

Key Highlights of the New York State Public Health and Health Planning Council's Recommendations for Oversight of Ambulatory Care Services

March 2014

In the setting of a more sophisticated, cost-conscious patient population coupled with a potential crisis with respect to primary care access, more and more ambulatory and stand-alone clinic services are becoming available to the public. With the growth in the number of ambulatory facilities available to patients, so grows the potential for confusion with regard to what services are rendered by which facilities and what regulations apply to all.

In response to this growth, on January 7, 2014, the Public Health and Health Planning Council of the New York Department of Health ("PHHPC") issued [recommendations](#) to the New York State Commissioner of Health for new rules regarding ambulatory care services offered by various health care providers. PHHPC identified five issues influencing the need to streamline and regulate these services: (i) the changing models of care in the health services ecosystem, (ii) the potential confusion for consumers with multiple types of care models in the ambulatory marketplace, (iii) the creation of safety standards, (iv) the promotion of continuity of care and maintaining the use of primary care physicians, and (v) the support of health information systems for both care improvement and reporting efficacy.

The proposed recommendations involving Retail Clinics, Urgent Care Providers, and office-based surgery will first require the passage of authorizing legislation currently included in the [2014-2015 New York State Executive Budget](#), Health and Mental Hygiene Bill, Part A, Sections 21-23. The other recommendations, requiring only regulatory authorization, are currently moving through the rulemaking process. Public comment will be available for a minimum of 45 days after the rules are proposed and published in the *New York State Register*.¹

¹ N.Y. A.P.A. Law §202(1)(a)(ii).

The recommendations focus on five types of ambulatory care providers:

- I. Limited Services Clinics (Retail Clinics)
- II. Urgent Care Providers
- III. Freestanding Emergency Departments
- IV. Non-Hospital Surgery, Office-Based Surgery
- V. Upgraded Diagnostic and Treatment Centers

Key highlights of the recommendations for each of the five types of providers are summarized, in turn, as follows:

I. Limited Services Clinics (Retail Clinics)

Customer Recognition: Patients would know “Limited Services Clinics” or Retail Clinics typically by a pharmacy or drug store trade name, such as Walgreens or CVS. Patients are becoming accustomed to utilizing these store-based clinics for immunizations, and antibiotic administration for minor infections. The walk-in clinic advertising for these services can pose confusion with stand-alone Urgent Care centers that are posed to offer more expansive services.

Change in Name: Per the new recommendations, Retail Clinics will be required to be formally named “Limited Services Clinics.” Use of this name would be required in materials describing the clinic and/or the services provided.

Accreditation: Limited Services Clinics will be required to receive accreditation from a national accreditation organization approved by the Department of Health.

Scope of Services: The services available at these types of locations will be limited to wellness and screening services and basic health services related to minor ailments and immunizations. These clinics will be prohibited from:

- providing surgical, dental, physical rehabilitation, mental health, substance abuse, and birth center services;
- providing care to patients 24 months or younger (an additional note—the American Academy of Pediatrics recently issued an opinion cautioning patients against using Retail Clinics for the treatment of infants);
- administering childhood immunizations, except for the flu vaccine, to those under 18 years of age; and
- dispensing controlled substances, and conducting certain laboratory testing.

Use of a Corporate Medical Director: To ensure the quality of care, the corporate entity responsible for the Limited Services Clinic will be required to maintain a medical director, licensed to practice medicine in New York State.

Additional Requirements: See below for additional requirements that are common to both limited service and Urgent Care clinics.

II. **Urgent Care**

Customer Recognition: Urgent Care centers, or stand-alone, extended-hour clinics, are being frequented by patients who do not have access to a primary care physician or patients who have a primary care physician but cannot manage care within typical office hours. Access and convenience are driving an increase in the formation of Urgent Care centers in New York and elsewhere.

“Urgent Care” Defined and Scope of Services: Per the recommendations, “Urgent Care” is defined to include the treatment of an acute episode of illness or minor trauma. “Urgent Care” does not include emergency intervention or prolonged services. The recommendations would require Urgent Care Providers to offer a range of services that would include, but not be limited to, accepting unscheduled patient visits during extended hours and providing diagnostic and treatment services, such as x-rays and EKGs, along with simple laceration treatment and cardiac support capabilities.

Accreditation: To be called an “Urgent Care Provider,” certification or accreditation by a Department of Health approved accrediting organization will be required. This includes non-Article 28 providers, such as physician offices affiliated with an Article 28² facility. However, no Certificate of Need (“CON”) review is necessary for non-Article 28 providers.

While most Article 28 providers already obtain accreditation, the provider’s accreditation review must specifically include the Urgent Care Provider in order to offer those specified services. Additionally, varying levels of CON review are required in order for Article 28 hospitals or Diagnostic and Treatment Centers to provide Urgent Care services.

Use of the name “Urgent Care”: The name “Urgent Care” will be restricted to only providers offering the specified services and “Urgent Care” will be required to be included in a provider’s banner. In addition, providers will be prohibited from using the word or any variation of “Emergency” in their name to avoid confusion and to try and prevent the more serious conditions from self-triaging themselves to the wrong facility. If specialized services are being provided—for example, treating a specific patient population—the provider’s name must indicate this (e.g., “Pediatric Urgent Care”).

² Article 28 of the New York Public Health Law governs hospitals, nursing homes, and certain other health care facilities.

Common Requirements for Limited Services Clinics and Urgent Care Ambulatory Service Providers:

Disclosures to Consumers: Prominently displayed signage must inform consumers of both the services offered by the provider and, when applicable, the ability to purchase prescriptions and supplies at other locations.

Quality and Safety: Providers must develop policies and procedures for referral of patients whose needs cannot be met at the providers' location and for repeat patient encounters. Providers are prohibited from offering incentives to the clinical staff to recommend that purchases be made at the location of the providers.

Promotion of the Medical Home: In an effort to enhance overall care and implement the concept of the medical home, for patients that indicate they do not have a primary care provider, a list of those providers accepting new patients must be given to the patient. The list must contain a range of providers, including:

- providers with the designation of a Patient-Centered Medical Home ("PCMH") or other designation and a corresponding description of the designation;
- Federally Qualified Health Center providers and those serving Medicaid and low-income patients; and
- providers who serve individuals with disabilities.

Health Information Technology: Providers will be required to implement certain practices regarding health information. These include the required use of certified electronic health records and ePrescribing. Documentation and execution of a discharge plan of care will also be required for every patient.

III. Freestanding Emergency Departments

Customer Recognition: Hospitals struggling to keep doors open sometimes opt to close all operations and offer only emergency department services. This allows continued use of capital investments such as CT scanners and laboratory equipment, while at the same time serving a patient population that relies upon the facility. Patients typically know their local hospital by virtue of the emergency department and, particularly in highly populated areas, Emergency Medicine Services ("EMS") are critical to community health and well-being.

Facility Designation: An emergency department owned by a hospital, but at a separate physical location, will be designated a "Hospital-Sponsored Off-Campus Emergency Department." In an effort to reduce confusion with consumers, this

type of facility should use the hospital's name followed by "Satellite Emergency Department."

Scope of Services: These off-campus facilities will be held to the same standards and applicable federal laws and requirements as hospital-based emergency departments. In addition, they will have to be able to receive ambulance patients and must have protocols in place with EMS providers and other emergency departments for transfer of patients, when necessary.

Hours of Operation: Hospital-Sponsored Off-Campus Emergency Departments may operate on a part-time basis at a minimum of 12 hours per day. Full CON review will be required for a new facility operating on a part-time basis or an existing facility seeking to reduce its hours of operation.

Methodology of Need: There is currently no need methodology addressing Hospital-Sponsored Off-Campus Emergency Departments. Specific criteria for this methodology will be developed.

Accreditation and CON Review: The Hospital-Sponsored Off-Campus Emergency Departments must be included in the accreditation review of the general hospital owner in order for the hospital to comply with the minimum operational standards currently required in the state rules and regulations. If a new off-campus emergency department is established, full CON review will be required.

Disclosures to Consumers: Information indicating hours of operation and the ability of a facility to provide emergency services must be clearly and accurately conveyed to consumers. This information must be provided through signage and the development of a communication plan and public information campaign through collaboration with other emergency medical services in the region.

Promotion of the Medical Home and Information Technology: Hospital-Sponsored Off-Campus Emergency Departments will supply patients with the same type of information regarding availability of primary care providers and implement the same types of health information technology that are required of both Limited Services Clinics and Urgent Care Providers.

IV. Non-Hospital Surgery (Office-Based Surgery)

The recommendations for office-based surgical practices focus on registration, accreditation, and reporting requirements for both providers and the accrediting agencies. The recommendations also add two new reportable adverse events and extend the time that providers are required to report adverse events from one day to three days.

For providers: All office-based surgery and office-based anesthesia practices will have to register with the Department of Health and, if requested, submit procedure and quality data. Accreditation will be required for physician and podiatrist practices for non-invasive procedures if more than minimal sedation is used.

For Accrediting Organizations: When requested by the Department of Health, accrediting agencies will need to provide the Department of Health with survey and complaint/referral investigation information and initiate reviews or investigations of specific provider practices.

V. Upgraded Diagnostic and Treatment Centers

This specific category of diagnostic and treatment centers will be eliminated.

Although these recommendations are preliminary, it is likely that the Department of Health will be working to create definitive legislative and regulatory proposals over the next few months, and there is an opportunity to provide comments and input in an informal manner that may influence its thinking at this time. Once the legislation and regulations are proposed, comments can still be submitted, but the process to do so will be more formal and the Department of Health's views are likely to be less flexible.

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*As these recommendations are considered and move through the legislative and regulatory process, if you have any questions or would like to submit comments to the Department of Health regarding the rules as they are proposed please contact **Jeffrey H. Becker, Linda V. Tiano, Mollie K. O'Brien**, or the Epstein Becker Green attorney who regularly handles your legal matters.*

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