Reade health centers can also transfer a patient's medical information to any physician (at Continuum or elsewhere) whom the patient specifies. The Duane Reade model in New York does appear to capture a successful middle ground between a nurse-practitioner-based retail clinic and an urgent-care center,<sup>87</sup> given the regulations currently in effect. (Because they operate as a physician's office, Duane Reade health centers are not subject to any requirements beyond physician licensure.) Medical societies have also been much more approving of physician-based retail clinics than nurse-practitioner-based clinics.

This does not mean that only one retail clinic or "health store" model should be allowed to operate in New York. The historical justification for CPOM regulations is not without merit, insofar as it preserves physicians' independent judgment by insulating it from cost pressures that could result in substandard care. Such pressures could also incite the pursuit of the most profitable lines of business, regardless of their relationship to medical need.

However, since the era when the prohibition of the CPOM doctrine first evolved, numerous other safeguards have been established to protect patient health and deter the provision of substandard care. First, the state maintains a robust system of provider education and licensure to maintain the quality of nurse-practitioners and penalize providers of inappropriate or substandard care. The state also has a robust tort system that polices serious lapses in the standard of care, as well as a highly regulated insurance industry that sees its own financial self-interest in building high-quality provider networks for its policyholders. Clinics that offered low-quality care, that were the repeated targets of malpractice claims, or that regularly recommended or provided unnecessary care would face the loss of their commercial insurance coverage. They would also forfeit their ability to hire highly skilled providers.

As a further assurance of quality, some retail clinics have sought third-party certification from the Joint Commission<sup>88</sup> or the Accreditation Association for Ambulatory Health Care. Finally, strict anti-kickback and fee-splitting prohibitions at the state and federal level provide additional safeguards against wasteful or fraudulent billing by retail clinics.

While the motives behind the prohibition of the corporate practice of medicine are legitimate, policymakers should explore whether similar safeguards can be obtained without stifling competition to the same extent. The staff at the Federal Trade Commission has repeatedly reminded state regulators and legislators that ownership structure or location should not be a basis for further interventions in clinics' business, especially since they tend to reduce competition among providers and raise costs for consumers.<sup>89</sup>

Providers offering similar services should compete on the basis of the cost and quality of those services, as long as those services meet appropriate licensure and quality standards. Insurers' experience with the retail-clinic model in other states, such as Minnesota, suggests that traditional physicians' offices as well as retail clinics employing nurse-practitioners offer distinct services of value to health-care consumers. Indeed, the entry of health systems and physicians' groups into the retail-clinic market demonstrates

## Retail Clinics and the Medical Home: Collaboration or Competition?

As we noted earlier, a debate is emerging about how retail clinics can help fulfill the goal of creating a more integrated, comprehensive health-care system that implements the medical home concept, personified by a primary-care physician who orchestrates all the medical care that a patient receives. In the May 2010 issue of *Health Affairs*, Pollack et al. discuss whether the emerging medical home concept and retail clinics will be able to coexist productively. While physician opposition to retail clinics may seem to put the two at loggerheads, Pollack argues that “on closer examination, it becomes clear that the medical home and retail clinics share a number of the same principles,” including “improved access to care, the incorporation of electronic medical records and evidence-based guidelines; and the use of nonphysicians for services that do not require physician-level training.”<sup>90</sup> In addition, both are “patient-centered” innovations.<sup>91</sup>

The differences result from how one conceptualizes the two models: to Pollack, “medical homes emphasize comprehensiveness of care, while retail clinics provide only episodic care for acute conditions or preventive care services.” Under the medical home concept, patients access care through a single entry point, while patients can visit any retail clinic that suits their convenience. What they have in common is a similar menu of services and a policy of maintaining electronic health records (EHRs). Proponents of the medical home point to the benefits of care coordination, which is understood to involve “the integration of care across all providers for patients with chronic illness,”<sup>92</sup> in Pollack’s words. Treatment for minor but acute episodic conditions at retail clinics should not require a high degree of coordination. Preferably, the technology would exist in both places to permit the sharing of EHRs, especially when a more serious underlying health condition is suspected. Pollack identifies three types of relationships between retail clinics and the medical home:

*Integrated model:* Retail clinics are owned and operated by physicians’ groups or hospital/health systems such as Geisinger or the Mayo Clinic. “Each retail clinic is linked to a primary care practice and the larger health system through a shared electronic provider.” Retail clinics in this model “can be reasonably seen as simply an extension of the medical home.”

*Hybrid model:* Independent retail-clinic operators and medical practices formally collaborate and “co-brand.” An example is the partnership between the Cleveland Clinic and MinuteClinic. According to Pollack, the two say that they are “moving towards a shared electronic health record.” Some observers worry that clinics will neither suggest nor render chronic or preventive care. They also worry that clinics will draw away fees on which primary-care providers depend; supporters think that primary-care providers will be freed to concentrate on more lucrative procedures.

*Independent model:* Clinics are owned and operated by unaffiliated companies. Such clinics do not necessarily have technology that would allow them to share EHRs with primary-care physicians and others, complicating continuity of care and denying physicians referrals that could compensate them for the loss of fees for procedures that the clinics now perform.

Another question is whether the full medical home format suits all patients. Those with multiple chronic illnesses would probably be the ones to benefit most. But restricting basically healthy patients with occasional acute episodes to the format would mean offering them a level of costly services that they did not need. For such patients, the retail clinic can be an alternative to the medical home for basic care, as long as an EHR is available to the primary-care physician when needed. With shared EHRs, there is every reason to believe that retail clinics could play an integral role in a more comprehensive health-care system.

their receptiveness to competition, or at least competition's ability to elicit defensive measures from more traditional service formats that have left large numbers of patients underserved.

### ***Facility Licensing***

Licensed professionals may operate a walk-in clinic as a limited liability corporation. Facility licensing may prove to be another significant regulatory barrier for retail-clinic operators to overcome—one so difficult that they might decide to take their business elsewhere. In New York, “diagnostic and treatment centers” are required to undergo what is called a certificate-of-need (CON) review.<sup>93</sup> (See box on facing page for a definition.) One expert who has examined the regulation of retail clinics in other states notes that many states do not conduct CON reviews or do not require CON for ambulatory-care facilities. New York State law requires a CON for any new diagnostic and treatment center, which retail clinics are considered to be, under Article 28 of the Public Health Law. She also confirmed that it can currently take twelve to eighteen months for regulators to approve or to reject a CON application.

Both for-profit and nonprofit health-care enterprises are subject to CON laws, unlike the private professional practices of physicians and nurse-practitioners, a fact that gives a huge advantage to the latter in the competition to open retail clinics.<sup>94</sup> If a hospital decides to open a series of retail clinics or walk-in medical centers, it must obtain administrative approval for each satellite facility under its original operating license. However, each clinic must then comply with the full requirements for Article 28 diagnostic and treatment centers.

A large national chain that leases store space to health systems explained that all the hospitals that that company has contacted in New York have expressed uncertainty about how to proceed in obtaining approval for retail clinics that they may wish to start, or what legal criteria are used in reviewing applications, or how long a review of a CON application is supposed to take. They therefore share a reluctance to be the first to go through the process. The chain expressed hope that the state Department

of Health would consider creating specific guidelines for retail clinics.

New rules recently took effect that may help reduce the cost of CON review, as well as the time it takes. Construction standards for all health-care facilities are now the national standards promulgated by the American Institute of Architects. In addition, the responsibilities and separate procedures of the State Hospital Review and Planning Council (SHRPC) and the Public Health Council have been merged in a new agency, the Public Health and Health Planning Council (PHHPC),<sup>95</sup> which will now handle CON applications for permission to establish new Article 28 diagnostic and treatment centers. The previous process had required prior approval from the SHRPC before an application could be reviewed by the Public Health Council.

The new PHHPC will also have responsibility for reviewing “regulations and procedures governing the establishment and construction” of health-care facilities; and every five years, it will have to submit recommendations for revision to the state health commissioner. It also appears that once an operator establishes a new diagnostic and treatment center, additional centers under the same license need undergo only administrative review. Department of Health staff say that CON reviews have been taking six to eighteen months, with applications for approval of new facilities (as opposed to changes to or expansions of existing facilities) more likely to take the longer time.

Ideally, the CON process for retail clinics would be waived entirely. Alternatively, the CON process could be streamlined by automatically awarding a license to any operator who promises to conform his business to one or more preapproved retail-clinic models. While deregulation of these facilities would be the best approach, regulatory reform would help level the playing field.

### ***Scope-of-Practice Regulations for Nurse-Practitioners***

State scope-of-practice regulations can limit the services that nurse-practitioners (NPs) offer in retail

## What Is Certificate-of-Need (CON) Regulation?

Ohsfeldt and Schneider (2006) explain that, under certificate-of-need regulations, new health-care market entrants, or incumbents offering a new health-care service, “must demonstrate a justifiable need for the new capacity, to the satisfaction of the regulators, before being allowed to proceed.”<sup>96</sup> By regulating the supply of health-care services and overall capacity, particularly that of hospitals, the state hopes to control health-care costs.

CON regulations were born in the mid-1960s, when Medicare reimbursed providers on a “cost-plus” basis, which guaranteed payments that exceeded costs by a set amount, regardless of what those costs were. Policymakers came to believe that such arrangements encouraged providers to offer unneeded services or to develop duplicative facilities. Despite repeal of cost-plus reimbursement, CON supporters continue to maintain that restricting supply can help contain costs. In the words of one such supporter, “excess capacity (in the form of facility overbuilding) directly results in health care price inflation. When a hospital cannot fill its beds, fixed costs must be met through higher charges for the beds that are used.”<sup>97</sup>

In 1964, New York enacted the first statute requiring a government inquiry into the need for any proposed health-care facility before it could go forward. In 1974, a federal law, the Health Planning Resources Development Act, directed all fifty states to develop such procedures. Many did so to receive CON federal funds; the federal mandate was repealed in 1987, and fourteen states have repealed their own CON regulations since then.<sup>98</sup>

In their review of the economic literature on CON regulation—including studies on states that were early adopters, on long-term effects, and on the impact of CON repeal—Ohsfeldt and Schneider conclude that CON has not succeeded in its stated goal of containing costs, with the majority of studies showing that CON regulations increase costs.

A 2004 report from the Federal Trade Commission and the Department of Justice concluded that “CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits,”<sup>99</sup> at least in part because incumbents can capture the regulatory process and influence it to approve expansion of their own facilities and services. The report notes: “CON programs can retard entry of firms that could provide higher quality services than the incumbents. By protecting incumbents, CON programs likewise can ‘delay the introduction and acceptance of innovative alternatives to costly treatment methods.’”<sup>100</sup> The FTC/DOJ report recommends that states lower barriers to entry and resort to less anticompetitive tools to control health-care costs.<sup>101</sup>

clinics and can drive up the cost of offering those services. In contrast to CPOM and CON regulations, New York’s scope-of-practice regulations are considered fairly reasonable by the NPs with whom we spoke. Currently, there are about 15,000 NPs in New York State, with about 5,000 of them practicing family medicine. New York has more NPs than any other state except California.<sup>102</sup>

To be allowed to practice in New York, all NPs since 1988 must have a degree and a license in a specialty, and must have entered into a “collaborative-practice agreement” (CPA) with a physician practicing in the same specialty. Many states require some type of

CPA. One problem with requiring such agreements, according to a staff member of the New York State Board of Nursing, is that if a nurse-practitioner’s physician-collaborator leaves the state or becomes unavailable for some other reason, the nurse-practitioner, even one with his or her own patients, cannot continue practicing until another physician with whom to collaborate is found.

The official we spoke with described the agreement as similar to those governing relationships in a law firm, where a senior partner functions alongside a more junior one. The relationship is not supervisory but collaborative, insofar as the nurse-practitioner

performs all the functions of the practice of medicine short of surgery and does so autonomously. However, the law requires the collaborating physician to review patients' medical charts quarterly, and the physician is the person to make a "final ruling" if there is a disagreement over the proper treatment to render. New York's statute also insists on at least one physician for every four nurse-practitioners, unless the physician is practicing on-site, as, for example, the medical director of a hospital or a large medical practice would be.

A representative from the New York State nurse-practitioner association contends that performing a chart review after the care has been rendered does nothing to ensure patients' safety.<sup>103</sup> Practice protocols, she says, can be harmful because they cannot anticipate every conceivable variable that the patient might present. She also argues that the CPA is superfluous, given research indicating that NPs produce outcomes as good as those of primary-care physicians.<sup>104</sup> (And they manage to do so while receiving Medicare fees that are 85 percent of physicians'.) At present, the statutes of sixteen states give NPs complete autonomy, and twenty-eight states have legislation pending to drop the CPA requirement as it applies to them. The New York State Legislature recently rescinded the requirement that nurse-midwives practice under a CPA. (The bill, the Midwifery Modernization Act, was signed into law by Governor David Paterson on July 30, 2010, and is now in effect.)

Nurse-practitioners in CPAs must pay the collaborating physician to perform the mandated chart reviews and must wait for the collaborating physician, who receives the insurance reimbursement even if he never saw the patient, to pass it along. A nurse-practitioner we spoke with believes that, given the shortage of primary-care providers and the increase in the number of insured parties that the federal Affordable Care Act will bring about, retail clinics are an essential development if needed care is to be rendered.

Would no longer requiring CPAs impair the quality of treatment offered by retail clinics? Nurse-practitioners say that it would not because practitioner licensure

supports quality, as do board certification and the oversight performed by the Occupational Safety and Health Administration and the Joint Commission (which accredits and certifies health-care organizations and programs). In addition, retail-clinic operations follow quality-assurance protocols that are disclosed to insurers and regulators. In short, nurse-practitioners see the CPA as adding cost to the system without improving the quality of care.

Eliminating CPAs in New York might encourage nurse-practitioners who were recent graduates or were practicing elsewhere to enter into practice in New York, since they tend to favor states with more permissive scopes of practice. They would be especially welcome if primary-care shortages worsen over the next several years, as many experts suggest that they will.<sup>105</sup>

If the CPA is retained, the four-to-one ratio governing the collaborations of nurse-practitioners and physicians should be widened. Given the use of electronic medical records and proven treatment protocols, not to mention technologies permitting instantaneous consultation with knowledgeable specialists based elsewhere, such a close ratio should no longer be necessary.

## The Legislative Landscape in New York

In 2008, Massachusetts moved to streamline the approval process for retail clinics after recognizing that the existing guidelines demanded an extensive and time-consuming waiver process. In his written statement supporting MinuteClinic's proposal to open retail clinics staffed by nurse-practitioners, Jon Kingsdale, executive director of the Massachusetts Commonwealth Health Insurance Connector Authority, testified that an ongoing shortage of primary-care physicians could "frustrate the goal of the new Massachusetts Health Care Reform law to improve access for patients." Because of that, he praised MinuteClinics' ability to "relieve the pressure on primary care doctors," especially in light of the increased demand that the new law was expected to generate. Since the new regulations took effect in 2008, Massachusetts has gone from having no retail clinics to having more than twenty.

In the wake of national health-care reforms, New York policymakers have an equally strong incentive to expand their state's provider network and, accordingly, patient access. Essentially, New York policymakers have three choices:

*Embrace the status quo:* Since New York already permits clinics to operate, so long as they are physician-owned, simply preserving the status quo would seem to represent the path of least resistance to their spread. Indeed, physician-operated retail clinics are already operating in the state. The few now in existence appear to be successful, but their numbers are growing slowly. However, physician-owned clinics probably have higher personnel costs and receive larger reimbursements than nurse-practitioner-based clinics, and thus may be more expensive for insurers.

*Repeal or substantially modify regulations that suppress provider competition:* As discussed earlier, existing CON and CPOM regulations do not appear to improve quality of care to such a degree that their value outweighs their effect on competitive pricing.<sup>106</sup> Policymakers should consider whether alternative consumer protections requiring disclosure of outcomes could achieve the same ends, while also permitting comparison shopping. However, resistance to regulatory reform is rather entrenched.

*Create a level playing field:* As their counterparts did in Massachusetts, New York regulators could recognize that the existing regulatory structure for traditional retail clinics is ill-fitting, expensive, and burdensome; in its place, they could clear a specially designated regulatory pathway for this new type of clinic. At the same time, they could lift restrictions on nurse-practitioners' independence. Regulatory reforms would involve leveling the playing field for different clinic models. Meanwhile, the Department of Health could integrate retail clinics into existing public programs, including Medicaid. There seems to be no reason that retail clinics should not be allowed to participate in projects testing the use of interoperable EHRs or to participate in Accountable Care Orga-

nization (ACO) pilots, as a recent RAND report recommends.<sup>107</sup> This path—fair competition and participation in emerging models of care—could win the support of incumbent providers, which say that they are concerned about the impact of retail clinics on continuity and comprehensiveness of care.

Our recommendation is to level the playing field, which would, among other things, remove the regulatory difficulties caused by the curtailment of the corporate practice of medicine, the imposition of a certificate-of-need process, and the insistence that nurse-practitioners enter into collaborative-practice agreements.

The most common model for retail clinics—a facility in which nurse-practitioners offer a limited set of services—sits uneasily beneath New York State's regulatory scheme for health-care facilities generally. At present, such clinics are, so to speak, neither fish nor fowl: neither a doctor's office nor an Article 28 clinic. Article 28 reforms to accommodate retail clinics may already be in motion. Last summer, legislation was introduced in the New York State Assembly and the Senate that would create an opening for retail clinics (or "convenient care clinics," as they are called in the legislation).<sup>108</sup> It would "grant the Commissioner the authority to promulgate regulations for convenient care clinics that are different from regulations applicable to diagnostic and treatment centers." In effect, the Public Health and Health Planning Council would amend the public health law to permit the establishment and operation of convenient-care clinics directly employing nurse-practitioners.

We spoke with a member of the staff of one of the legislation's sponsors. She emphasized that the law would change only the nurse-practitioners' practice setting, not what they were allowed to do. The bill has since been referred to the Assembly Committee on Health for consideration. This legislation appears to address some concerns among legislators. For example, it emulates the regime governing dialysis treatment centers by establishing a revocable facility license. While the bill appears to expand the nurse practitioners' practice setting, it doesn't address the regulatory requirement for collaborative practice

agreements, which limit their independence. Concerns about whether retail clinics might hurt the financial viability of primary-care physician practices will also need to be addressed, which this report begins to do.

Convenient-care clinics are expected to be the subject of legislative hearings in early 2011. Even if legislation is enacted, regulations promulgated by the Public Health and Health Planning Council would have to be careful to avoid hamstringing retail-clinic development in New York.

## CONCLUSION

American health care is in the midst of a sea change. Beginning in 2014, the federal Affordable Care Act will provide an estimated 32 million Americans access to both Medicaid and private insurance. In New York, it is expected that over 40 percent of the state's 2.7 million uninsured will receive premium subsidies with which to purchase commercial coverage on the state's new health-insurance exchange. Hundreds of thousands of New Yorkers eligible for the state's Medicaid program but not enrolled in it may also decide to obtain coverage.

Insurance coverage, however, does not ensure access to care. Because of a shortage of primary-care physicians, patients in many states, including New York, often do not get the care that they need in a timely fashion, even when they have high-quality private insurance. In this environment, expanding insurance coverage could actually reduce access—leading to longer wait times, even worse health problems, and resorting under duress to hospital emergency rooms, which are far more expensive. In Massachusetts, which implemented a similar reform program in 2006, patients, physicians, and policymakers are grappling with exactly these issues.

Retail clinics are one important response to these challenges. They use innovations such as evidence-based, computer-indicated treatment protocols and electronic health records to standardize and streamline services; harness the retailer's proficiency at

providing rapid service and satisfying customers; and put forward a transparent, competitive pricing model designed to appeal to cost-conscious consumers and insurers.

Reassuringly, retail clinics internalize high levels of professionalism rooted in the ethos of the medical profession. Providers in retail clinics, mostly nurse-practitioners, have their patients' charts reviewed by medical directors (who are physicians), undergo frequent review by their colleagues, and, in some cases, have even undergone rigorous certification by outside bodies. For complex health problems, retail clinics usually can be counted on to make referrals, not only because some states and their own professionalism require it, but because the economics of their business depends on it. Yet to ensure continuity of care, many clinic chains have entered into partnerships with local health-care providers.

Research has shown that retail clinics are a high-quality, low-cost, convenient form of health-care access. But retail clinics also face a number of challenges that have raised their operating costs and have sometimes barred their operation outright. This is currently the case in New York, where restrictions on the corporate practice of medicine, extensive certificate-of-need regulations, and some rules hedging in nurse-practitioners limit the number and type of retail clinics that can operate.

The time to start removing these obstacles is now. But even if repeal is not in the offing, New York could become more welcoming by marking out a pathway to approval for the several different retail-clinic models currently in operation. The identity of a clinic's proprietor—hospital, corporation, or medical practitioner—should not count. If it does not count, competition based on service, quality of care, and price would be able to proceed.

We also ask state policymakers to integrate retail clinics into existing demonstration projects in which providers are incentivized to organize and coordinate patient care and promote partnerships between Medicaid and Medicaid HMOs and retail clinics. Doing so

could help redirect poor nonemergency ER visitors to retail clinics without disrupting their relationship with their primary-care physician, if they have one.

Some physicians' groups worry that the interposition of clinics into the health-care continuum will interfere with continuity of care. But the advent of electronic records that follow patients from provider to provider, along with strict protocols for their handling, should allay that concern. Others fear that they will lose much revenue to this new format. We do

not believe, however, that the health-care market is evolving to the detriment of physicians. To the contrary, physicians will be freed to spend more time diagnosing and treating patients with subtler or more complex ailments. The medical practices that result should be more interesting, more fulfilling, and less hectic. And if treatment of more difficult conditions were reimbursed at a rate that fairly reflected that difficulty, primary-care practices could actually become more lucrative.

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Executive Secretary, NY State Board for Nursing

1. On January 19, 2011, the U. S. House of Representatives voted to repeal the Affordable Care Act. As of early February, 2011, a U.S. District Court in Virginia had ruled that an aspect of the Affordable Care Act was unconstitutional, and a U.S. District Court in Florida had ruled that the Act was unconstitutional in its entirety. The Obama administration has filed an appeal in the Virginia case and is expected to appeal the Florida ruling.
2. For a primer on the legislation and its implementation timeline, see Kaiser Family Foundation, <http://healthreform.kff.org/the-basics.aspx>.
3. New York State Health Foundation, "Implementing Federal Health Care Reform: A Roadmap for New York State," August 2010.
4. Robert Pear, "Shortage of Doctors an Obstacle to Obama Goals," *New York Times*, April 26, 2009. See also Luran Neergaard, "Health Overhaul Likely to Strain Doctor Shortage," *Boston Globe*, March 28, 2010.
5. For an overview of the medical home concept, see Jane E. Brody, "A Personal, Coordinated Approach to Care," *New York Times*, June 22, 2009.
6. Kevin Sack, "In Massachusetts, Universal Coverage Strains Care," *New York Times*, April 5, 2008.
7. Liz Kowalczyk, "Waits to See Hub Doctors Grow Longer," *Boston Globe*, May 15, 2009.
8. Idem, "Emergency Room Visits Grow in Mass.," *Boston Globe*, July 4, 2010.
9. See Suzanne Sataline and Shirley S. Wang, "Medical Schools Can't Keep Up," *Wall Street Journal*, April 12, 2010.
10. See our discussion in the literature review section on the quality of care offered by retail clinics and other providers and how they compare on cost, particularly Mehrotra et al. (2009), Thygeson et al. (2008), and Woodburn et al. (2007).
11. Convenience involves not only physical proximity to patients but walk-in service.
12. As staff at the Federal Trade Commission noted, "a new category of limited service medical clinics has the potential to expand access to health care by making very basic medical care more convenient and less costly. In addition, such clinics might spur price or quality competition with more traditional clinics or physician practices." Letter from FTC staff to Massachusetts Department of Health, regarding limited-service clinic regulation (September 27, 2007).
13. New York State Health Foundation, "Bending the Health Care Cost Curve in New York State," July 2010.
14. "Urgent care" is defined as an outpatient facility that treats patients with urgent, but not life-threatening, conditions during fixed hours, typically on a walk-in basis.
15. Carla K. Johnson, "Health Overhaul May Mean Longer ER Waits, Crowding," *USA Today*, July 2, 2010. Studies suggest that Medicaid patients utilize emergency rooms at a higher rate than commercial or uninsured patients. See National Center for Health Statistics, "Emergency Department Visitors and Visits: Who Used the Emergency Room in 2007," data brief no. 38 (May 2010). Weinick et al. (*Health Affairs*, 2010) estimate that 13–27 percent of all ER visits could be appropriately treated at less expensive urgent-care centers or retail clinics, for an estimated annual cost savings of \$4.4 billion.
16. E.g., in April and May of 2010, Walgreens Take Care Clinics offered free blood-pressure screenings at all 359 of its outlets: "Nearly 22 percent of individuals in the United States with hypertension are unaware of their condition, according to the American Heart Association," said Sandra Ryan, RN, MSN, CPNP, FAANP, and chief nurse practitioner officer for Take

Care Health Systems. 'Take Care nurse practitioners and physician assistants will provide free blood-pressure screenings to identify at-risk patients, and refer them to the appropriate level of care for treatment. In addition, Take Care health providers will serve as an educational resource to answer questions about hypertension and risk factors associated with the disease.'... If a patient's blood pressure is elevated, the provider will recommend a return visit to a Take Care Clinic or follow-up with a primary care provider to rule out or confirm a diagnosis of hypertension. If a patient does not have a primary-care provider, the Take Care health provider will offer a list of area providers accepting new patients." Walgreens press release, April 14, 2010, [http://news.walgreens.com/article\\_display.cfm?article\\_id=5298](http://news.walgreens.com/article_display.cfm?article_id=5298).

17. Deloitte Center for Health Solutions, "Retail Clinics: Update and Implications" (2009), <http://www.deloitte.com/us/retailclinics>.
18. Merchant Medicine, *The ConvUrgentCare Report*, July 1, 2010. The slight difference in retail-clinic concentration among large operators depends on how one classifies them. The Little Clinic operates more clinics than Target (a Fortune 500 company), but the Little Clinic is a smaller, independent company.
19. According to the websites of DR Walk-In Medical Care and CVS/MinuteClinic, accessed January 24, 2011.
20. Deloitte, "Retail Clinics: Update and Implications."
21. "By some estimates, clinics need to see 17–23 patients per day and stay open 18–36 months just to break even.... However, many clinics see fewer patients, and profit margins are slim and depend on the services provided and the amount that insurers reimburse for those services. In addition, demand for retail clinic services is seasonal, and clinics have struggled to offer services that attract patients during the slower summer season" (Weinick et al., *Policy Implications of the Use of Retail Clinics*, p. 21).
22. James Ritchie, "Consumers Aren't Sold on Retail Health Clinics," *Business Courier*, April 17, 2010, <http://www.bizjournals.com/cincinnati/stories/2010/04/19/story13.html?b=1271649600percent5E3202381>.
23. Milt Freudenheim, "Wal-Mart Begins to Rebuild Health Clinic Business," *New York Times*, May 11, 2009, <http://www.nytimes.com/2009/05/12/business/12clinicside.html>.
24. Ritchie, "Consumers Aren't Sold on Retail Health-Care Clinics."
25. Carol Wolf, "CVS to Double Number of In-Store Clinics after Health-Care Law, CEO Says," *Bloomberg News*, April 13, 2010.
26. Kowalczyk, "Emergency Room Visits Grow in Mass."
27. Office of Health and Human Services, "Public Health Council Approves Rules for Limited Service Medical Clinics," January 9, 2008, [http://www.mass.gov/?pageID=eohhs2pressrelease&L=4&L0=Home&L1=Government&L2=Departments%20and%20Divisions&L3=Department%20of%20Public%20Health&sid=Eeohhs2&b=pressrelease&f=080109\\_medical\\_clinics&csid=Eeohhs2](http://www.mass.gov/?pageID=eohhs2pressrelease&L=4&L0=Home&L1=Government&L2=Departments%20and%20Divisions&L3=Department%20of%20Public%20Health&sid=Eeohhs2&b=pressrelease&f=080109_medical_clinics&csid=Eeohhs2).
28. This is because health systems operate fewer clinics and have smaller markets than national retail-clinic chain operators.
29. Scott Harris, "Open for Business: Health Systems Explore Retail Clinics," *AAMC Reporter* (September 2008), [https://www.aamc.org/newsroom/reporter/sept08/47504/sept08\\_clinics.html](https://www.aamc.org/newsroom/reporter/sept08/47504/sept08_clinics.html).
30. "Health systems" is something of a catchall term that primarily refers to hospitals, health systems (such as Geisinger or Sutter Health), and physicians' groups.
31. Careworks, "Geisinger and Lowe's Open Innovative Worksite Health Clinic," [http://www.careworkshealth.com/news/press\\_releases/lowes\\_worksite\\_health\\_clinic\\_opens.html](http://www.careworkshealth.com/news/press_releases/lowes_worksite_health_clinic_opens.html).

32. Last year, Milwaukee Health Services, Inc. (MHSI) became the first FQHC (in October 2009) to open a retail-based clinic, the MHS Convenient Care Clinic, inside a Piggly Wiggly grocery store (*Milwaukee Community Journal*, August 12, 2010). See also National Association of Community Health Centers, "Dealing with the Emergence of Convenient Care Retail Clinics: A Guide for Health Centers" (June 2008).
33. Although FQHCs reimburse at higher rates than traditional retail clinics do, they still charge less for similar services offered in emergency rooms.
34. As we note above in n. 18 Merchant Medicine, an industry publication following the retail and urgent-care industries, reports higher and more recent numbers for retail clinics.
35. In New York, e.g., the State Education Department defines the collaborative-practice agreement as including: "provisions for referral and consultation, coverage for absences of either the nurse practitioner or the collaborating physician, resolution of disagreements between the nurse practitioner and the collaborating physician regarding matters of diagnosis and treatment, the review of a representative sample of patient records every three months by the collaborating physician, record keeping provisions and any other provisions jointly determined by the nurse practitioner and the physician to be appropriate," New York State Education Department, Office of the Professions, "License Requirements: Nurse Practitioner," <http://www.op.nysed.gov/prof/nurse/np.htm>.
36. This is not to play down the importance of standard construction, fire-code, and zoning-compliance regulations that ensure the soundness and safety of any public space. Retail clinics are also subject to patient safety, privacy, and infection-control rules applicable to all health-care providers.
37. A recent RAND technical report on retail clinics for the Department of Health and Human Services identified only eighteen peer-reviewed studies on retail clinics; Weinick et al., *Policy Implications of the Use of Retail Clinics*.
38. Not all insurers reimburse for retail-clinic services.
39. Rudavsky and Mehrotra, p. 44.
40. Ibid., p. 45.
41. Tu and Cohen, p. 2.
42. Ibid., p. 4.
43. Ibid., p. 5.
44. Ibid., p. 7.
45. Under the Affordable Care Act, physician reimbursements under Medicaid will rise to Medicare levels in two years beginning in 2013. Reimbursements have not increased for the nurse-practitioners or physicians' assistants employed by most retail clinics.
46. Takach and Witgert (2009) note: "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" (p. 5).
47. Takach and Witgert (2009) note that estimating retail-clinic usage by the underserved is difficult because "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 claim submission" (p. 4). In many states, providers with Medicaid provider numbers can submit Medicaid claims directly to the program for services at retail clinics, although "most Medicaid officials interviewed thought it unlikely that Medicaid beneficiaries are seeking services at retail clinics." Massachusetts's Medicaid program is working with retail clinics to become recognized providers. Takach and Witgert note that in some states (Georgia, Kansas, and Tennessee), Medicaid Managed Care plans include retail clinics.

48. Mary Kate Scott, "Establishing Retail Clinics among Community Health Centers: Notes from the Field," California HealthCare Foundation (2010), <http://www.chcf.org/publications/2010/09/establishing-retail-clinics-among-community-health-centers-notes-from-the-field#ixzz10laPZexj>.
49. RAND Corporation, "Health Care on Aisle 7," p. 3.
50. Ibid., p. 130.
51. Ibid., p. 133.
52. Deloitte Center for Health Solutions, "Retail Clinics: Facts, Trends, and Implications" (2008).
53. Idem, "Retail Clinics: Update and Implications."
54. The Minnesota Community Measurement's 2006 Health Care Quality Report gave MinuteClinic a 100 percent rating for the treatment of sore throats. MinuteClinic achieved the highest score for this indication out of the sixty providers evaluated, including the Mayo Clinic and large pediatric groups.
55. "MinuteClinic Receives Highest Rating in Minnesota Health-Care Quality Report," *Drug Store News*, December 11, 2006.
56. Mehrotra et al. caution that their study has several important potential limitations. First, the rate of co-morbidities among commercially insured patients in Minnesota is low, indicating a relatively healthy baseline population. Most patients treated at retail clinics were young and female and tended to live in zip codes where people had higher incomes than those treated by other providers. Since an insurance company was the source of the data, all patients studied were insured—another point of departure, since there is evidence that about 30 percent of all retail-clinic patients are uninsured. In addition, the market in Minnesota is dominated by one operator, MinuteClinic, so the results may not be applicable to other states.
57. Originally, triage referred to the battlefield practice of treating those wounded soldiers most likely to survive in situations where all could not be adequately cared for. In the modern context, triage or self-triage refers to prioritizing the treatment of patients in a given health-care context on the basis of the urgency or severity of their conditions. "Self-triage," in this sense, describes patients assigning themselves to retail clinics for appropriate care instead of utilizing the more expensive and comprehensive care available in emergency rooms or urgent-care centers.
58. Follow-up visits to other health-care providers (such as a physician) after a MinuteClinic encounter occurred slightly more frequently (2 percent) than they did after office and urgent-care encounters. While this may be indicative of poor-quality care in a small percentage of cases, Thygeson et al. speculate that this increase is due to the appropriateness of referrals for indications beyond MinuteClinic's scope of practice.
59. Parente and Town, 2009, p. 4.
60. Ibid., p. 18.
61. Parente and Town estimate a per-capita consumer surplus of about \$2.05 for every privately insured U.S. resident under age sixty-five.

62. Eibner et al., *Controlling Health Care Spending in Massachusetts: An Analysis of Options*, RAND Health, 2009.
63. Based on the scope of services offered by mid-level practitioners as well as the need for clinics to maintain an open-access model characterized by a fifteen-to-twenty-minute treatment or evaluation encounter.
64. In early 2010, New Hampshire passed regulations governing nonemergency walk-in care centers, which includes retail-based clinics. In July 2010, Kentucky passed regulations affecting "limited service clinics."
65. See Kaj Rozga, "Retail Health Clinics: How the Next Innovation in Market-Driven Health Care Is Testing State and Federal Law," *American Journal of Law and Medicine* (2009), p. 12. "Retail clinics are a low-margin business in a highly regulated field. They are sensitive to changes in health law, and their progress can be easily deterred by over-restrictive legislation. These clinics are a unique innovation in the delivery of basic health care and are deserving of a legal framework crafted by a modern perspective on the validity of market solutions in a historically heavily regulated industry."
66. See Sarah Kershaw, "Drugstore Clinics Spread, and Scrutiny Grows," *New York Times*, August 23, 2007.
67. Weinick et al., 2010a, p. 1630.
68. Primary Care Development Corporation and New York City Health and Hospitals Corporation, "A Primary Care Capacity Shortage in New York City and the Potential Impact of Hospital Closures" (September 2006), p. 7.
69. MinuteClinic announced the survey results at a "Medicine in a Minute" forum on retail clinics in Albany, N.Y., on September 27, 2007. The survey, conducted by KRC Research, asked New York residents their views on health-care access; it was conducted in August 2007 and consisted of phone interviews with 590 adult residents of New York State, of whom 300 were residents of New York City.
70. Office of the New York City Comptroller (2007), p. 8.
71. Harris et al. (2010). *Seasonal Influenza Vaccine Use by Adults in the U.S.: A Snapshot from the End of the 2009–2010 Vaccination Season*.
72. Lee et al., p. 4255. They also found, however, that alternative locations such as workplaces and retail stores "are not serving many other population segments (e.g., rural or lower income patients) that do not regularly interact with the traditional health-care system" (ibid.).
73. New York City Department of Health and Mental Hygiene, "Influenza Prevention and Control, 2009–2010," *City Health Information* 28, no. 6 (October 2009): 49–56, <http://www.nyc.gov/html/doh/downloads/pdf/chi/chi28-6.pdf>.
74. Business corporations can, however, offer administrative support services to a professional corporation, provided that those services are also based on fair market value.
75. "Practice of medicine and use of title 'physician.' Only a person licensed or otherwise authorized under this article shall practice medicine or use the title 'physician.' "
76. Including hospital service corporations and nonprofit hospitals. See Convenient Care Association, "State-by-State Policy Guide to Corporate Practice of Medicine Laws" (2007).
77. Francis J. Serbaroli, "Legal Guidelines for Operators of 'Walk-In' Clinics," *New York Law Journal* 237, no. 61 (March 30, 2007).
78. Ibid.
79. Ibid.

80. Experts with whom we spoke suggested two potential reasons for this lack. First, nurse-practitioners are reimbursed at a lower level than physicians, and so may not have the financial resources—given retail clinics’ already thin margins—to launch and sustain a retail-clinic presence over the time (eighteen to twenty-four months) required to make it profitable. Second, the collaborative-practice requirements in New York would require a nurse-practitioner-based clinic to have one physician collaborator for every four nurse-practitioners working at a retail clinic—potentially one per clinic. This represents an added cost burden that may be prohibitive.
81. From 2006 to 2010, a professional corporation owned by nurse-practitioners operated the CVS retail clinics in New York, leasing space and administrative services from CVS. In 2010, the nurse-practitioners relinquished ownership to a professional corporation of physicians. In conversations with the author, the nurse-practitioners cited ongoing regulatory costs and uncertainty as the principal reason for ending the contract with CVS. The CVS stores today, however, remain solely staffed by nurse-practitioners under physician supervision, as required by the state’s CPA.
82. This is to differentiate them from clinics as defined by Article 28 of New York’s Public Health Law and to maintain compliance with the state’s prohibition on the corporate practice of medicine.
83. Source: Healthcare 311 ([www.healthcare311.com](http://www.healthcare311.com)). Used with permission.
84. MSA is “a geographic entity designated by [the U.S. Office of Management and Budget] for use by federal statistical agencies. A metropolitan statistical area consists of at least one urbanized area with a population of 50,000 or more, along with adjacent territory with a high degree of social and economic integration with the core—a factor measured by commuting ties.” *Forbes.com*, <http://www.forbes.com/2009/10/01/cities-census-metro-lifestyle-metropolitan-statistical-area.html>.
85. The firm is doing business in New York as DR Walk-In Medical Care.
86. Gale Scott, “Putting Docs in Duane Reade Pays Off,” *Crain’s New York Business*, January 26, 2010.
87. There also seems to be a growing market for for-profit urgent-care centers in New York, driven by spillovers from New York City’s crowded emergency rooms. See Barbara Benson, “For Impatient Patients, An Urgent-Care Boomlet,” *Crain’s New York Business*, December 20, 2010.
88. See [www.jointcommission.org](http://www.jointcommission.org).
89. Letter to the Kentucky Cabinet for Health and Family Services, expressing the views of the FTC Office of Policy Planning, Bureau of Economics, and Bureau of Competition, January 28, 2010.
90. *Ibid.*, p. 998-1000.
91. *Ibid.*
92. *Ibid.*
93. Ruth E. Granfors, “Development and Operation of Convenient Care Clinics: Legal and Policy Considerations,” ABA 10th Annual Conference on Emerging Issues in Healthcare Law, February 18–20, 2009. See New York Public Health Code, Article 28, Sec. 2801.
94. However, if physicians were operating a commercial entity providing such services, they would be subject to CON.
95. Previously, the State Hospital Review and Planning Council and the Public Health Council were jointly responsible for CON reviews. The SHRPC “was charged with making recommendations to the Public Health Council concerning applications to establish or transfer ownership of health care facilities and home care agencies,” changes to existing

facilities, or the closing of a facility; [http://www.health.state.ny.us/facilities/state\\_hospital\\_review\\_planning\\_council](http://www.health.state.ny.us/facilities/state_hospital_review_planning_council). Final decisions for CON review rested with the Public Health Council.

96. Ohsfeldt and Schneider, 2006, p. 38.

97. National Conference of State Legislatures, "Certificate of Need: State Health Laws and Programs," <http://www.ncsl.org/IssuesResearch/Health/CONCertificateofNeedStateLaws/tabid/14373/Default.aspx>.

98. Ibid.

99. Federal Trade Commission and Department of Justice (2004), p. 22.

100. Ibid., p. 4.

101. See chap. 8 of the FTC/DOJ report, <http://www.ftc.gov/opa/2004/07/healthcarerpt.shtm>. Ohsfeldt and Schneider also conclude that "a fundamental problem with CON is that it awards a property right—a monopoly franchise—to the recipient, often in perpetuity. The resulting rent-seeking behavior on the part of incumbents is as predictable as it is pervasive. CON ossifies market structure and stifles innovation" (p.39).

102. Kaiser State Health Facts, "United States: Total Nurse Practitioners, 2009," <http://www.statehealthfacts.org/comparemaptable.jsp?ind=773&cat=8>.

103. For discussion of the quality of nurse-practitioner care, see *American Journal for Nurse Practitioners* 11, no. 4 (April 2007).

104. See Mary D. Naylor and Ellen T. Kurtzman, "The Role of Nurse Practitioners in Reinventing Primary Care," *Health Affairs* 29, no. 5 (May 2010): 893–99.

105. "Currently, there is considerable discussion about a looming physician shortage in primary and specialty medicine. These shortages, real or speculative, are driven in part by rigid practice models that focus on physicians as sole providers. Indeed, researchers are noticing a trend indicating that NPs are migrating to states that have enacted more permissive scopes of practice. The clustering of NPs in progressive states will not alleviate, and may exacerbate, the existing maldistribution of primary care providers." Sharon Christian et al., "Overview of Nurse Practitioner Scopes of Practice in the United States—Discussion," Center for the Health Professions, University of California, San Francisco (2007), p. 16.

106. For a history of the prohibition of the corporate practice of medicine and suggestions for reform, see Nicole Huberfeld, "Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine," *Health Matrix: Journal of Law-Medicine* 14, no. 2 (2004): 243–91.

107. See Weinick, 2010b.

108. State Assembly bill A81:

Diagnostic or treatment centers established to provide health care services within the space of a retail business operation, including but not limited to a pharmacy, a store open to the general public or a shopping mall, or within space used by an employer for providing health care services to its employees, may be operated by legal entities formed under the laws of New York whose stockholders and members, as applicable, are not natural persons and whose principal stockholders and members, as applicable, and controlling persons comply with all applicable requirements of this section and demonstrate to the satisfaction of the Public Health Council, sufficient experience and expertise in delivering high quality health care services.

The bill was referred to the Committee on Health on May 10, 2010.





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