

STATE OF NEW YORK

7178

2023-2024 Regular Sessions

IN SENATE

May 18, 2023

Introduced by Sen. FERNANDEZ -- read twice and ordered printed, and when printed to be committed to the Committee on Finance

AN ACT to amend the public health law, in relation to establishing an epinephrine auto-injector affordability program to provide low-cost epinephrine auto-injectors; to amend the insurance law, in relation to requiring coverage for epinephrine auto-injectors and capping the co-pay or deductible for such at sixty dollars; and to amend the general business law, in relation to making failure to comply with the epinephrine auto-injectors affordability program a deceptive business practice; and making an appropriation therefor

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

1 Section 1. Legislative intent. The legislature finds and declares
2 that:
3 Individuals who have moderate to severe allergies, severe asthma, or
4 genetic conditions such as angioedema are at risk of reactions that can
5 occur within seconds or minutes and that can lead to anaphylaxis, a
6 potentially fatal reaction.
7 Epinephrine works quickly to improve breathing, stimulate the heart,
8 raise dropping blood pressure, prevent airways from closing, prevent or
9 decrease shock, reverse hives, and reduce swelling of the face, lips,
10 and throat.
11 A delay in appropriate treatment for anaphylaxis almost certainly
12 contributes to death in individuals, so it is critical that all anaphy-
13 laxis reactions are treated as a medical emergency.
14 Epinephrine auto-injectors are essential because they are the easiest
15 and most efficient way to potentially save the life of an individual
16 exhibiting symptoms of or experiencing anaphylactic shock.
17 Rising costs of epinephrine auto-injectors make this life-saving medi-
18 cation difficult or impossible to obtain for many people, even those
19 with private health insurance or who are enrolled in a public health

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

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benefit program. Many individuals are unable to afford an epinephrine auto-injector because they cannot pay the copayment amount required under their insurance plan or, if they are uninsured, the cost of an epinephrine auto-injector; these individuals risk their lives every day by not having access to this life-saving medicine if faced with an allergic reaction.

Therefore, it is the intent of the general assembly to establish an epinephrine auto-injector affordability program to ensure that New York state residents have greater access to epinephrine.

§ 2. The public health law is amended by adding a new section 280-d to read as follows:

§ 280-d. Epinephrine auto-injector affordability program. 1. As used in this section:

(a) "Epinephrine auto-injector device" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body, based on the weight of the person who is to receive the injection, for the purpose of emergency treatment of a person appearing to experience anaphylactic symptoms approved by the food and drug administration.

(b) "Manufacturer" means any person or business entity engaged in manufacturing or producing epinephrine auto-injectors that are available for purchase in this state.

(c) "Pharmacy" means any place registered in accordance with section sixty-eight hundred eight of the education law in which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.

(d) "Program" means the epinephrine auto-injector affordability program created in subdivision two of this section.

(e) "Proof of residency" means a current and valid document that is in English, or is translated into English and is unaltered, and that includes the individual's, or in the case of a minor, the minor's parent or legal guardian, printed name and residential address. Documents that may be used for proof of residency are:

(i) a New York-issued driver's license or non-driver identification card issued pursuant to the provisions of article seventeen-A of title four of the vehicle and traffic law, as added by chapter two hundred ninety-five of the laws of nineteen hundred eighty-three;

(ii) a printed bill, including a utility, telephone, internet, cable, insurance, mortgage, rent, waste disposal, water or sewer, medical, or other bill;

(iii) a credit card or bank statement;

(iv) a pay stub or earnings statement;

(v) a piece of post-marked first-class mail or United States postal service change of address confirmation;

(vi) a printed rent receipt or residential lease;

(vii) a transcript or report card from an accredited school;

(viii) a vehicle title or registration;

(ix) an insurance policy;

(x) a government-issued letter or state or federal government-issued check; or

(xi) a record of medical service from a shelter, treatment facility, or assisted living facility, including a homeless shelter, women's shel-

1 ter, other nonprofit shelter, halfway house, nursing home, or rehabili-
2 tation facility.

3 2. (a) By January first, two thousand twenty-four, the department
4 shall establish and implement the epinephrine auto-injector affordabili-
5 ty program to provide low-cost epinephrine auto-injectors to eligible
6 individuals.

7 (b) By January first, two thousand twenty-five, each manufacturer
8 shall establish and implement procedures to make epinephrine auto-injec-
9 tors available in accordance with subdivision eight of this section to
10 eligible individuals who hold a valid prescription for epinephrine auto-
11 injectors.

12 3. To be eligible to receive epinephrine auto-injectors through the
13 program, an individual must:

14 (a) demonstrate proof of residency in New York state;

15 (b) not be eligible for assistance provided through the NY State of
16 Health, The Official Health Plan Marketplace or through Medicare or
17 Medicaid;

18 (c) have a valid epinephrine auto-injector prescription; and

19 (d) not be enrolled in prescription drug coverage that limits the
20 total amount of cost sharing that the enrollee is required to pay for a
21 covered prescription to not more than sixty dollars for a two-pack of
22 epinephrine auto-injectors, regardless of the amount or type of epineph-
23 rine needed to fill the prescription.

24 4. (a) The commissioner, in conjunction with the superintendent of
25 financial services, shall develop an application form to be used by an
26 individual who is seeking epinephrine auto-injectors through the
27 program. At a minimum, the application form must:

28 (i) provide information related to program eligibility and coverage in
29 English, Spanish and in each language spoken by at least two and one-
30 half percent of the population of any county in which such population
31 speaks English less than very well, as defined by the United States
32 bureau of the Census American Community survey or comparable census
33 data, and speaks a shared minority language at home; and

34 (ii) require the individual to show proof that the individual meets
35 the requirements of subdivision three of this section.

36 (b) The department and the department of financial services shall make
37 the application form available on their respective websites. The depart-
38 ment of financial services shall also make the application form avail-
39 able to pharmacies, health care providers, and health facilities that
40 prescribe or dispense epinephrine auto-injectors.

41 5. To access epinephrine auto-injectors through the program, an indi-
42 vidual must present, at a pharmacy, a completed, signed, and dated
43 application form with proof of residency. If the individual is under
44 eighteen years of age, the individual's parent or legal guardian may
45 provide the pharmacist with proof of residency.

46 6. (a) Upon receipt of an individual's proof of residency and
47 completed, signed, and dated application form demonstrating that the
48 individual is eligible pursuant to subdivision three of this section, a
49 pharmacist shall dispense the prescribed epinephrine auto-injectors. An
50 individual who is eligible to receive epinephrine auto-injectors through
51 the program may receive epinephrine auto-injectors as prescribed for
52 twelve months.

53 (b) The pharmacist dispensing the epinephrine auto-injectors is
54 encouraged to inform the individual:

1 (i) that the individual may be eligible for medical assistance
2 programs under title eleven of article five of the social services law;
3 and

4 (ii) of any manufacturer-sponsored programs that assist individuals
5 who cannot afford their prescription epinephrine auto-injectors.

6 (c) The pharmacist dispensing the epinephrine auto-injectors shall
7 retain a copy of the application form submitted by the individual for
8 two years after the date the epinephrine auto-injector was initially
9 dispensed.

10 7. A pharmacy that dispenses epinephrine auto-injectors pursuant to
11 paragraph (a) of subdivision six of this section may collect a copayment
12 from the individual to cover the pharmacy's costs of processing and
13 dispensing the epinephrine auto-injector, which copayment amount must
14 not exceed sixty dollars for each two-pack of epinephrine auto-injectors
15 that the pharmacy dispenses to the individual.

16 8. (a) Unless the manufacturer agrees to send to the pharmacy a
17 replacement supply of the same number of epinephrine auto-injectors
18 dispensed through the program, the pharmacy may submit to the manufac-
19 turer of the dispensed epinephrine auto-injectors, directly or through
20 the manufacturer's delegated representative, subcontractor, or other
21 vendor, an electronic claim for payment that is made in accordance with
22 the National Council for Prescription Drug Programs; standards for elec-
23 tronic claims processing.

24 (b) By January first, two thousand twenty-five, each manufacturer
25 shall develop a process for a pharmacy to submit an electronic claim for
26 reimbursement, including an accessible online application for reimburse-
27 ment claims from pharmacies under the program, as provided in paragraph
28 (a) of this subdivision.

29 (c) If the pharmacy submits an electronic claim to the manufacturer
30 pursuant to paragraph (a) of this subdivision, the manufacturer or the
31 manufacturer's delegated representative, subcontractor, or other vendor
32 shall, within thirty days after receipt of the claim, reimburse the
33 pharmacy the amount that the pharmacy paid the manufacturer for the
34 number of epinephrine auto-injectors dispensed through the program.

35 9. The department and the department of financial services shall
36 promote the availability of the program to state residents. The promo-
37 tional material must include information about each manufacturer's
38 consumer epinephrine auto-injector program, as applicable. Each depart-
39 ment may seek and accept gifts, grants, and donations to fulfill the
40 requirements of this subdivision.

41 10. A manufacturer's reimbursement pursuant to paragraph (c) of subdivi-
42 vision eight of this section shall not be deemed to be a kickback.

43 11. A manufacturer that fails to comply with the requirements of this
44 section:

45 (a) is subject to a fine of ten thousand dollars for each month of
46 noncompliance; and

47 (b) engages in a deceptive trade practice under section three hundred
48 ninety-six-xx of the general business law.

49 § 3. Subsection (i) of section 3216 of the insurance law is amended by
50 adding a new paragraph 39 to read as follows:

51 (39) (A) Every policy which provides medical coverage that includes
52 coverage for physician services in a physician's office and every policy
53 which provides major medical or similar comprehensive-type coverage
54 shall include coverage for epinephrine auto-injectors for the treatment
55 of moderate to severe allergies, severe asthma, or genetic conditions
56 such as angioedema that can lead to anaphylaxis, if recommended or

1 prescribed by a physician or other licensed health care provider legally
2 authorized to prescribe under title eight of the education law.

3 (B) Such coverage may be subject to annual deductibles and coinsurance
4 as may be deemed appropriate by the superintendent and as are consistent
5 with those established for other benefits within a given policy;
6 provided however, the total amount that a covered person is required to
7 pay out of pocket for a covered prescription allowing for two epineph-
8 rine auto-injectors shall be capped at an amount not to exceed sixty
9 dollars per thirty-day supply, regardless of the amount or type of
10 epinephrine needed to fill such covered person's prescription and
11 regardless of the insured's deductible, copayment, coinsurance or any
12 other cost sharing requirement.

13 (C) Nothing in this section shall prevent an insurer from reducing a
14 covered person's cost sharing to an amount that is lower than the amount
15 specified in subparagraph (B) of this paragraph.

16 § 4. Subsection (l) of section 3221 of the insurance law is amended by
17 adding a new paragraph 22 to read as follows:

18 (22) (A) Every group or blanket accident and health insurance policy
19 issued or issued for delivery in this state which provides medical
20 coverage that includes coverage for physician services in a physician's
21 office and every policy which provides major medical or similar compre-
22 hensive-type coverage shall include coverage for epinephrine auto-injec-
23 tors for the treatment of moderate to severe allergies, severe asthma,
24 or genetic conditions such as angioedema that can lead to anaphylaxis,
25 if recommended or prescribed by a physician or other licensed health
26 care provider legally authorized to prescribe under title eight of the
27 education law.

28 (B) Such coverage may be subject to annual deductibles and coinsurance
29 as may be deemed appropriate by the superintendent and as are consistent
30 with those established for other benefits within a given policy;
31 provided however, the total amount that a covered person is required to
32 pay out of pocket for a covered prescription allowing for two epineph-
33 rine auto-injectors shall be capped at an amount not to exceed sixty
34 dollars per thirty-day supply, regardless of the amount or type of
35 epinephrine needed to fill such covered person's prescription and
36 regardless of the insured's deductible, copayment, coinsurance or any
37 other cost sharing requirement.

38 (C) Nothing in this section shall prevent an insurer from reducing a
39 covered person's cost sharing to an amount that is lower than the amount
40 specified in subparagraph (B) of this paragraph.

41 § 5. Section 4303 of the insurance law is amended by adding a new
42 subsection (vv) to read as follows:

43 (vv) (1) A medical expense indemnity corporation or a health service
44 corporation which provides medical coverage that includes coverage for
45 physician services in a physician's office and every policy which
46 provides major medical or similar comprehensive-type coverage shall
47 include coverage for epinephrine auto-injectors for the treatment of
48 moderate to severe allergies, severe asthma, or genetic conditions such
49 as angioedema that can lead to anaphylaxis, if recommended or prescribed
50 by a physician or other licensed health care provider legally authorized
51 to prescribe under title eight of the education law.

52 (2) Such coverage may be subject to annual deductibles and coinsurance
53 as may be deemed appropriate by the superintendent and as are consistent
54 with those established for other benefits within a given policy;
55 provided however, the total amount that a covered person is required to
56 pay out of pocket for a covered prescription allowing for two epineph-

rine auto-injectors shall be capped at an amount not to exceed sixty dollars per thirty-day supply, regardless of the amount or type of epinephrine needed to fill such covered person's prescription and regardless of the insured's deductible, copayment, coinsurance or any other cost sharing requirement.

(3) Nothing in this section shall prevent an insurer from reducing a covered person's cost sharing to an amount that is lower than the amount specified in paragraph two of this subsection.

§ 6. The general business law is amended by adding a new section 396-zz to read as follows:

§ 396-zz. Unfair or deceptive trade practices; medical. A person engages in a deceptive trade practice when, in the course of the person's business, vocation, or occupation, the person fails to comply with the requirements of section two hundred eighty-d of the public health law.

§ 7. Appropriation. The sum of two million dollars (\$2,000,000), or so much thereof as may be necessary, is hereby appropriated to the department of health from any moneys in the state treasury in the general fund to the credit of the state purposes account not otherwise appropriated for the purposes of carrying out the provisions of this act. Such sum shall be payable on the audit and warrant of the state comptroller on vouchers certified or approved by the commissioner of health, or his or her duly designated representative in the manner provided by law.

§ 8. Severability. If any clause, sentence, paragraph, subdivision, section or part of this act shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part thereof directly involved in the controversy in which such judgment shall have been rendered. It is hereby declared to be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.

§ 9. This act shall take effect on the one hundred eightieth day after it shall have become a law; provided that the provisions of sections three, four and five of this act shall take effect on the first of January next succeeding the date on which it shall have become a law and shall apply to all policies and contracts issued, renewed, modified, altered, or amended on or after such date. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.