STATE OF NEW YORK

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IN ASSEMBLY

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Introduced by M. of A. PAULIN, GOTTFRIED, BENEDETTO, RODRIGUEZ, STIRPE, QUART, CRESPO, CROUCH, MURRAY, SIMON, PICHARDO, ARROYO, COOK, TITONE, DINOWITZ -- Multi-Sponsored by -- M. of A. HIKIND, HOOPER, LUPARDO, LUPINACCI, McDONALD, McDONOUGH, PERRY, SEPULVEDA, WRIGHT -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to retail clinics and limited services clinics

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The public health law is amended by adding a new section 230-e to read as follows:

§ 230-e. Retail clinics. 1. As used in this section, "retail clinic" means a facility or portion of a facility that is operated by any entity that is authorized under the laws of this state to provide professional services to the public and that provides health care services or treatment provided by a health care practitioner licensed, certified, registered or authorized to practice under title eight of the education law, acting within his or her lawful scope of practice, that: (a) operates within the space of a retail business operation, such as a pharmacy or a store open to the general public; (b) is labeled, branded, advertised or marketed with the name or symbol of a retail business entity; or (c) is labeled, branded, advertised or marketed with the name or symbol of a business entity, other than a business entity that provides health care services or treatment provided at the facility. However, a facility or portion of a facility shall not be deemed to be a retail clinic if it ordinarily is used only for providing health care services to employees of the retail business operation. A facility shall not be deemed to be a retail clinic if the health care service under title eight of the education law it provides is limited to pharmacy or ophthalmic dispensing and ophthalmologic or optometric services provided in connection with ophthalmic dispensing.

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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2. The treatments and services that may be provided by a retail clinic shall be limited to the provision of treatment and services to patients for acute episodic illness or condition; episodic preventive treatment and services such as immunizations; ophthalmic dispensing and ophthalmologic or optometric services provided in connection with ophthalmic dispensing; or treatment and services for minor injuries that are not reasonably likely to be life-threatening or potentially disabling or have complications if ambulatory care within the capacity of the retail clinic is provided; but the treatments and services provided by a retail clinic shall not include monitoring or treatment and services over multiple visits over prolonged periods.

3. A retail clinic shall be deemed to be a "health care provider" for the purposes of title two-D of this article. A prescriber practicing in a retail clinic shall not be deemed to be in the employ of a pharmacy or practicing in a hospital for purposes of subdivision two of section sixty-eight hundred seven of the education law.

4. (a) The commissioner shall make regulations setting forth operational and physical plant standards for retail clinics, which may be different from the regulations otherwise applicable to diagnostic and treatment centers, including, but not limited to:

(i) requiring that retail clinics attain and maintain accreditation by an appropriate accrediting entity approved by the commissioner and requiring timely reporting to the department if a retail clinic loses its accreditation;

(ii) designating or limiting the treatments and services that may be provided, including limiting the scope of services to the following, provided that such services shall not include monitoring or treatment and services over multiple visits or prolonged periods:

(A) the provision of treatment and services to patients for minor acute episodic illnesses or conditions;

(B) episodic prevention and wellness treatments and services such as immunizations;

(C) ophthalmic dispensing and ophthalmologic or optometric services provided in connection with ophthalmic dispensing;

(D) treatment and services for minor injuries that are not reasonably likely to be life threatening or potentially disabling or have complications if ambulatory care within the capacity of the retail clinic is provided;

(E) prohibiting the provision of services to patients twenty-four months of age or younger;

(iii) requiring retail clinics to accept walk-ins and offer extended business hours;

(iv) setting forth guidelines for advertising and signage, which shall include signage indicating that prescriptions and over-the-counter supplies may be purchased by a patient from any business and do not need to be purchased on-site;

(v) setting forth guidelines for informed consent, record keeping, referral for treatment and continuity of care, case reporting to the patient's primary care or other health care providers, design, construction, fixtures, and equipment.

(b) Such regulations also shall promote and strengthen primary care by requiring retail clinics to:

(i) inquire of each patient whether he or she has a primary care provider;

(ii) maintain and regularly update a list of local primary care providers and provide such list to each patient who indicates that he or

she does not have a primary care provider. Such roster (A) shall be drawn from a list of primary care providers maintained and periodically updated by the department on its website (in searchable form) including the information required in clauses (B) and (C) of this subparagraph, located in the zip code area and adjacent zip code areas of the retail clinic, and may include additional primary care providers added by the retail clinic; (B) shall identify preferred providers who have achieved recognition as a patient centered medical home (pcmh) or other similar designation and a description of what such designation means; and (C) shall include federally qualified health centers and other providers who serve medicaid, low-income and uninsured patients, and people with disabilities and shall identify cultural and linguistic capabilities when available;

(iii) refer patients to their primary care providers or other health care providers where appropriate;

(iv) transmit by electronic means whenever possible, records of services to patients' primary care providers;

(v) decline to treat any patient for the same condition or illness more than three times in a year; and

(vi) report to the department relevant data, as may be deemed necessary by the department, related to services provided and patients served, provided that such reporting shall comply with all privacy laws related to patient data.

(c) Retail clinics already in operation at the time this section takes effect must comply with accreditation requirements under this subdivision within one year after the effective date of this section.

(d) The department shall routinely review the compliance by retail clinics with the provisions of this section and if a retail clinic fails to comply with the provisions of this section, or regulations adopted pursuant to this section, the department shall have the authority to take enforcement actions under title two of article one of this chapter.

(e) In making regulations under this section, the commissioner may consult with a workgroup including, but not limited to, representatives of health care consumers and representatives of professional societies of appropriate health care professionals, including those in primary care and other specialties.

5. A retail clinic shall provide treatment without discrimination as to source of payment.

6. The department shall provide an annual report which it shall make available on its website; the report shall include locations of retail clinics in the state and shall indicate which clinics are located in medically underserved areas; such report shall also include an analysis as to whether retail clinics have improved access to health care in underserved areas, recommendations related thereto and any other information the department may deem necessary.

7. This section does not authorize any form of ownership or organization of a retail clinic or practice of any profession that would not otherwise be legal, and does not expand the scope of practice of any health care practitioner. Where any regulation under this section would affect the scope of practice that may be provided in a retail clinic a health care practitioner licensed, registered, certified or authorized to practice under title eight of the education law, the regulation shall be made in consultation with the commissioner of education.

8. The host business entity of a retail clinic shall not, directly or indirectly, by contract, policy, communication, incentive or otherwise, influence or seek to influence any clinical decision, policy or practice

of any health care practitioner providing any health care service in the retail clinic, including prescribing or recommending drugs, devices or supplies. This subdivision shall not preclude the host business entity from establishing, consistent with this section and applicable law, limitations on or requirements as to the scope of health care services to be provided in the retail clinic or activities to assure maintaining quality standards of health care services. As used in this section, "host business entity" means any retail business organization, retail business entity or business entity within whose space the retail clinic is located or with whose name or symbol the retail clinic is labeled, branded, advertised or marketed.

§ 2. Section 2801-a of the public health law is amended by adding a new subdivision 17 to read as follows:

17. (a) A diagnostic or treatment center that is a retail clinic under section two hundred thirty-e of this chapter, where the retail business organization, retail business entity or business entity within whose space the retail clinic is located is a pharmacy registered under article one hundred thirty-seven of the education law, or established within space used by an employer for providing health care services to its employees, may be owned or operated by a legal entity formed under the laws of New York:

(i) that is, or is owned and controlled by, the applicable business entity under paragraph (a), (b) or (c) of subdivision one of section two hundred thirty-e of this chapter or, in the case of a limited services clinic providing health care services to an employer's employees, the employer to whose employees it provides health care services;

(ii) whose stockholders or members, as applicable, may include other than natural persons;

(iii) whose principal stockholders and members, as applicable, and controlling persons comply with all applicable requirements of this section; and

(iv) that demonstrates, to the satisfaction of the public health and health planning council, sufficient experience and expertise in delivering high quality health care services, and a commitment to operate limited services clinics in medically underserved areas of the state.

(b) A diagnostic and treatment center under this subdivision shall be referred to in this subdivision as a "limited services clinic".

(c) For purposes of this subdivision, the public health and health planning council shall adopt and amend rules and regulations, notwithstanding any inconsistent provision of this section, to address any matter it deems pertinent to the establishment of limited services clinics; provided that such rules and regulations shall include, but not be limited to, provisions governing or relating to:

(i) any direct or indirect changes or transfers of ownership interests or voting rights in such entities or their stockholders or members, as applicable;

(ii) providing for public health and health planning council approval of any change in controlling interests, principal stockholders, controlling persons, parent company or sponsors;

(iii) oversight of the operator and its shareholders or members, as applicable, including local governance of the limited services clinics;

(iv) relating to the character and competence and qualifications of, and changes relating to, the directors and officers of the operator and its principal stockholders, controlling persons, parent company or sponsors; and

(v) in determining whether to approve additional limited services clinic locations for the operator, the department shall consider whether the operator has fulfilled its commitment to operate limited services clinics in medically underserved areas of the state.

(d) The following provisions of this section shall not apply to limited services clinics:

(i) paragraph (a) of subdivision three of this section;

(ii) paragraph (b) of subdivision three of this section, relating to stockholders and members other than principal stockholders and principal members;

(iii) paragraph (c) of subdivision four of this section, relating to the disposition of stock or voting rights; and

(iv) paragraph (e) of subdivision four of this section, relating to the ownership of stock or membership.

(e) A limited services clinic shall be deemed to be a "health care provider" for the purposes of title two-D of article two of this chapter. A prescriber practicing in a limited services clinic shall not be deemed to be in the employ of a pharmacy or practicing in a hospital for purposes of subdivision two of section sixty-eight hundred seven of the education law.

(f) The commissioner shall promulgate regulations setting forth operational and physical plant standards for limited services clinics, which may be different from the regulations otherwise applicable to diagnostic or treatment centers, including, but not limited to:

(i) requiring that limited services clinics attain and maintain accreditation by an appropriate accrediting entity approved by the commissioner and requiring timely reporting to the department if a limited services clinic loses its accreditation;

(ii) designating or limiting the treatments and services that may be provided, including limiting the scope of services to the following, provided that such services shall not include monitoring or treatment and services over multiple visits or prolonged periods:

(A) the provision of treatment and services to patients for minor acute episodic illnesses or conditions;

(B) episodic prevention and wellness treatments and services such as immunizations;

(C) ophthalmic dispensing and ophthalmologic or optometric services provided in connection with ophthalmic dispensing;

(D) treatment and services for minor injuries that are not reasonably likely to be life threatening or potentially disabling or have complications if ambulatory care within the capacity of the retail clinic is provided;

(E) prohibiting the provision of services to patients twenty-four months of age or younger;

(iii) requiring limited services clinics to accept walk-ins and offer extended business hours;

(iv) guidelines for advertising and signage, disclosure of ownership interests, informed consent, record keeping, referral for treatment and continuity of care, case reporting to the patient's primary care or other health care providers, design, construction, fixtures, and equipment; signage shall also be required to indicate that prescriptions and over-the-counter supplies may be purchased by a patient from any business and do not need to be purchased on-site; and

(v) where a limited services clinic is a retail clinic, not treating any patient for the same condition or illness more than three times in a year.

(g) Such regulations also shall promote and strengthen primary care by requiring limited services clinics to:

(i) inquire of each patient whether he or she has a primary care provider;

(ii) maintain and regularly update a list of local primary care providers and provide such list to each patient who indicates that he or she does not have a primary care provider. Such roster (A) shall be drawn from a list of primary care providers maintained and periodically updated by the department on its website (in searchable form) including the information required in clauses (B) and (C) of this subparagraph, located in the zip code area and adjacent zip code areas of the retail clinic, and may include additional primary care providers added by the retail clinic; (B) shall identify preferred providers who have achieved recognition as a patient centered medical home (pcmh) or other similar designation and a description of what such designation means; and (C) shall include federally qualified health centers and other providers who serve medicaid, low-income and uninsured patients, and people with disabilities and shall identify cultural and linguistic capabilities when available;

(iii) refer patients to their primary care providers or other health care providers where appropriate;

(iv) transmit by electronic means whenever possible, records of services to patients' primary care providers;

(v) in the case of a limited services clinic that is a retail clinic, decline to treat any patient for the same condition or illness more than three times in a year; and

(vi) report to the department relevant data, as may be deemed necessary by the department, related to services provided and patients served, provided that such reporting shall comply with all privacy laws related to patient data.

(h) Each limited services clinic shall use its best efforts to execute participation agreements with health information organizations, also known as qualified entities, pursuant to which the limited services clinic agrees to participate in the statewide health information network of New York (SHIN-NY).

(i) A limited services clinic shall provide treatment without discrimination as to source of payment.

(j) The host business entity of a limited services clinic shall not, directly or indirectly, by contract, policy, communication, incentive or otherwise, influence or seek to influence any clinical decision, policy or practice of any health care practitioner providing any health care service in the retail clinic, including prescribing or recommending drugs, devices or supplies. This subdivision shall not preclude the host business entity from establishing, consistent with this section and applicable law, limitations on or requirements as to the scope of health care services to be provided in the retail clinic or activities to assure maintaining quality standards of health care services. As used in this section, "host business entity" means the retail business organization, retail business entity or business entity within whose space the limited services clinic is located or the employer for whose employees it provides health care services.

§ 3. This act shall take effect on the one hundred eightieth day after it shall have become a law; provided that effective immediately, the commissioner of health shall make regulations and take other actions reasonably necessary to implement the provisions of the public health law enacted by this act when they take effect.