

SENATE, No. 3030

STATE OF NEW JERSEY 220th LEGISLATURE

INTRODUCED SEPTEMBER 22, 2022

Sponsored by:
Senator VIN GOPAL
District 11 (Monmouth)

SYNOPSIS

Authorizes pharmacists to dispense HIV prophylaxis without individual prescription under certain circumstances; mandates prescription benefits coverage.

CURRENT VERSION OF TEXT

As introduced.



1 AN ACT concerning pharmacists and supplementing Titles 17, 26,
2 45, and 52 of the Revised Statutes and Title 17B of the New
3 Jersey Statutes.

4
5 **BE IT ENACTED** *by the Senate and General Assembly of the State*
6 *of New Jersey:*

7
8 1. As used in this act:

9 “CDC PEP guidelines” means the “Updated Guidelines for
10 Antiretroviral Postexposure Prophylaxis After Sexual, Injection
11 Drug Use, or Other Nonoccupational Exposure to HIV – United
12 States, 2016,” or any subsequent guidelines, published by the
13 federal Centers for Disease Control and Prevention.

14 “CDC PReP guidelines” means the “2017 Preexposure
15 Prophylaxis for the Prevention of HIV Infection in the United States
16 – 2017 Update: A Clinical Practice Guideline,” or any subsequent
17 guidelines, published by the federal Centers for Disease Control and
18 Prevention.

19 “HIV” means the human immunodeficiency virus.

20 “HIV preexposure prophylaxis” means a fixed-dose combination
21 of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine
22 (FTC) (200 mg), or another drug or drug combination determined
23 by the State Board of Pharmacy to meet the same clinical eligibility
24 recommendations provided in the CEC PReP guidelines.

25 “HIV postexposure prophylaxis” means: tenofovir disoproxil
26 fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken
27 once daily, in combination with either raltegravir (400mg), taken
28 twice daily, or dolutegravir (50mg), taken once daily; tenofovir
29 disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200
30 mg), taken once daily, in combination with darunavir (800mg) and
31 ritonavir (100mg), taken once daily; or another drug or drug
32 combination determined by the State Board of Pharmacy to meet
33 the same clinical eligibility recommendations provided in the CEC
34 PRP guidelines.

35
36 2. a. Notwithstanding any other provision of law to the
37 contrary, a pharmacist may initiate and furnish HIV preexposure
38 prophylaxis or HIV postexposure prophylaxis to a patient without
39 an individual prescription pursuant to a standing order issued to the
40 pharmacist by the Commissioner of Health or, if the commissioner
41 is not a duly licensed physician, the Deputy Commissioner for
42 Public Health Services. A standing order shall be issued to a
43 pharmacist upon request, provided that the pharmacist satisfies the
44 training requirements set forth in subsection b. of this section and
45 certifies that the pharmacist will adhere to the requirements set
46 forth in subsection c. of this section concerning the protocols for
47 initiating and furnishing HIV preexposure prophylaxis and the
48 requirements set forth in subsection d. of this section concerning the

1 protocols for initiating and furnishing HIV postexposure
2 prophylaxis to patients without an individual prescription. In no
3 case shall a patient be authorized to waive the consultation required
4 pursuant to subsection c. or subsection d. of this section.

5 b. A pharmacist shall not be authorized to furnish HIV
6 preexposure prophylaxis or HIV postexposure prophylaxis to a
7 patient without an individual prescription unless the pharmacist
8 completes a training program, approved by the State Board of
9 Pharmacy in consultation with the Department of Health,
10 concerning the use of HIV preexposure prophylaxis and HIV
11 postexposure prophylaxis. At a minimum, the training program
12 shall include information about financial assistance programs
13 available to patients to assist with the costs of HIV preexposure
14 prophylaxis and HIV postexposure prophylaxis.

15 c. A pharmacist shall furnish at least a 30-day supply, and up
16 to a 60-day supply, of HIV preexposure prophylaxis to a patient
17 without an individual prescription if the following requirements are
18 met:

19 (1) The patient is HIV-negative, as documented by a negative
20 HIV test result obtained within the previous seven days from an
21 HIV antigen/antibody test or antibody-only test or from a rapid,
22 point-of-care fingerstick blood test approved by the federal Food
23 and Drug Administration. If the patient does not provide evidence
24 of a negative HIV test in accordance with this paragraph, the
25 pharmacist shall order an HIV test. If the test results are not
26 ordered directly to a pharmacist, the pharmacist shall verify the test
27 results to the pharmacist's satisfaction. If the patient tests positive
28 for HIV infection, the pharmacist or person administering the test
29 shall direct the patient to a primary care provider, provide the
30 patient with information and resources concerning treatment
31 providers and HIV treatment clinics in the region, and take all other
32 actions required under State and federal law in response to a
33 positive test for HIV;

34 (2) The patient does not report any signs or symptoms of acute
35 HIV infection on a self-reported checklist of acute HIV infection
36 signs and symptoms;

37 (3) The patient does not report taking any contraindicated
38 medications, and the pharmacist reviews the patient's prescription
39 monitoring information to confirm no contraindicated prescriptions
40 have been issued or dispensed to the patient in the past six months;

41 (4) The patient has not been furnished with HIV preexposure
42 prophylaxis without an individual prescription within the past two
43 years;

44 (5) The pharmacist provides counseling to the patient on the
45 ongoing use of HIV preexposure prophylaxis, which may include
46 education about side effects, safety during pregnancy and
47 breastfeeding, adherence to recommended dosing, and the
48 importance of timely testing and treatment, as applicable, for HIV,

1 renal function, hepatitis B, hepatitis C, sexually transmitted
2 diseases, and pregnancy for individuals of child-bearing capacity.
3 The pharmacist shall notify the patient that the patient will not be
4 eligible to continue receiving HIV preexposure prophylaxis unless
5 the patient is seen by a primary care provider and issued a
6 prescription for the HIV preexposure prophylaxis, and that the
7 patient may be furnished with no more than a 60-day supply of HIV
8 preexposure prophylaxis by a pharmacist without an individual
9 prescription within any given two year period;

10 (6) The pharmacist documents, to the extent possible, the
11 services provided by the pharmacist in the patient's record in the
12 record system maintained by the pharmacy, and includes the
13 dispensation of the HIV preexposure prophylaxis in the prescription
14 monitoring database established pursuant to P.L.2007, c.244
15 (C.45:1-45 et al.) with a note indicating the HIV preexposure
16 prophylaxis was provided without an individual prescription
17 pursuant to this section; and

18 (7) The pharmacist notifies the patient's primary care provider
19 that the pharmacist furnished the patient with HIV preexposure
20 prophylaxis pursuant to this section. If the patient does not have a
21 primary care provider, or refuses to consent to the pharmacist
22 providing notice to the primary care provider pursuant to this
23 paragraph, the pharmacist shall provide the patient with a list of
24 physicians and surgeons, clinics, or other health care service
25 providers to contact regarding ongoing care for HIV preexposure
26 prophylaxis. The Department of Health shall publish and maintain
27 a current list of providers for pharmacists to use for the purposes of
28 this paragraph, which list may be made available on the
29 department's Internet website.

30 d. A pharmacist shall furnish a complete course of HIV
31 postexposure prophylaxis to a patient without an individual
32 prescription if the following requirements are met:

33 (1) The pharmacist confirms with the patient that the exposure
34 to HIV occurred within the previous 72 hours and the patient
35 otherwise meets the clinical criteria for HIV postexposure
36 prophylaxis consistent with the CDC PEP guidelines;

37 (2) The pharmacist provides HIV testing that is classified as
38 waived under the federal "Clinical Laboratory Improvement
39 Amendments of 1988," 42 U.S.C. s.263a, or determines the patient
40 is willing to undergo HIV testing consistent with the CDC PEP
41 guidelines;

42 (3) The pharmacist provides counseling to the patient on the use
43 of HIV postexposure prophylaxis consistent with the CDC PEP
44 guidelines, which may include education about side effects, safety
45 during pregnancy and breastfeeding, adherence to recommended
46 dosing, and the importance of timely testing and treatment, as
47 applicable, for HIV and sexually transmitted diseases. The
48 pharmacist shall additionally inform the patient of the availability

1 of HIV preexposure prophylaxis for persons who are at substantial
2 risk of acquiring HIV; and

3 (4) The pharmacist notifies the patient's primary care provider
4 that the pharmacist provided the patient with a complete course of
5 HIV postexposure prophylaxis. If the patient does not have a
6 primary care provider, or refuses to consent to the pharmacist
7 providing notice to the primary care provider pursuant to this
8 paragraph, the pharmacist shall provide the patient with a list of
9 physicians and surgeons, clinics, or other health care service
10 providers to contact regarding followup care for HIV postexposure
11 prophylaxis. The Department of Health shall publish and maintain
12 a current list of providers for pharmacists to use for the purposes of
13 this paragraph, which list may be made available on the
14 department's Internet website.

15

16 3. a. (1) Except as provided in paragraph (2) of this
17 subsection, no group or individual hospital service corporation
18 contract providing hospital or medical expense benefits shall be
19 delivered, issued, executed, or renewed in this State or approved for
20 issuance or renewal in this State by the Commissioner of Banking
21 and Insurance, on or after the effective date of this act, unless the
22 contract provides benefits to any subscriber or other person covered
23 thereunder for HIV preexposure prophylaxis and HIV postexposure
24 prophylaxis furnished without an individual prescription pursuant to
25 the requirements of section 2 of P.L. , c. (C.) (pending
26 before the Legislature as this bill) without requiring prior
27 authorization or step therapy.

28 (2) If the federal Food and Drug Administration has approved
29 one or more therapeutic equivalents of a drug, device, or product
30 for the prevention of HIV and AIDS, paragraph (1) of this
31 subsection shall not be construed to require the contract to cover all
32 therapeutically equivalent versions without prior authorization or
33 step therapy, if at least one version is covered without prior
34 authorization or step therapy.

35 b. A contract offered by a group or individual hospital service
36 corporation shall not:

37 (1) prohibit, or permit a delegated pharmacy benefits manager to
38 prohibit, a pharmacist from dispensing HIV preexposure
39 prophylaxis or HIV postexposure prophylaxis; and

40 (2) be required to cover HIV preexposure prophylaxis that has
41 been furnished by a pharmacist without an individual prescription
42 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
43 before the Legislature as this bill) in excess of a 60-day supply for a
44 single patient within a given two year period.

45 c. Nothing in this section shall be construed to require a
46 contract offered by a group or individual hospital service
47 corporation to provide coverage for HIV preexposure prophylaxis
48 or HIV postexposure prophylaxis furnished by a pharmacist at an

1 out-of-network pharmacy, unless the contract has an out-of-network
2 pharmacy benefit.

3 d. The provisions of this section shall apply to all contracts in
4 which the hospital service corporation has reserved the right to
5 change the premium.

6 e. As used in this section:

7 “HIV preexposure prophylaxis” means the same as that term is
8 defined in section 1 of P.L. , c. (C.) (pending before the
9 Legislature as this bill).

10 “HIV postexposure prophylaxis” means the same as that term is
11 defined in section 1 of P.L. , c. (C.) (pending before the
12 Legislature as this bill).

13 “Step therapy” means requiring that a lower-cost alternative to
14 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
15 shown to have been ineffective as a condition of providing
16 prescription benefits coverage for the prophylaxis.

17

18 4. a. (1) Except as provided in paragraph (2) of this
19 subsection, no group or individual medical service corporation
20 contract providing hospital or medical expense benefits shall be
21 delivered, issued, executed, or renewed in this State or approved for
22 issuance or renewal in this State by the Commissioner of Banking
23 and Insurance, on or after the effective date of this act, unless the
24 contract provides benefits to any subscriber or other person covered
25 thereunder for HIV preexposure prophylaxis and HIV postexposure
26 prophylaxis furnished without an individual prescription pursuant to
27 the requirements of section 2 of P.L. , c. (C.) (pending
28 before the Legislature as this bill) without requiring prior
29 authorization or step therapy.

30 (2) If the federal Food and Drug Administration has approved
31 one or more therapeutic equivalents of a drug, device, or product
32 for the prevention of HIV and AIDS, paragraph (1) of this
33 subsection shall not be construed to require the contract to cover all
34 therapeutically equivalent versions without prior authorization or
35 step therapy, if at least one version is covered without prior
36 authorization or step therapy.

37 b. A contract offered by a group or individual medical service
38 corporation shall not:

39 (1) prohibit, or permit a delegated pharmacy benefits manager to
40 prohibit, a pharmacist from dispensing HIV preexposure
41 prophylaxis or HIV postexposure prophylaxis; and

42 (2) be required to cover HIV preexposure prophylaxis that has
43 been furnished by a pharmacist without an individual prescription
44 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
45 before the Legislature as this bill) in excess of a 60-day supply for a
46 single patient within a given two year period.

47 c. Nothing in this section shall be construed to require a
48 contract offered by a group or individual medical service

1 corporation to provide coverage for HIV preexposure prophylaxis
2 or HIV postexposure prophylaxis furnished by a pharmacist at an
3 out-of-network pharmacy, unless the contract has an out-of-network
4 pharmacy benefit.

5 d. The provisions of this section shall apply to all contracts in
6 which the group or individual medical service corporation has
7 reserved the right to change the premium.

8 e. As used in this section:

9 “HIV preexposure prophylaxis” means the same as that term is
10 defined in section 1 of P.L. , c. (C.) (pending before the
11 Legislature as this bill).

12 “HIV postexposure prophylaxis” means the same as that term is
13 defined in section 1 of P.L. , c. (C.) (pending before the
14 Legislature as this bill).

15 “Step therapy” means requiring that a lower-cost alternative to
16 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
17 shown to have been ineffective as a condition of providing
18 prescription benefits coverage for the prophylaxis.

19
20 5. a. (1) Except as provided in paragraph (2) of this
21 subsection, no group or individual health service corporation
22 contract providing hospital or medical expense benefits shall be
23 delivered, issued, executed, or renewed in this State or approved for
24 issuance or renewal in this State by the Commissioner of Banking
25 and Insurance, on or after the effective date of this act, unless the
26 contract provides benefits to any subscriber or other person covered
27 thereunder for HIV preexposure prophylaxis and HIV postexposure
28 prophylaxis furnished without an individual prescription pursuant to
29 the requirements of section 2 of P.L. , c. (C.) (pending
30 before the Legislature as this bill) without requiring prior
31 authorization or step therapy.

32 (2) If the federal Food and Drug Administration has approved
33 one or more therapeutic equivalents of a drug, device, or product
34 for the prevention of HIV and AIDS, paragraph (1) of this
35 subsection shall not be construed to require the contract to cover all
36 therapeutically equivalent versions without prior authorization or
37 step therapy, if at least one version is covered without prior
38 authorization or step therapy.

39 b. A contract offered by a group or individual health service
40 corporation shall not:

41 (1) prohibit, or permit a delegated pharmacy benefits manager to
42 prohibit, a pharmacist from dispensing HIV preexposure
43 prophylaxis or HIV postexposure prophylaxis; and

44 (2) be required to cover HIV preexposure prophylaxis that has
45 been furnished by a pharmacist without an individual prescription
46 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
47 before the Legislature as this bill) in excess of a 60-day supply for a
48 single patient within a given two year period.

1 c. Nothing in this section shall be construed to require a
2 contract offered by a health service corporation to provide coverage
3 for HIV preexposure prophylaxis or HIV postexposure prophylaxis
4 furnished by a pharmacist at an out-of-network pharmacy, unless
5 the contract has an out-of-network pharmacy benefit.

6 d. The provisions of this section shall apply to all contracts in
7 which the health service corporation has reserved the right to
8 change the premium.

9 e. As used in this section:

10 “HIV preexposure prophylaxis” means the same as that term is
11 defined in section 1 of P.L. , c. (C.) (pending before the
12 Legislature as this bill).

13 “HIV postexposure prophylaxis” means the same as that term is
14 defined in section 1 of P.L. , c. (C.) (pending before the
15 Legislature as this bill).

16 “Step therapy” means requiring that a lower-cost alternative to
17 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
18 shown to have been ineffective as a condition of providing
19 prescription benefits coverage for the prophylaxis.

20
21 6. a. (1) Except as provided in paragraph (2) of this
22 subsection, no individual health insurance policy providing hospital
23 or medical expense benefits shall be delivered, issued, executed, or
24 renewed in this State or approved for issuance or renewal in this
25 State by the Commissioner of Banking and Insurance, on or after
26 the effective date of this act, unless the policy provides benefits to
27 any named insured or other person covered thereunder for HIV
28 preexposure prophylaxis and HIV postexposure prophylaxis
29 furnished without an individual prescription pursuant to the
30 requirements of section 2 of P.L. , c. (C.) (pending before
31 the Legislature as this bill) without requiring prior authorization or
32 step therapy.

33 (2) If the federal Food and Drug Administration has approved
34 one or more therapeutic equivalents of a drug, device, or product
35 for the prevention of HIV and AIDS, paragraph (1) of this
36 subsection shall not be construed to require the policy to cover all
37 therapeutically equivalent versions without prior authorization or
38 step therapy, if at least one version is covered without prior
39 authorization or step therapy.

40 b. An individual health insurance policy shall not:

41 (1) prohibit, or permit a delegated pharmacy benefits manager to
42 prohibit, a pharmacist from dispensing HIV preexposure
43 prophylaxis or HIV postexposure prophylaxis; and

44 (2) be required to cover HIV preexposure prophylaxis that has
45 been furnished by a pharmacist without an individual prescription
46 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
47 before the Legislature as this bill) in excess of a 60-day supply for a
48 single patient within a given two year period.

1 c. Nothing in this section shall be construed to require an
2 individual health insurance policy to provide coverage for HIV
3 preexposure prophylaxis or HIV postexposure prophylaxis
4 furnished by a pharmacist at an out-of-network pharmacy, unless
5 the contract has an out-of-network pharmacy benefit.

6 d. The provisions of this section shall apply to all policies in
7 which the insurer has reserved the right to change the premium.

8 e. As used in this section:

9 “HIV preexposure prophylaxis” means the same as that term is
10 defined in section 1 of P.L. , c. (C.) (pending before the
11 Legislature as this bill).

12 “HIV postexposure prophylaxis” means the same as that term is
13 defined in section 1 of P.L. , c. (C.) (pending before the
14 Legislature as this bill).

15 “Step therapy” means requiring that a lower-cost alternative to
16 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
17 shown to have been ineffective as a condition of providing
18 prescription benefits coverage for the prophylaxis.

19
20 7. a. (1) Except as provided in paragraph (2) of this
21 subsection, no group health insurance policy providing hospital or
22 medical expense benefits shall be delivered, issued, executed, or
23 renewed in this State or approved for issuance or renewal in this
24 State by the Commissioner of Banking and Insurance, on or after
25 the effective date of this act, unless the policy provides benefits to
26 any named insured or other person covered thereunder for HIV
27 preexposure prophylaxis and HIV postexposure prophylaxis
28 furnished without an individual prescription pursuant to the
29 requirements of section 2 of P.L. , c. (C.) (pending before
30 the Legislature as this bill) without requiring prior authorization or
31 step therapy.

32 (2) If the federal Food and Drug Administration has approved
33 one or more therapeutic equivalents of a drug, device, or product
34 for the prevention of HIV and AIDS, paragraph (1) of this
35 subsection shall not be construed to require the policy to cover all
36 therapeutically equivalent versions without prior authorization or
37 step therapy, if at least one version is covered without prior
38 authorization or step therapy.

39 b. A group health insurance policy shall not:

40 (1) prohibit, or permit a delegated pharmacy benefits manager to
41 prohibit, a pharmacist from dispensing HIV preexposure
42 prophylaxis or HIV postexposure prophylaxis; and

43 (2) be required to cover HIV preexposure prophylaxis that has
44 been furnished by a pharmacist without an individual prescription
45 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
46 before the Legislature as this bill) in excess of a 60-day supply for a
47 single patient within a given two year period.

1 c. Nothing in this section shall be construed to require a group
2 health insurance policy to provide coverage for HIV preexposure
3 prophylaxis or HIV postexposure prophylaxis furnished by a
4 pharmacist at an out-of-network pharmacy, unless the contract has
5 an out-of-network pharmacy benefit.

6 d. The provisions of this section shall apply to all policies in
7 which the insurer has reserved the right to change the premium.

8 e. As used in this section:

9 “HIV preexposure prophylaxis” means the same as that term is
10 defined in section 1 of P.L. , c. (C.) (pending before the
11 Legislature as this bill).

12 “HIV postexposure prophylaxis” means the same as that term is
13 defined in section 1 of P.L. , c. (C.) (pending before the
14 Legislature as this bill).

15 “Step therapy” means requiring that a lower-cost alternative to
16 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
17 shown to have been ineffective as a condition of providing
18 prescription benefits.

19
20 8. a. (1) Except as provided in paragraph (2) of this
21 subsection, every individual health benefits plan that is delivered,
22 issued, executed, or renewed in this State pursuant to P.L.1992,
23 c.161 (C.17B:27A-2 et seq.) or approved for issuance or renewal in
24 this State, on or after the effective date of this act, shall provide
25 benefits to any person covered thereunder for expenses incurred for
26 HIV preexposure prophylaxis and HIV postexposure prophylaxis
27 furnished without an individual prescription pursuant to the
28 requirements of section 2 of P.L. , c. (C.) (pending before
29 the Legislature as this bill) without requiring prior authorization or
30 step therapy.

31 (2) If the federal Food and Drug Administration has approved
32 one or more therapeutic equivalents of a drug, device, or product
33 for the prevention of HIV and AIDS, paragraph (1) of this
34 subsection shall not be construed to require the plan to cover all
35 therapeutically equivalent versions without prior authorization or
36 step therapy, if at least one version is covered without prior
37 authorization or step therapy.

38 b. An individual health benefits plan shall not:

39 (1) prohibit, or permit a delegated pharmacy benefits manager to
40 prohibit, a pharmacist from dispensing HIV preexposure
41 prophylaxis or HIV postexposure prophylaxis; and

42 (2) be required to cover HIV preexposure prophylaxis that has
43 been furnished by a pharmacist without an individual prescription
44 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
45 before the Legislature as this bill) in excess of a 60-day supply for a
46 single patient within a given two year period.

47 c. Nothing in this section shall be construed to require an
48 individual health benefit plan to provide coverage for HIV

1 preexposure prophylaxis or HIV postexposure prophylaxis
2 furnished by a pharmacist at an out-of-network pharmacy, unless
3 the contract has an out-of-network pharmacy benefit.

4 d. The provisions of this section shall apply to all health
5 benefit plans in which the carrier has reserved the right to change
6 the premium.

7 e. As used in this section:

8 “HIV preexposure prophylaxis” means the same as that term is
9 defined in section 1 of P.L. , c. (C.) (pending before the
10 Legislature as this bill).

11 “HIV postexposure prophylaxis” means the same as that term is
12 defined in section 1 of P.L. , c. (C.) (pending before the
13 Legislature as this bill).

14 “Step therapy” means requiring that a lower-cost alternative to
15 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
16 shown to have been ineffective as a condition of providing
17 prescription benefits.

18

19 9. a. (1) Except as provided in paragraph (2) of this
20 subsection, every small employer health benefits plan that is
21 delivered, issued, executed, or renewed in this State pursuant to
22 P.L.1992, c.162 (C.17B:27A-17 et seq.) or approved for issuance or
23 renewal in this State, on or after the effective date of this act, shall
24 provide benefits to any person covered thereunder for HIV
25 preexposure prophylaxis and HIV postexposure prophylaxis
26 furnished without an individual prescription pursuant to the
27 requirements of section 2 of P.L. , c. (C.) (pending before
28 the Legislature as this bill) without requiring prior authorization or
29 step therapy.

30 (2) If the federal Food and Drug Administration has approved
31 one or more therapeutic equivalents of a drug, device, or product
32 for the prevention of HIV and AIDS, paragraph (1) of this
33 subsection shall not be construed to require the plan to cover all
34 therapeutically equivalent versions without prior authorization or
35 step therapy, if at least one version is covered without prior
36 authorization or step therapy.

37 b. A small employer health benefits plan shall not:

38 (1) prohibit, or permit a delegated pharmacy benefits manager to
39 prohibit, a pharmacist from dispensing HIV preexposure
40 prophylaxis or HIV postexposure prophylaxis; and

41 (2) be required to cover HIV preexposure prophylaxis that has
42 been furnished by a pharmacist without an individual prescription
43 pursuant to section 2 of P.L. , c. (C.) (pending
44 before the Legislature as this bill) in excess of a 60-day supply for a
45 single patient within a given two year period.

46 c. Nothing in this section shall be construed to require a small
47 employer health benefit plan to provide coverage for HIV
48 preexposure prophylaxis or HIV postexposure prophylaxis

1 furnished by a pharmacist at an out-of-network pharmacy, unless
2 the contract has an out-of-network pharmacy benefit.

3 d. The provisions of this section shall apply to all health
4 benefit plans in which the carrier has reserved the right to change
5 the premium.

6 e. As used in this section:

7 “HIV preexposure prophylaxis” means the same as that term is
8 defined in section 1 of P.L. , c. (C.) (pending before the
9 Legislature as this bill).

10 “HIV postexposure prophylaxis” means the same as that term is
11 defined in section 1 of P.L. , c. (C.) (pending before the
12 Legislature as this bill).

13 “Step therapy” means requiring that a lower-cost alternative to
14 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
15 shown to have been ineffective as a condition of providing
16 prescription benefits.

17

18 10. a. (1) Except as provided in paragraph (2) of this
19 subsection, notwithstanding any provision of law to the contrary, a
20 certificate of authority to establish and operate a health maintenance
21 organization in this State shall not be issued or continued by the
22 Commissioner of Banking and Insurance on or after the effective
23 date of this act unless the health maintenance organization provides
24 health care services to any enrollee for expenses incurred for HIV
25 preexposure prophylaxis and HIV postexposure prophylaxis
26 furnished without an individual prescription pursuant to the
27 requirements of section 2 of P.L. , c. (C.) (pending before
28 the Legislature as this bill) without requiring prior authorization or
29 step therapy.

30 (2) If the federal Food and Drug Administration has approved
31 one or more therapeutic equivalents of a drug, device, or product
32 for the prevention of HIV and AIDS, paragraph (1) of this
33 subsection shall not be construed to require the plan to cover all
34 therapeutically equivalent versions without prior authorization or
35 step therapy, if at least one version is covered without prior
36 authorization or step therapy.

37 b. A health maintenance organization shall not:

38 (1) prohibit, or permit a delegated pharmacy benefits manager to
39 prohibit, a pharmacist from dispensing HIV preexposure
40 prophylaxis or HIV postexposure prophylaxis; and

41 (2) be required to cover HIV preexposure prophylaxis that has
42 been furnished by a pharmacist without an individual prescription
43 pursuant to section 2 of P.L. , c. (C.) (pending
44 before the Legislature as this bill) in excess of a 60-day supply for a
45 single patient within a given two year period.

46 c. Nothing in this section shall be construed to require a health
47 maintenance organization to provide coverage for HIV preexposure
48 prophylaxis or HIV postexposure prophylaxis furnished by a

1 pharmacist at an out-of-network pharmacy, unless the contract has
2 an out-of-network pharmacy benefit.

3 d. The benefits shall be provided to the same extent as for any
4 other medical condition under the contract.

5 e. As used in this section:

6 “HIV preexposure prophylaxis” means the same as that term is
7 defined in section 1 of P.L. , c. (C.) (pending before the
8 Legislature as this bill).

9 “HIV postexposure prophylaxis” means the same as that term is
10 defined in section 1 of P.L. , c. (C.) (pending before the
11 Legislature as this bill).

12 “Step therapy” means requiring that a lower-cost alternative to
13 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
14 shown to have been ineffective as a condition of providing
15 prescription benefits.

16
17 11. a. (1) Notwithstanding any State law or regulation to the
18 contrary, and except as provided in paragraph (2) of this subsection,
19 the Department of Human Services shall ensure that the provision
20 of benefits for HIV preexposure prophylaxis and HIV postexposure
21 prophylaxis furnished without an individual prescription pursuant to
22 the requirements of section 2 of P.L. , c. (C.) (pending
23 before the Legislature as this bill) to eligible persons under the
24 Medicaid program, established pursuant to P.L.1968, c.413
25 (C.30:4D-1 et seq.), shall be provided without the imposition of any
26 prior authorization or step therapy requirements.

27 (2) If the federal Food and Drug Administration has approved
28 one or more therapeutic equivalents of a drug, device, or product
29 for the prevention of HIV and AIDS, paragraph (1) of this
30 subsection shall not be construed to require the department to
31 ensure coverage of all therapeutically equivalent versions without
32 prior authorization or step therapy, if at least one version is covered
33 without prior authorization or step therapy.

34 b. As used in this section:

35 “HIV preexposure prophylaxis” means the same as that term is
36 defined in section 1 of P.L. , c. (C.) (pending before the
37 Legislature as this bill).

38 “HIV postexposure prophylaxis” means the same as that term is
39 defined in section 1 of P.L. , c. (C.) (pending before the
40 Legislature as this bill).

41 “Step therapy” means requiring that a lower-cost alternative to
42 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
43 shown to have been ineffective as a condition of providing
44 prescription benefits coverage for the prophylaxis.

45
46 12. a. (1) Except as provided in paragraph (2) of this
47 subsection, the State Health Benefits Commission shall provide
48 benefits to each person covered under the State Health Benefits

1 Program for expenses incurred for HIV preexposure prophylaxis
2 and HIV postexposure prophylaxis furnished without an individual
3 prescription pursuant to the requirements of section 2 of P.L. ,
4 c. (C.) (pending before the Legislature as this bill) without
5 requiring prior authorization or step therapy.

6 (2) If the federal Food and Drug Administration has approved
7 one or more therapeutic equivalents of a drug, device, or product
8 for the prevention of HIV and AIDS, paragraph (1) of this
9 subsection shall not be construed to require the contract to cover all
10 therapeutically equivalent versions without prior authorization or
11 step therapy, if at least one version is covered without prior
12 authorization or step therapy.

13 b. The State Health Benefits Commission shall not:

14 (1) prohibit, or permit a delegated pharmacy benefits manager to
15 prohibit, a pharmacist from dispensing HIV preexposure
16 prophylaxis or HIV postexposure prophylaxis; and

17 (2) be required to cover HIV preexposure prophylaxis that has
18 been furnished by a pharmacist without an individual prescription
19 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
20 before the Legislature as this bill) in excess of a 60-day supply for a
21 single patient within a given two year period.

22 c. Nothing in this section shall be construed to require the State
23 Health Benefits Commission to provide coverage for HIV
24 preexposure prophylaxis or HIV postexposure prophylaxis
25 furnished by a pharmacist at an out-of-network pharmacy, unless
26 the contract has an out-of-network pharmacy benefit.

27 d. The benefits shall be provided to the same extent as for any
28 other medical condition under the contract.

29 e. As used in this section:

30 “HIV preexposure prophylaxis” means the same as that term is
31 defined in section 1 of P.L. , c. (C.) (pending before the
32 Legislature as this bill).

33 “HIV postexposure prophylaxis” means the same as that term is
34 defined in section 1 of P.L. , c. (C.) (pending before the
35 Legislature as this bill).

36 “Step therapy” means requiring that a lower-cost alternative to
37 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
38 shown to have been ineffective as a condition of providing
39 prescription benefits.

40
41 13. The Commissioner of Human Services shall apply for such
42 State plan amendments or waivers as may be necessary to
43 implement the provisions of section 11 of this act and to secure
44 federal financial participation for State Medicaid expenditures
45 under the federal Medicaid program.

46
47 14. a. Within 90 days after the date of enactment of this act, and
48 notwithstanding the provisions of the “Administrative Procedure

1 Act,” P.L.1968, c.410 (C.52:14B-1 et seq.) to the contrary, the State
2 Board of Pharmacy, in consultation with the Department of Health,
3 immediately upon filing proper notice with the Office of
4 Administrative Law, shall adopt rules and regulations as may be
5 necessary to implement the provisions of this act.

6 b. The rules and regulations adopted pursuant to subsection a.
7 of this section shall be in effect for a period not to exceed one year
8 from the date of filing. These rules and regulations shall thereafter
9 be adopted, amended, or readopted by the board, in consultation
10 with the Department of Health, in accordance with the requirements
11 of the “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-
12 1 et seq.).

13
14 15. This act shall take effect immediately.

15 16 17 STATEMENT

18
19 This bill authorizes pharmacists to dispense HIV prophylaxis
20 without an individual prescription under certain circumstances, and
21 requires prescription benefits coverage for prophylaxis furnished
22 under the bill.

23 HIV prophylaxis is a course of treatment involving certain drug
24 combinations that can prevent HIV infection notwithstanding
25 exposure to the virus under circumstances in which it is normally
26 transmitted, such as through unprotected sexual contact, sharing
27 needles, or other contact with an infected person’s blood or bodily
28 fluids. HIV prophylaxis includes both HIV preexposure
29 prophylaxis (PrEP), which is taken by a person who anticipates
30 engaging in conduct that risks HIV infection, and HIV postexposure
31 prophylaxis (PEP), which is taken by a person who may have been
32 exposed to HIV.

33 Under the bill, pharmacists will be permitted to furnish PrEP and
34 PEP to patients without an individual prescription pursuant to a
35 standing order issued by the Commissioner of Health or, if the
36 commissioner is not a duly licensed physician, the Deputy
37 Commissioner for Public Health Services. A standing order will be
38 issued to a pharmacist upon request, provided that the pharmacist
39 completes a training program approved by the State Board of
40 Pharmacy in consultation with the Department of Health, and
41 certifies that the pharmacist will meet the requirements set forth in
42 the bill to furnish PrEP and PEP without an individual prescription.
43 The training program is to include information about financial
44 assistance programs available to patients to assist with the costs of
45 PrEP and PEP.

46 The bill allows a patient to receive up to a 60-day supply of PrEP
47 without an individual prescription in any given two-year period.
48 Thereafter, to continue receiving PrEP, the patient will be required

1 to obtain a prescription for the drugs. A pharmacist furnishing
2 PrEP to a patient without an individual prescription will be required
3 to document that the patient is HIV negative, as demonstrated by a
4 test administered in the past seven days, and that the patient does
5 not report any signs or symptoms of acute HIV infection. If the
6 patient does not have a current HIV test, the pharmacist may order a
7 test. If the patient tests positive for HIV, the pharmacist will be
8 required to provide the patient with information and resources
9 concerning HIV treatment and comply with State and federal
10 requirements for a positive HIV test, which includes certain
11 reporting requirements.

12 Additionally, the pharmacist will be required to confirm that the
13 patient is not taking any contraindicated medications, provide the
14 patient with counseling on the ongoing use of PrEP, advise the
15 patient that the patient will require a prescription to continue
16 receiving PrEP, confirm the patient has not already been provided
17 with a 60-day supply of PrEP without an individual prescription in
18 the past two years, document the services provided, and notify the
19 patient's primary care provider that the patient was furnished with
20 PrEP, unless the patient does not consent to the pharmacist
21 providing this notice.

22 Pharmacists may furnish a complete course of PEP to a patient
23 who may have been exposed to HIV if the pharmacist confirms with
24 the patient that the exposure to HIV occurred within the previous 72
25 hours, the patient otherwise meets the clinical criteria for PEP
26 consistent with guidelines published by the federal Centers for
27 Disease Control and Prevention (CDC), the pharmacist tests the
28 patient for HIV, the pharmacist counsels the patient on the use of
29 PEP consistent with CDC guidelines, the pharmacist informs the
30 patient of the availability of PrEP, and the pharmacist notifies the
31 patient's primary care provider the patient was furnished with PEP,
32 unless the patient does not consent to the pharmacist providing this
33 notice.

34 If a patient being furnished with PrEP or PEP does not have a
35 primary care provider, or refuses to consent to the pharmacist
36 providing notice to the primary care provider, the pharmacist will
37 be required to provide the patient with a list of health care providers
38 to contact regarding ongoing treatment using PrEP or follow-up
39 care for PEP, as applicable. The DOH will be required to publish
40 and maintain a current list of providers for pharmacists to use for
41 this purpose, which list may be made available on the department's
42 Internet website.

43 In no case will a patient be authorized to waive the consultation
44 required under the bill to receive PrEP or PEP without an individual
45 prescription.

46 The bill requires health benefits plans that include prescription
47 benefits, as well as the State Employee's Health Benefits Plan, the
48 School Employees' Health Benefits Plan, and Medicaid, to provide

1 coverage for PrEP and PEP furnished under the bill without any
2 prior authorization or step therapy requirements. If therapeutic
3 equivalents to prevent HIV and AIDS are approved, the health plans
4 may apply prior authorization or step therapy requirements to other
5 versions of the treatment, provided at least one version is covered
6 without prior authorization or step therapy. Health plans will not be
7 authorized to prohibit a pharmacist from dispensing PrEP and PEP.
8 Health plans will not be required to provide coverage for PrEP
9 furnished without an individual prescription in a quantity that
10 exceeds a 60-day supply within a given two-year period. Health
11 plans will not be required to cover PrEP or PEP furnished by a
12 pharmacist at an out-of-network pharmacy unless the plan includes
13 an out-of-network pharmacy benefit.