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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:

1 Section 1. The public health law is amended by adding a new section
2 230-e to read as follows:

3 § 230-e. Retail clinics. 1. As used in this section, "retail clinic"
4 means a facility or portion of a facility that is operated by any entity
5 that is authorized under the laws of this state to provide professional
6 services to the public and that provides health care services or treat-
7 ment provided by a health care practitioner licensed, certified, regis-
8 tered or authorized to practice under title eight of the education law,
9 acting within his or her lawful scope of practice, that: (a) operates
10 within the space of a retail business operation, such as a pharmacy or a
11 store open to the general public; (b) is labeled, branded, advertised or
12 marketed with the name or symbol of a retail business entity; or (c) is
13 labeled, branded, advertised or marketed with the name or symbol of a
14 business entity, other than a business entity that provides health care
15 services or treatment provided at the facility. However, a facility or
16 portion of a facility shall not be deemed to be a retail clinic if it
17 ordinarily is used only for providing health care services to employees
18 of the retail business operation. A facility shall not be deemed to be
19 a retail clinic if the health care service under title eight of the
20 education law it provides is limited to pharmacy or ophthalmic dispens-
21 ing and ophthalmologic or optometric services provided in connection
22 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

38 (c) For purposes of this subdivision, the public health and health
39 planning council shall adopt and amend rules and regulations, notwith-
40 standing any inconsistent provision of this section, to address any
41 matter it deems pertinent to the establishment of limited services clin-
42 ics; provided that such rules and regulations shall include, but not be
43 limited to, provisions governing or relating to:

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

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

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

52 (iv) relating to the character and competence and qualifications of,
53 and changes relating to, the directors and officers of the operator and
54 its principal stockholders, controlling persons, parent company or spon-
55 sors; and

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

5 (d) The following provisions of this section shall not apply to limit-
6 ed services clinics:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36 (i) A limited services clinic shall provide treatment without discrim-
37 ination as to source of payment.

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

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