New Massachusetts regulations pave the way for 'limited service clinics'

In regulations that took effect February 8, 2008, the Massachusetts Department of Public Health ("DPH") has cleared the way for the establishment of retail clinics in Massachusetts, to be known in the state as "limited service clinics." The Massachusetts regulations were drafted after MinuteClinic, a subsidiary of CVS Caremark Corporation, sought waivers from existing clinic regulations in order to open 20 to 30 MinuteClinics stores in the state in the next year. Rather than adopt a piecemeal approach, DPH chose to create a new type of entity. At this early stage, Planned Parenthood and a large physician group practice in western Massachusetts are also reported to be interested in opening limited service clinics.

Limited service clinics emerged in Minneapolis in 2000; at year-end 2007 there were over 900, located in 35 states. While strategies vary from operator to operator and state to state, all of the existing players in the retail clinic market adhere to a common model, offering a limited menu of medical services — typically provided by non-physician practitioners — with transparent pricing in a walk-in environment. Charges range from $39 to $69 per visit, and most visits take about 15 minutes. Most retail clinics are located in, and some are owned by, pharmacies, grocery stores and mass merchandisers.

The new Massachusetts regulations, located at 105 CMR 140, are amendments to the existing clinic regulations. The regulations streamline the clinic licensure requirements for limited service clinics, but also add new policies and physical plant requirements applicable to the new model. Limited services are defined in the regulations as:

A prescribed set of preidentified diagnostic and treatment services that:

(1) require only a focused history and physical examination that does not require venipuncture;

(2) may make use of only CLIA-waived tests;

(3) are of a nature that may be provided within the projected duration of patient encounters, using available facilities and equipment;

(4) are for episodic, urgent care related to an illness or for immunizations; and

(5) are included in a proposed list of services submitted to and approved by DPH.

The clinic regulations already required that all clinics retain practitioners able to render the services the clinic holds itself out as providing. The new amendments add that the qualifications of practitioners must extend to appropriate training for the age range of clinic patients. (The state boards of registration oversee the scope of practice of medicine and nursing.) Limited service clinics may not provide treatment to children younger than 24 months. Each limited service clinic must develop clinical practice guidelines for each of its service categories, and guidelines for determining when patients' needs are beyond the scope of the clinic's services. They must have policies for referring patients whose needs exceed the clinic's services and for obtaining physician consultation on unclear services. Each clinic must maintain a roster of primary-care practitioners in its geographic area who are accepting new patients and are willing to accept a referral from the clinic. Existing regulations already required all clinics to have a written agreement with a nearby hospital for the transfer of

patients for emergency treatment. Clinics must provide a copy of the medical record of each visit to the patient as soon as possible and, with the patient's consent, to the patient's primary-care practitioner.

Massachusetts tackled concerns about the impact of retail clinics on the "medical home" model by requiring that each patient who does not have a primary-care practitioner be provided with a referral from the clinic's roster. Furthermore, in a unique provision with which clinic operators will have to grapple, the regulations require limited service clinics to develop policies designed to "identify and limit, if necessary, the number of repeat encounters with individual patients." Clinics that are affiliated with, or satellites of, health care facilities are permitted to develop alternate mechanisms for assuring continuity of care within the health care facility's system. Even if a limited services clinic is an affiliate or satellite of a licensed health care facility, the clinic must be named in a way that makes clear that only limited services are being offered at that location. Note that any type of clinic conducted by a hospital licensed under M.G.L. c. 111, § 51 is not subject to Massachusetts clinic regulations.

In response to concerns about conflicts of interest, the regulations require policies that ensure that clinic personnel do not promote the use of services provided by the host retailer; that the clinic post a statement indicating that patients are not required to buy prescription medicines or other supplies at the host retailer; and, in the case of a clinic located within a retailer that sells tobacco products, that the clinic post information about tobacco usage. The regulations also cover the physical plant, including requirements regarding hand sanitizers, toilet facilities, examination rooms and closets.

Physicians around the country, and now in Massachusetts, have expressed concerns about the impact of retail clinics on quality of care, in part because of the belief that retail clinics contribute to fragmentation in health care delivery. The American Academy of Pediatrics opposes retail clinics, and the American Medical Association has called for an investigation into potential conflicts of interest. Furthermore, providers have argued that clinics "skim off the top" by treating easy to diagnose conditions. On the other hand, in a state where the average wait for an appointment with a primary-care doctor is more than seven weeks, and where the rising bill for health care reform is focusing even more attention on issues of cost, access, and quality, some in Massachusetts believe that retail clinics may ease the burden of overloaded practices and serve as a welcome alternative to costly and inefficient trips to the emergency room. Physicians in other states have chosen to integrate retail clinics into their practices (for instance, by referring patients to them on weekends), and 10 percent of the member clinics of the Convenient Care Association, an industry group, are now physician-owned.

As for the quality of care provided, the clinics have made a concerted effort to demonstrate that, through the use of computer-guided algorithms applicable to a short list of common illnesses, "cookbook medicine" has an extremely high rate of adherence to clinical guidelines, even without direct physician supervision. The technology aspect of retail clinics also extends to record-keeping, as retail clinics' commitment to sharing electronic records (reinforced in some states by regulatory requirements) may play a role in convincing providers of the contribution these clinics could make to continuity of care.

Regulation of physician oversight and the scope of practice of non-physician practitioners, along with corporate practice of medicine rules, result in significant variation in operating costs, scalability and corporate structure from state to state. The provision of preventive care and wellness services, as opposed to solely acute care, varies primarily based on operators' strategies, but regulation can also play a role, as the Massachusetts definition of limited services demonstrates. While the early retail clinics accepted only out-of-pocket payments and in large part targeted the uninsured, demand from insured patients, insurers' recognition of potential cost savings, and the acquiescence by some of those insurers to simplified billing systems, have led to a reversal such that most clinics now accept insurance and some do not even require co-payments. An April 2007 Harris Interactive survey found that 78 percent of clinic patients had insurance, and 42 percent of retail clinic visits were covered by insurance. Even with the welcome change in payor attitudes, most clinics

are not yet profitable, in part because it is taking them up to three years to recoup initial investment. According to the California HealthCare Foundation, a clinic must see 17 to 23 customers per day to break even.

Hospitals and health systems have been closely watching the rise of retail clinics, wary of the impact on their patients' health and on their own bottom line. Some are now starting to join in, either on their own or with retail partners. They are interested in the clinics not only as potentially successful independent ventures, but as extensions of their delivery systems and brands. Consequently, health systems may stand to realize economies of scope in operating limited service clinics alongside their existing institutions; may retain patients in their care network; and may be even better suited than some independent operators to ride out the wait for profitability. (Health systems should recognize, however, that some of the attractive aspects of opening affiliated clinics, such as brand extension and the linking of electronic records systems, may also contribute to a finding of enterprise liability down the line.) The Mayo Health System and several other Minnesota health systems got into the limited service clinic business relatively early, opening their own stand-alone clinics, while the AtlantiCare system in New Jersey is partnered with a grocery chain and Memorial Hermann hospital in Houston with RediClinic. On the other hand, a Missouri-based system, SSM Health Care, has already ended its relationship with Take Care Health Systems because of concerns raised by its physicians. In the wake of the sudden closure of 23 CheckUps clinics located in its stores, Wal-Mart announced earlier this month that it will now open co-branded clinics, to be known as The Clinic at Wal-Mart, partnering with local hospitals in Atlanta, Dallas and Little Rock. In mid-2007, Wal-Mart announced plans to open 2,000 clinics in its stores in five to seven years, so the opportunities for hospitals to join forces with the mega-retailer are potentially vast.

Massachusetts's cautious authorization of limited service clinics reflects the recognition that the clinics are a response — perhaps stopgap, perhaps permanent — to the dearth of primary-care providers. The health care community will now have another arena in which to observe and participate in the evolving relationship between retail clinics and the health care system.