

## HEALTH LAW

BY FRANCIS J. SERBAROLI

### *Legal Guidelines for Operators of “Walk-In” Clinics*

As is the case with most of the learned professions, the practice of medicine has undergone major changes over the decades. At one time, medicine was practiced by physicians, patients were treated in a doctor's office, a hospital or a clinic, and that was pretty much that.

Then came private health insurance, followed by government programs such as Medicare and Medicaid. Costs escalated as new technologies and treatments were introduced and as more people sought medical care.

In the 1970s and 1980s, states attempted well-meaning efforts to control costs through the creation of the certificate-of-need process, regulating the premiums that health insurers could charge, and other market interventions. The result: costs continued to escalate. The advent of managed care seemed to offer some hope for reining in costs, but after a few years of somewhat lower inflation in the health care sector, costs have been escalating again. Health care expenditures in the United States are now approximately \$2 trillion per year, or about 16 percent of gross domestic product. The National Health Statistics Group at the Centers for Medicare and Medicaid Services has projected that this will rise to an astonishing \$4 trillion, or 20 percent of GDP by 2015.

Health care costs have exceeded the rate of inflation every year for many years. Hospitals, physicians and other providers keep raising prices to meet escalating costs. Insurance premiums in turn keep rising. The result is that consumers, especially those with modest incomes, must seek lower-cost alternatives to what is available. Consumers are choosing and health insurers are encouraging the use of more nonhospital care and procedures, either in the doctor's office or in lower-cost facilities

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like ambulatory surgery centers.

The market is also responding with other innovative alternatives, one of which is popularly referred to as the “walk-in” clinic. These are compact spaces located in heavily trafficked places such as malls, superstores, drugstores, supermarkets, even train stations and airports. They are sometimes staffed by a physician, but more often by a licensed nurse practitioner or a licensed physician's assistant. They offer fast diagnosis and treatment of low-level medical problems: cold and flu symptoms, sore throats and minor infections, rashes and allergies, minor injuries, as well as preventive services such as flu shots and blood-pressure checks.

The medical community has reacted with predictable concern that patients with serious problems who seek assistance at these facilities rather than a doctor's office will not be properly diagnosed. However, consumers appear to be enthusiastic about these clinics, since they offer a lower-cost and fast alternative to a hospital emergency room or waiting for an appointment and traveling to a doctor's office. Investors are raising capital to open or expand operations, and major national chains such as Wal-Mart, Target and Walgreen have introduced walk-in clinics in a number of states. CVS, one of the largest drugstore chains, announced earlier this year that it would acquire the Minute Clinic chain of some 83 walk-in clinics, many of which are already located in CVS stores. With fees ranging from \$30 to \$100 or more depending on the service,

these clinics appeal to many uninsured individuals as well as to those who have insurance but want quick and simple care.

Some major health care systems have taken notice of this trend and are establishing their own satellite walk-in clinics in retail locations as a way not only to keep ahead of the competition but also to capture referrals to their hospitals and physicians. A patient treated for a minor problem for a few minutes in a walk-in clinic can then be referred to a system-affiliated primary care physician and potentially begin a long-term relationship with the physician and the system. Health insurers also seem to favor these inexpensive facilities, and more managed care plans are approving them as in-network providers.

New York undoubtedly will be a magnet for these clinics, and, indeed, a number have already opened in New York City and elsewhere. However, anyone considering opening walk-in clinics must be fully aware of the legal and regulatory requirements for the delivery of health care services. For purposes of our analysis, we will use as an example the most common type of walk-in clinic, one staffed by a licensed nurse practitioner and located in a drugstore.

#### **Restrictions**

New York still has a strict prohibition on the corporate practice of most professions, including medicine.<sup>1</sup> Simply put, this century-old 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>2</sup> 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. For example, a licensed nurse practitioner can form a professional corporation and lease space in a drugstore to operate a walk-in clinic. However, this professional corporation must be owned only by nurses; ownership or control

by unlicensed lay individuals is prohibited.

The nurse practitioner may provide only those services and write only those prescriptions that are within the scope of his license. The nurse may hire other licensed nurse practitioners to work in the clinic, but may not hire other professionals such as physicians or other higher-level medical professionals. (If a physician-owned professional corporation operates the walk-in clinic, however, such a corporation may hire other professionals such as nurse practitioners and physician assistants.) Unlicensed individuals or general business corporations that purport to "own" a walk-in clinic in New York could be guilty of practicing the profession without a license<sup>1</sup> and/or illegally operating an unlicensed facility providing medical care,<sup>2</sup> both of which can result in criminal prosecution.

Next, the rent paid to the drugstore by the walk-in clinic must be based strictly upon the fair market value of the space actually occupied by the walk-in clinic. It may not be based upon the volume or value of the professional services provided by the nurses or it can run afoul of New York's statutory prohibition on fee-splitting,<sup>3</sup> as well as the federal anti-kickback law<sup>4</sup> if Medicare or Medicaid pays for any of the walk-in clinic's services. The federal anti-kickback law carries both criminal and civil penalties. Fee-splitting can result in disciplinary action against the nurse practitioner, up to and including license revocation. The same holds true for any franchise fees. If the nurse practitioner wants to operate the walk-in clinic under one of the various national service marks that are available, the franchise fee cannot be tied to the volume or value of professional fees, or be calculated as a percentage of the clinic's gross or net income.

## Choice

Nurse practitioners are permitted to write prescriptions for a limited variety of medications. While patients can choose to fill any prescriptions written by the nurse practitioner at the drugstore's pharmacy counter, patients must be free to get their prescriptions filled wherever they choose. There can be no referral fees, kickbacks or consideration of any sort (e.g., no sales commissions, no reduced rent) given by the drugstore to the nurse practitioner for sales of drugs prescribed by the nurse practitioner. Nurse practitioners, physician assistants and most other licensed medical professionals are prohibited by New York's patient antireferral law<sup>5</sup> from referring patients to pharmacies and certain other providers in which they have an ownership or investment interest, or with which they have a compensation arrangement.

The relationship between the walk-in clinic and the drugstore must be a strictly arm's-length landlord-tenant relationship. The nurse practitioner and the drugstore's licensed pharmacist may consult

with each other about patient care matters such as the efficacy of certain prescriptions or whether certain medicines may be contra-indicated given a particular patient's symptoms or other medications being taken. However, the drugstore and its pharmacists cannot improperly influence the nurse's judgment as far as the diagnosis or treatment of the walk-in clinic's patients is concerned. The nurse has a direct relationship with and responsibility to the patient, and must at all times exercise independent judgment in diagnosing that patient's condition and what, if any, prescription or treatment would be appropriate.

Nurse practitioners may order certain types of laboratory tests and the patient antireferral law applies to laboratory testing as does the federal anti-kickback law if Medicare or Medicaid is implicated. Moreover, New York has a Laboratory Business Practices Act<sup>6</sup> that places strict limits on billing and collection for laboratory services, as well as the offering or accepting of payments for laboratory services. Under this statute, for example, the franchisor of a nurse-owned walk-in clinic franchise may not directly bill a patient for an outside laboratory's services, or share in any fees for clinical laboratory testing.

Once the nurse practitioner's professional partnership or professional corporation is set up, it may hire other nurse practitioners, and may own and operate multiple walk-in clinics. However, all locations must be in compliance with the restrictions noted above. The nurse-owner must also be actively involved, either in providing services directly, or in supervising the other nurse practitioners who provide care in the walk-in clinics.

Since the fees charged by walk-in clinics are relatively low, some operators may be tempted to order unnecessary treatments or diagnostic testing in order to generate more income. However, the Medicare and Medicaid programs and private insurers are quick to pick up patterns of unusual utilizations of services, which in turn can trigger financial and clinical audits.

While a general business corporation is prohibited from owning and operating a walk-in clinic or hiring licensed professionals, it can provide non-clinical business management support services such as computers, clerical and billing services, book and record-keeping, and the like. Once again, the fees paid by the walk-in clinic for these services must be based on the value of the services themselves, and not on a percentage of the walk-in clinic's revenues.

Walk-in clinics are usually so small that privacy becomes an issue. The federal HIPAA regulations<sup>7</sup> as well as state laws<sup>8</sup> protect the confidentiality of a patient's medical information. The operator of a walk-in clinic must take steps to assure that discussions with a patient being treated are not

overheard by other patients or passersby, and that medical records are properly secured.

If a licensed hospital or diagnostic and treatment center wishes to operate walk-in clinics, it may do so provided that it receives administrative approval from the Department of Health. Each walk-in clinic is then added to the facility's operating certificate as a satellite location. Upon approval, such walk-in clinics can be staffed by a full range of medical professionals. However, satellite clinics must meet specific architectural requirements set forth in the Health Department's regulations. The small size and configuration of most walk-in clinics do not meet these standards.

Managed care plans and other health insurers that are approached about admitting a walk-in clinic to their network of approved providers should perform an appropriate due diligence review to determine that the clinic is owned and operated by properly licensed professionals. Clinics that are illegally structured can be denied payment for services provided.

## Conclusion

Due to space limitations, we have touched on only some of the significant legal issues facing walk-in clinics in New York. Walk-in clinics can be profitable and successful and can fill a growing consumer demand, but like any other medical service, they must comply with a wide variety of legal and regulatory requirements and restrictions before and after they open for business.



1. See, Serbaroli, "Corporate Practice of Medicine: A Clear and Present Danger," NYLJ, Sept. 23, 1993, p.3.

2. See., e.g., N.Y. Bus. Corp. Law §201(e).

3. N.Y. Ed. Law §6512.

4. N.Y. PHL §2801-a.

5. N.Y. Ed. Law §6509-a; 6509(9); 6531.

6. 42 USC §1320a-7b(b).

7. N.Y. PHL §238 et seq.

8. N.Y. PHL §585 et seq.

9. 45 CFR Parts 160 and 164.

10. See, e.g., N.Y. PHL §17-18.