

SENATE, No. 1039

STATE OF NEW JERSEY 219th LEGISLATURE

INTRODUCED JANUARY 30, 2020

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 P.L.2003,
2 c.280 (C.45:14-40 et seq.), P.L.1997, c.192 (C.26:2S-1 et seq.),
3 and P.L.1968, c.413 (C.30:4D-1 et seq.).
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 shall take all
32 other 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 screens the patient and determines the
34 exposure to HIV occurred within the previous 72 hours and the
35 patient 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 is
40 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. Within 90 days after the date of enactment of this act, and
17 notwithstanding the provisions of the "Administrative Procedure
18 Act," P.L.1968, c.410 (C.52:14B-1 et seq.) to the contrary, the State
19 Board of Pharmacy, in consultation with the Department of Health,
20 immediately upon filing proper notice with the Office of
21 Administrative Law, shall adopt rules and regulations as may be
22 necessary to implement the provisions of this act.

23 b. The rules and regulations adopted pursuant to subsection a.
24 of this section shall be in effect for a period not to exceed one year
25 from the date of filing. These rules and regulations shall thereafter
26 be adopted, amended, or readopted by the board, in consultation
27 with the Department of Health, in accordance with the requirements
28 of the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-
29 1 et seq.).

30

31 4. a. (1) Except as provided in paragraph (2) of this
32 subsection, a health benefits plan that provides prescription benefits
33 shall cover HIV preexposure prophylaxis and HIV postexposure
34 prophylaxis furnished without an individual prescription pursuant to
35 the requirements of section 2 of P.L. , c. (C.) (pending
36 before the Legislature as this bill) without requiring prior
37 authorization or step therapy.

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

45 b A health benefits plan shall not prohibit, or permit a
46 delegated pharmacy benefits manager to prohibit, a pharmacist from
47 dispensing HIV preexposure prophylaxis or HIV postexposure
48 prophylaxis.

1 c. A health benefits plan shall not be required to cover HIV
2 preexposure prophylaxis that has been furnished by a pharmacist
3 without an individual prescription pursuant to section 2
4 of P.L. , c. (C.) (pending before the Legislature as this bill)
5 in excess of a 60-day supply for a single patient within a given two
6 year period.

7 d. Nothing in this section shall be construed to require a health
8 benefits plan to provide coverage for HIV preexposure prophylaxis
9 or HIV postexposure prophylaxis furnished by a pharmacist at an
10 out-of-network pharmacy, unless the health benefits plan has an
11 out-of-network pharmacy benefit.

12 e. As used in this section:

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

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

23

24 5. a. (1) Notwithstanding any State law or regulation to the
25 contrary, and except as provided in paragraph (2) of this subsection,
26 the Department of Human Services shall ensure that the provision
27 of benefits 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) to eligible persons under the
31 Medicaid program, established pursuant to P.L.1968, c.413
32 (C.30:4D-1 et seq.), shall be provided without the imposition of any
33 prior authorization or step therapy requirements.

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

41 b. As used in this section:

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

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

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

5
6 6. The Commissioner of Human Services shall apply for such
7 State plan amendments or waivers as may be necessary to
8 implement the provisions of section 5 of this act and to secure
9 federal financial participation for State Medicaid expenditures
10 under the federal Medicaid program.

11
12 7. a. (1) Except as provided in paragraph (2) of this
13 subsection, the State Health Benefits Commission shall ensure that
14 every contract purchased by the commission on or after the
15 effective date of this act that provides hospital or medical expense
16 benefits that include prescription benefits shall cover HIV
17 preexposure prophylaxis and HIV postexposure prophylaxis
18 furnished without an individual prescription pursuant to the
19 requirements of section 2 of P.L. , c. (C.) (pending before
20 the Legislature as this bill) without requiring prior authorization or
21 step therapy.

22 (2) If the federal Food and Drug Administration has approved
23 one or more therapeutic equivalents of a drug, device, or product
24 for the prevention of HIV and AIDS, paragraph (1) of this
25 subsection shall not be construed to require the contract purchased
26 by the commission to cover all therapeutically equivalent versions
27 without prior authorization or step therapy, if at least one version is
28 covered without prior authorization or step therapy.

29 b The contract purchased by the commission shall not prohibit,
30 or permit a delegated pharmacy benefits manager prohibit, a
31 pharmacist from dispensing HIV preexposure prophylaxis or HIV
32 postexposure prophylaxis.

33 c. The contract purchased by the commission shall not be
34 required to cover HIV preexposure prophylaxis that has been
35 furnished by a pharmacist without an individual prescription
36 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
37 before the Legislature as this bill) in excess of a 60-day supply for a
38 single patient within a given two year period.

39 d. Nothing in this section shall be construed to require a
40 contract purchased by the commission to provide coverage for HIV
41 preexposure prophylaxis or HIV postexposure prophylaxis
42 furnished by a pharmacist at an out-of-network pharmacy, unless
43 the contract has an out-of-network pharmacy benefit.

44 e. As used in this section:

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

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

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

8

9 8. a. (1) Except as provided in paragraph (2) of this
10 subsection, the School Employees’ Health Benefits Commission
11 shall ensure that every contract purchased by the commission on or
12 after the effective date of this act that provides hospital or medical
13 expense benefits that include prescription benefits shall cover HIV
14 preexposure prophylaxis and HIV postexposure prophylaxis
15 furnished without an individual prescription pursuant to the
16 requirements of section 2 of P.L. , c. (C.) (pending before
17 the Legislature as this bill) without requiring prior authorization or
18 step therapy.

19 (2) If the federal Food and Drug Administration has approved
20 one or more therapeutic equivalents of a drug, device, or product
21 for the prevention of HIV and AIDS, paragraph (1) of this
22 subsection shall not be construed to require the contract purchased
23 by the commission to cover all therapeutically equivalent versions
24 without prior authorization or step therapy, if at least one version is
25 covered without prior authorization or step therapy.

26 b The contract purchased by the commission shall not prohibit,
27 or permit a delegated pharmacy benefits manager prohibit, a
28 pharmacist from dispensing HIV preexposure prophylaxis or HIV
29 postexposure prophylaxis.

30 c. The contract purchased by the commission shall not be
31 required to cover HIV preexposure prophylaxis that has been
32 furnished by a pharmacist without an individual prescription
33 pursuant to pursuant to section 2 of P.L. , c. (C.) (pending
34 before the Legislature as this bill) in excess of a 60-day supply for a
35 single patient within a given two year period.

36 d. Nothing in this section shall be construed to require a
37 contract purchased by the commission to provide coverage for HIV
38 preexposure prophylaxis or HIV postexposure prophylaxis
39 furnished by a pharmacist at an out-of-network pharmacy, unless
40 the contract has an out-of-network pharmacy benefit.

41 e. As used in this section:

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

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

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

5
6 9. This act shall take effect immediately.
7

8
9 STATEMENT
10

11 This bill authorizes pharmacists to dispense HIV prophylaxis
12 without an individual prescription under certain circumstances and
13 requires prescription benefits coverage for prophylaxis furnished
14 under the bill.

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

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

38 The bill allows a patient to receive up to a 60-day supply of PrEP
39 without an individual prescription in any given two-year period.
40 Thereafter, to continue receiving PrEP, the patient will be required
41 to obtain a prescription for the drugs. A pharmacist furnishing
42 PrEP to a patient without an individual prescription will be required
43 to document that the patient is HIV negative, as demonstrated by a
44 test administered in the past seven days, and that the patient does
45 not report any signs or symptoms of acute HIV infection. If the
46 patient does not have a current HIV test, the pharmacist may order a
47 test. If the patient tests positive for HIV, the pharmacist will be
48 required to provide the patient with information and resources

1 concerning HIV treatment and comply with State and federal
2 requirements for a positive HIV test, which includes certain
3 reporting requirements.

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

14 Pharmacists may furnish a complete course of PEP to a patient
15 who may have been exposed to HIV if the pharmacist determines
16 the exposure occurred within the previous 72 hours, the patient
17 otherwise meets the clinical criteria for PEP consistent with
18 guidelines published by the federal Centers for Disease Control and
19 Prevention (CDC), the pharmacist tests the patient for HIV, the
20 pharmacist counsels the patient on the use of PEP consistent with
21 CDC guidelines, the pharmacist informs the patient of the
22 availability of PrEP, and the pharmacist notifies the patient's
23 primary care provider the patient was furnished with PEP, unless
24 the patient does not consent to the pharmacist providing this notice.

25 If a patient being furnished with PrEP or PEP does not have a
26 primary care provider, or refuses to consent to the pharmacist
27 providing notice to the primary care provider, the pharmacist will
28 be required to provide the patient with a list of health care providers
29 to contact regarding ongoing treatment using PrEP or followup care
30 for PEP, as applicable. The DOH will be required to publish and
31 maintain a current list of providers for pharmacists to use for this
32 purpose, which list may be made available on the department's
33 Internet website.

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

37 The bill requires health benefits plans that include prescription
38 benefits, as well as the State Employee's Health Benefits Plan, the
39 School Employees' Health Benefits Plan, and Medicaid, to provide
40 coverage for PrEP and PEP furnished under the bill without any
41 prior authorization or step therapy requirements. If therapeutic
42 equivalents to prevent HIV and AIDS are approved, the health plans
43 may apply prior authorization or step therapy requirements to other
44 versions of the treatment, provided at least one version is covered
45 without prior authorization or step therapy. Health plans will not be
46 authorized to prohibit a pharmacist from dispensing PrEP and PEP.
47 Health plans will not be required to provide coverage for PrEP
48 furnished without an individual prescription in a quantity that

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1 exceeds a 60-day supply within a given two-year period. Health
2 plans will not be required to cover PrEP or PEP furnished by a
3 pharmacist at an out-of-network pharmacy unless the plan includes
4 an out-of-network pharmacy benefit.