[First Reprint] 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 reported by the Senate Health, Human Services and Senior Citizens Committee on March 9, 2021, with amendments.



AN ACT concerning pharmacists and supplementing P.L.2003, 1 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: "CDC PEP guidelines" means the "Updated Guidelines for 9 10 Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV - United 11 12 States, 2016," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention. 13 "CDC PReP guidelines" means the "2017 Preexposure 14 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. "HIV" means the human immunodeficiency virus. 19 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 twice daily, or dolutegravir (50mg), taken once daily; tenofovir 28 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 combination determined by the State Board of Pharmacy to meet 32 33 the same clinical eligibility recommendations provided in the CEC 34 PRP guidelines.

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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

Matter underlined <u>thus</u> is new matter.

Matter enclosed in superscript numerals has been adopted as follows: ¹Senate SHH committee amendments adopted March 9, 2021.

EXPLANATION – Matter enclosed in **bold-faced brackets** [thus] in the above bill is not enacted and is intended to be omitted in the law.

1 certifies that the pharmacist will adhere to the requirements set 2 forth in subsection c. of this section concerning the protocols for 3 initiating and furnishing HIV preexposure prophylaxis and the 4 requirements set forth in subsection d. of this section concerning the 5 protocols for initiating and furnishing HIV postexposure prophylaxis to patients without an individual prescription. In no 6 7 case shall a patient be authorized to waive the consultation required 8 pursuant to subsection c. or subsection d. of this section.

9 b. A pharmacist shall not be authorized to furnish HIV 10 preexposure prophylaxis or HIV postexposure prophylaxis to a patient without an individual prescription unless the pharmacist 11 12 completes a training program, approved by the State Board of 13 Pharmacy in consultation with the Department of Health, 14 concerning the use of HIV preexposure prophylaxis and HIV postexposure prophylaxis. At a minimum, the training program 15 16 shall include information about financial assistance programs 17 available to patients to assist with the costs of HIV preexposure 18 prophylaxis and HIV postexposure prophylaxis.

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

23 (1) The patient is HIV-negative, as documented by a negative 24 HIV test result obtained within the previous seven days from an 25 HIV antigen/antibody test or antibody-only test or from a rapid, 26 point-of-care fingerstick blood test approved by the federal Food 27 and Drug Administration. If the patient does not provide evidence 28 of a negative HIV test in accordance with this paragraph, the 29 pharmacist shall order an HIV test. If the test results are not 30 ordered directly to a pharmacist, the pharmacist shall verify the test 31 results to the pharmacist's satisfaction. If the patient tests positive 32 for HIV infection, the pharmacist or person administering the test 33 shall direct the patient to a primary care provider, provide the 34 patient with information and resources concerning treatment 35 providers and HIV treatment clinics in the region, and ¹[shall]¹ 36 take all other actions required under State and federal law in 37 response to a positive test for HIV;

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

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

45 (4) The patient has not been furnished with HIV preexposure
46 prophylaxis without an individual prescription within the past two
47 years;

(5) The pharmacist provides counseling to the patient on the ongoing use of HIV preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist shall notify the patient that the patient will not be eligible to continue receiving HIV preexposure prophylaxis unless the patient is seen by a primary care provider and issued a

11 prescription for the HIV preexposure prophylaxis, and that the 12 patient may be furnished with no more than a 60-day supply of HIV 13 preexposure prophylaxis by a pharmacist without an individual 14 prescription within any given two year period;

(6) The pharmacist documents, to the extent possible, the 15 16 services provided by the pharmacist in the patient's record in the 17 record system maintained by the pharmacy, and includes the 18 dispensation of the HIV preexposure prophylaxis in the prescription 19 monitoring database established pursuant to P.L.2007, c.244 20 (C.45:1-45 et al.) with a note indicating the HIV preexposure 21 prophylaxis was provided without an individual prescription 22 pursuant to this section; and

23 (7) The pharmacist notifies the patient's primary care provider 24 that the pharmacist furnished the patient with HIV preexposure 25 prophylaxis pursuant to this section. If the patient does not have a 26 primary care provider, or refuses to consent to the pharmacist 27 providing notice to the primary care provider pursuant to this 28 paragraph, the pharmacist shall provide the patient with a list of 29 physicians and surgeons, clinics, or other health care service 30 providers to contact regarding ongoing care for HIV preexposure 31 prophylaxis. The Department of Health shall publish and maintain 32 a current list of providers for pharmacists to use for the purposes of 33 this paragraph, which list may be made available on the 34 department's Internet website.

35 d. A pharmacist shall furnish a complete course of HIV 36 postexposure prophylaxis to a patient without an individual 37 prescription if the following requirements are met:

38 (1) The pharmacist ¹[screens the patient and determines the exposure to HIV occurred] confirms with the patient that the 39 exposure to HIV occurred¹ within the previous 72 hours and the 40 41 patient otherwise meets the clinical criteria for HIV postexposure 42 prophylaxis consistent with the CDC PEP guidelines;

43 (2) The pharmacist provides HIV testing that is classified as waived under the federal ¹...¹ Clinical Laboratory Improvement 44 Amendments of 1988, 1.1 42 U.S.C. s.263a, or determines the 45 patient is willing to undergo HIV testing consistent with the CDC 46 47 PEP guidelines;

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1 (3) The pharmacist provides counseling to the patient on the use 2 of HIV postexposure prophylaxis consistent with the CDC PEP 3 guidelines, which may include education about side effects, safety 4 during pregnancy and breastfeeding, adherence to recommended 5 dosing, and the importance of timely testing and treatment, as 6 applicable, for HIV and sexually transmitted diseases. The 7 pharmacist shall additionally inform the patient of the availability 8 of HIV preexposure prophylaxis for persons who are at substantial 9 risk of acquiring HIV; and

10 (4) The pharmacist notifies the patient's primary care provider 11 that the pharmacist provided the patient with a complete course of 12 HIV postexposure prophylaxis. If the patient does not have a 13 primary care provider, or refuses to consent to the pharmacist 14 providing notice to the primary care provider pursuant to this 15 paragraph, the pharmacist shall provide the patient with a list of 16 physicians and surgeons, clinics, or other health care service 17 providers to contact regarding followup care for HIV postexposure 18 prophylaxis. The Department of Health shall publish and maintain 19 a current list of providers for pharmacists to use for the purposes of 20 this paragraph, which list may be made available on the 21 department's Internet website.

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¹[3. a. Within 90 days after the date of enactment of this act, and notwithstanding the provisions of the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) to the contrary, the State Board of Pharmacy, in consultation with the Department of Health, immediately upon filing proper notice with the Office of Administrative Law, shall adopt rules and regulations as may be necessary to implement the provisions of this act.

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

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38 ¹[4. a. (1) Except as provided in paragraph (2) of this 39 subsection, a health benefits plan that provides prescription benefits 40 shall cover HIV preexposure prophylaxis and HIV postexposure 41 prophylaxis furnished without an individual prescription pursuant to 42 the requirements of section 2 of P.L., c. (C.) (pending 43 before the Legislature as this bill) without requiring prior 44 authorization or step therapy.

(2) If the federal Food and Drug Administration has approved
one or more therapeutic equivalents of a drug, device, or product
for the prevention of HIV and AIDS, paragraph (1) of this
subsection shall not be construed to require a health benefits plan to

cover all therapeutically equivalent versions without prior
 authorization or step therapy, if at least one version is covered
 without prior authorization or step therapy.

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

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

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

19 e. As used in this section:

20 "HIV preexposure prophylaxis" means the same as that term is
21 defined in section 1 of P.L., c. (C.) (pending before the
22 Legislature as this bill).

23 "HIV postexposure prophylaxis" means the same as that term is
24 defined in section 1 of P.L., c. (C.) (pending before the
25 Legislature as this bill).

26 "Step therapy" means requiring that a lower-cost alternative to
27 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
28 shown to have been ineffective as a condition of providing
29 prescription benefits coverage for the prophylaxis.]¹

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31 ¹[5. a. (1) Notwithstanding any State law or regulation to the 32 contrary, and except as provided in paragraph (2) of this subsection, the Department of Human Services shall ensure that the provision 33 34 of benefits for HIV preexposure prophylaxis and HIV postexposure 35 prophylaxis furnished without an individual prescription pursuant to 36 the requirements of section 2 of P.L., c. (C.) (pending 37 before the Legislature as this bill) to eligible persons under the Medicaid program, established pursuant to P.L.1968, c.413 38 39 (C.30:4D-1 et seq.), shall be provided without the imposition of any 40 prior authorization or step therapy requirements.

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

48 b. As used in this section:

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

4 "HIV postexposure prophylaxis" means the same as that term is
5 defined in section 1 of P.L., c. (C.) (pending before the
6 Legislature as this bill).

7 "Step therapy" means requiring that a lower-cost alternative to
8 HIV preexposure prophylaxis or HIV postexposure prophylaxis be
9 shown to have been ineffective as a condition of providing
10 prescription benefits coverage for the prophylaxis.]¹

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¹**[**6. The Commissioner of Human Services shall apply for such State plan amendments or waivers as may be necessary to implement the provisions of section 5 of this act and to secure federal financial participation for State Medicaid expenditures under the federal Medicaid program. **]**¹

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18 ¹[7. a. (1) Except as provided in paragraph (2) of this 19 subsection, the State Health Benefits Commission shall ensure that 20 every contract purchased by the commission on or after the effective date of this act that provides hospital or medical expense 21 22 benefits that include prescription benefits shall cover HIV 23 preexposure prophylaxis and HIV postexposure prophylaxis 24 furnished without an individual prescription pursuant to the 25 requirements of section 2 of P.L., c. (C.) (pending before 26 the Legislature as this bill) without requiring prior authorization or 27 step therapy.

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

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

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

d. Nothing in this section shall be construed to require a
contract purchased by the commission to provide coverage for HIV
preexposure prophylaxis or HIV postexposure prophylaxis

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1 furnished by a pharmacist at an out-of-network pharmacy, unless 2 the contract has an out-of-network pharmacy benefit. 3 e. As used in this section: "HIV preexposure prophylaxis" means the same as that term is 4 5 defined in section 1 of P.L., c. (C.) (pending before the 6 Legislature as this bill). 7 "HIV postexposure 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 "Step therapy" means requiring that a lower-cost alternative to 11 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 12 shown to have been ineffective as a condition of providing 13 prescription benefits coverage for the prophylaxis.]¹ 14 15 ¹[8. a. (1) Except as provided in paragraph (2) of this 16 subsection, the School Employees' Health Benefits Commission 17 shall ensure that every contract purchased by the commission on or 18 after the effective date of this act that provides hospital or medical 19 expense benefits that include prescription benefits shall cover HIV 20 preexposure prophylaxis and HIV postexposure prophylaxis 21 furnished without an individual prescription pursuant to the 22 requirements of section 2 of P.L., c. (C.) (pending before 23 the Legislature as this bill) without requiring prior authorization or 24 step therapy. 25 (2) If the federal Food and Drug Administration has approved 26 one or more therapeutic equivalents of a drug, device, or product 27 for the prevention of HIV and AIDS, paragraph (1) of this 28 subsection shall not be construed to require the contract purchased 29 by the commission to cover all therapeutically equivalent versions 30 without prior authorization or step therapy, if at least one version is 31 covered without prior authorization or step therapy. 32 The contract purchased by the commission shall not prohibit, b 33 or permit a delegated pharmacy benefits manager prohibit, a 34 pharmacist from dispensing HIV preexposure prophylaxis or HIV 35 postexposure prophylaxis. 36 c. The contract purchased by the commission shall not be 37 required to cover HIV preexposure prophylaxis that has been furnished by a pharmacist without an individual prescription 38 39 pursuant to pursuant to section 2 of P.L., c. (C.) (pending 40 before the Legislature as this bill) in excess of a 60-day supply for a 41 single patient within a given two year period. 42 d. Nothing in this section shall be construed to require a 43 contract purchased by the commission to provide coverage for HIV 44 preexposure prophylaxis or HIV postexposure prophylaxis 45 furnished by a pharmacist at an out-of-network pharmacy, unless 46 the contract has an out-of-network pharmacy benefit. 47 e. As used in this section:

1 "HIV preexposure 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). "HIV postexposure prophylaxis" means the same as that term is 4 5 defined in section 1 of P.L., c. (C.) (pending before the 6 Legislature as this bill). 7 "Step therapy" means requiring that a lower-cost alternative to 8 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 9 shown to have been ineffective as a condition of providing prescription benefits coverage for the prophylaxis.]¹ 10 11 12 ¹3. a. (1) Except as provided in paragraph (2) of this 13 subsection, no group or individual hospital service corporation 14 contract providing hospital or medical expense benefits shall be 15 delivered, issued, executed, or renewed in this State or approved for 16 issuance or renewal in this State by the Commissioner of Banking 17 and Insurance, on or after the effective date of this act, unless the 18 contract provides benefits to any subscriber or other person covered 19 thereunder for HIV preexposure prophylaxis and HIV postexposure 20 prophylaxis furnished without an individual prescription pursuant to 21 the requirements of section 2 of P.L., c. (C.) (pending 22 before the Legislature as this bill) without requiring prior authorization or step therapy. 23 24 (2) If the federal Food and Drug Administration has approved 25 one or more therapeutic equivalents of a drug, device, or product 26 for the prevention of HIV and AIDS, paragraph (1) of this 27 subsection shall not be construed to require the contract to cover all 28 therapeutically equivalent versions without prior authorization or 29 step therapy, if at least one version is covered without prior 30 authorization or step therapy. b. A contract offered by a group or individual hospital service 31 32 corporation shall not: 33 (1) prohibit, or permit a delegated pharmacy benefits manager to 34 prohibit, a pharmacist from dispensing HIV preexposure 35 prophylaxis or HIV postexposure prophylaxis; and (2) be required to cover HIV preexposure prophylaxis that has 36 37 been furnished by a pharmacist without an individual prescription 38 pursuant to pursuant to section 2 of P.L., c. (C.) (pending 39 before the Legislature as this bill) in excess of a 60-day supply for a 40 single patient within a given two year period. 41 c. Nothing in this section shall be construed to require a contract offered by a group or individual hospital service 42 43 corporation to provide coverage for HIV preexposure prophylaxis 44 or HIV postexposure prophylaxis furnished by a pharmacist at an 45 out-of-network pharmacy, unless the contract has an out-of-network 46 pharmacy benefit.

1 d. The provisions of this section shall apply to all contracts in 2 which the hospital service corporation has reserved the right to 3 change the premium. 4 e. As used in this section: 5 "HIV preexposure prophylaxis" means the same as that term is 6 defined in section 1 of P.L., c. (C.) (pending before the 7 Legislature as this bill). 8 "HIV postexposure prophylaxis" means the same as that term is defined in section 1 of P.L., c. (C.) (pending before the 9 10 Legislature as this bill). 11 "Step therapy" means requiring that a lower-cost alternative to 12 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 13 shown to have been ineffective as a condition of providing 14 prescription benefits coverage for the prophylaxis.¹ 15 16 ¹4. a. (1) Except as provided in paragraph (2) of this subsection, no group or individual medical service corporation 17 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 before the Legislature as this bill) without requiring prior 26 27 authorization or step therapy. (2) If the federal Food and Drug Administration has approved 28 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 medical 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 pursuant to pursuant to section 2 of P.L., c. (C.) (pending 42 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 contract 46 offered by a group or individual medical service corporation to 47 provide coverage for HIV preexposure prophylaxis or HIV 48 postexposure prophylaxis furnished by a pharmacist at an out-of-

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1 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 group or individual medical service corporation has 5 reserved the right to 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 prescription benefits coverage for the prophylaxis.¹ 16 17 18 ¹5. a. (1) Except as provided in paragraph (2) of this 19 subsection, no group or individual health service corporation contract providing hospital or medical expense benefits shall be 20 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 the requirements of section 2 of P.L., c. (C.) (pending 27 before the Legislature as this bill) without requiring prior 28 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 health 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 before the Legislature as this bill) in excess of a 60-day supply for a 45 46 single patient within a given two year period. 47 c. Nothing in this section shall be construed to require a contract 48 offered by a health service corporation to provide coverage for HIV

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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 contracts in 5 which the health service corporation has reserved the right to 6 change 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). "Step therapy" means requiring that a lower-cost alternative to 14 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 15 16 shown to have been ineffective as a condition of providing 17 prescription benefits coverage for the prophylaxis.¹ 18 19 ¹6. a. (1) Except as provided in paragraph (2) of this 20 subsection, no individual health insurance policy providing hospital 21 or medical expense benefits shall be delivered, issued, executed, or 22 renewed in this State or approved for issuance or renewal in this 23 State by the Commissioner of Banking and Insurance, on or after 24 the effective date of this act, unless the policy provides benefits to 25 any named insured or other person covered thereunder for HIV preexposure prophylaxis and HIV postexposure prophylaxis 26 27 furnished without an individual prescription pursuant to the requirements of section 2 of P.L., c. (C.) (pending before 28 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 policy 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 insurance policy 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 insurance policy 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 policies in 5 which the insurer has reserved the right to 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 prescription benefits coverage for the prophylaxis.¹ 16 17 18 ¹7. a. (1) Except as provided in paragraph (2) of this 19 subsection, no group health insurance policy providing hospital or 20 medical expense benefits shall be delivered, issued, executed, or 21 renewed in this State or approved for issuance or renewal in this 22 State by the Commissioner of Banking and Insurance, on or after 23 the effective date of this act, unless the policy provides benefits to 24 any named insured or other person covered thereunder for HIV 25 preexposure prophylaxis and HIV postexposure prophylaxis furnished without an individual prescription pursuant to the 26 requirements of section 2 of P.L., c. (C.) (pending before 27 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 subsection shall not be construed to require the policy to cover all 33 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 group health insurance policy 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 pursuant to pursuant to section 2 of P.L., c. (C.) (pending 43 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 group 47 health insurance policy 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 provisions of this section shall apply to all policies in 4 which the insurer has reserved the right to change the premium. 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 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 13 shown to have been ineffective as a condition of providing 14 15 prescription benefits.¹ 16 17 ¹<u>8. a. (1) Except as provided in paragraph (2) of this</u> 18 subsection, every individual health benefits plan that is delivered, 19 issued, executed, or renewed in this State pursuant to P.L.1992, 20 c.161 (C.17B:27A-2 et seq.) or approved for issuance or renewal in 21 this State, on or after the effective date of this act, shall provide 22 benefits to any person covered thereunder for expenses incurred for 23 HIV preexposure prophylaxis and HIV postexposure prophylaxis 24 furnished without an individual prescription pursuant to the 25 requirements of section 2 of P.L., c. (C.) (pending before 26 the Legislature as this bill) without requiring prior authorization or 27 step therapy. (2) If the federal Food and Drug Administration has approved 28 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 plan 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. An individual health benefits plan shall not: 36 (1) prohibit, or permit a delegated pharmacy benefits manager to 37 prohibit, a pharmacist from dispensing HIV preexposure 38 prophylaxis or HIV postexposure prophylaxis; and 39 (2) be required to cover HIV preexposure prophylaxis that has 40 been furnished by a pharmacist without an individual prescription 41 pursuant to pursuant to section 2 of P.L., c. (C.) (pending 42 before the Legislature as this bill) in excess of a 60-day supply for a 43 single patient within a given two year period. 44 c. Nothing in this section shall be construed to require an 45 individual health benefit plan to provide coverage for HIV 46 preexposure prophylaxis or HIV postexposure prophylaxis 47 furnished by a pharmacist at an out-of-network pharmacy, unless 48 the contract has an out-of-network pharmacy benefit.

1 d. The provisions of this section shall apply to all health benefit 2 plans in which the carrier has reserved the right to change the 3 premium. 4 e. As used in this section: 5 "HIV preexposure prophylaxis" means the same as that term is 6 defined in section 1 of P.L., c. (C.) (pending before the 7 Legislature as this bill). 8 "HIV postexposure 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 "Step therapy" means requiring that a lower-cost alternative to 12 HIV preexposure prophylaxis or HIV postexposure prophylaxis be shown to have been ineffective as a condition of providing 13 14 prescription benefits.¹ 15 16 ¹9. a. (1) Except as provided in paragraph (2) of this subsection, every small employer health benefits plan that is 17 18 delivered, issued, executed, or renewed in this State pursuant to 19 P.L.1992, c.162 (C.17B:27A-17 et seq.) or approved for issuance or 20 renewal in this State, on or after the effective date of this act, shall 21 provide benefits to any person covered thereunder for HIV 22 preexposure prophylaxis and HIV postexposure prophylaxis 23 furnished without an individual prescription pursuant to the 24 requirements of section 2 of P.L., c. (C.) (pending before 25 the Legislature as this bill) without requiring prior authorization or 26 step therapy. 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 plan to cover all 31 therapeutically equivalent versions without prior authorization or 32 step therapy, if at least one version is covered without prior 33 authorization or step therapy. 34 b. A small employer health benefits plan shall not: 35 (1) prohibit, or permit a delegated pharmacy benefits manager to prohibit, a pharmacist from dispensing HIV preexposure 36 37 prophylaxis or HIV postexposure prophylaxis; and 38 (2) be required to cover HIV preexposure prophylaxis that has 39 been furnished by a pharmacist without an individual prescription 40 pursuant to pursuant to section 2 of P.L., c. (C.) (pending 41 before the Legislature as this bill) in excess of a 60-day supply for a 42 single patient within a given two year period. 43 c. Nothing in this section shall be construed to require a small 44 employer health benefit plan to provide coverage for HIV preexposure prophylaxis or HIV postexposure prophylaxis 45 46 furnished by a pharmacist at an out-of-network pharmacy, unless 47 the contract has an out-of-network pharmacy benefit.

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1
        d. The provisions of this section shall apply to all health benefit
 2
     plans in which the carrier has reserved the right to change the
 3
     premium.
 4
        e. As used in this section:
 5
        "HIV preexposure prophylaxis" means the same as that term is
 6
     defined in section 1 of P.L., c. (C. ) (pending before the
 7
     Legislature as this bill).
 8
        "HIV postexposure prophylaxis" means the same as that term is
     defined in section 1 of P.L., c. (C. ) (pending before the
9
10
     Legislature as this bill).
11
        "Step therapy" means requiring that a lower-cost alternative to
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     HIV preexposure prophylaxis or HIV postexposure prophylaxis be
     shown to have been ineffective as a condition of providing
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     prescription benefits.<sup>1</sup>
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16
        <sup>1</sup><u>10. a. (1) Except as provided in paragraph (2) of this</u>
     subsection, notwithstanding any provision of law to the contrary, a
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     certificate of authority to establish and operate a health maintenance
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     organization in this State shall not be issued or continued by the
20
     Commissioner of Banking and Insurance on or after the effective
21
     date of this act unless the health maintenance organization provides
22
     health care services to any enrollee for expenses incurred for HIV
23
     preexposure prophylaxis and HIV postexposure prophylaxis
24
     furnished without an individual prescription pursuant to the
25
     requirements of section 2 of P.L., c. (C.) (pending before
26
     the Legislature as this bill) without requiring prior authorization or
27
     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 plan 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 health maintenance organization shall not:
36
        (1) prohibit, or permit a delegated pharmacy benefits manager to
37
     prohibit, a pharmacist from dispensing HIV preexposure
38
     prophylaxis or HIV postexposure prophylaxis; and
39
        (2) be required to cover HIV preexposure prophylaxis that has
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     been furnished by a pharmacist without an individual prescription
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     pursuant to pursuant to section 2 of P.L., c. (C.) (pending
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     before the Legislature as this bill) in excess of a 60-day supply for a
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     single patient within a given two year period.
44
        c. Nothing in this section shall be construed to require a health
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     maintenance organization to provide coverage for HIV preexposure
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     prophylaxis or HIV postexposure prophylaxis furnished by a
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     pharmacist at an out-of-network pharmacy, unless the contract has
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     an out-of-network pharmacy benefit.
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d. The benefits shall be provided to the same extent as for any 1 2 other medical condition under the contract. 3 e. As used in this section: 4 "HIV preexposure prophylaxis" means the same as that term is 5 defined in section 1 of P.L., c. (C.) (pending before the 6 Legislature as this bill). 7 "HIV postexposure 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). "Step therapy" means requiring that a lower-cost alternative to 10 11 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 12 shown to have been ineffective as a condition of providing prescription benefits.¹ 13 14 15 ¹<u>11. a. (1) Notwithstanding any State law or regulation to the</u> 16 contrary, and except as provided in paragraph (2) of this subsection, 17 the Department of Human Services shall ensure that the provision 18 of benefits for HIV preexposure prophylaxis and HIV postexposure 19 prophylaxis furnished without an individual prescription pursuant to 20 the requirements of section 2 of P.L., c. (C.) (pending before the Legislature as this bill) to eligible persons under the 21 22 Medicaid program, established pursuant to P.L.1968, c.413 23 (C.30:4D-1 et seq.), shall be provided without the imposition of any 24 prior authorization or step therapy requirements. 25 (2) If the federal Food and Drug Administration has approved 26 one or more therapeutic equivalents of a drug, device, or product for the prevention of HIV and AIDS, paragraph (1) of this 27 28 subsection shall not be construed to require the department to 29 ensure coverage of all therapeutically equivalent versions without 30 prior authorization or step therapy, if at least one version is covered 31 without prior authorization or step therapy. 32 b. As used in this section: 33 "HIV preexposure 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). "HIV postexposure prophylaxis" means the same as that term is 36 37 defined in section 1 of P.L., c. (C.) (pending before the 38 Legislature as this bill). 39 "Step therapy" means requiring that a lower-cost alternative to 40 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 41 shown to have been ineffective as a condition of providing 42 prescription benefits coverage for the prophylaxis.¹ 43 44 ¹<u>12. a. (1) Except as provided in paragraph (2) of this</u> 45 subsection, the State Health Benefits Commission shall provide benefits to each person covered under the State Health Benefits 46 47 Program for expenses incurred for HIV preexposure prophylaxis

1 and HIV postexposure prophylaxis furnished without an individual 2 prescription pursuant to the requirements of section 2 of P.L., 3 c. (C.) (pending before the Legislature as this bill) without 4 requiring prior authorization or step therapy. 5 (2) If the federal Food and Drug Administration has approved 6 one or more therapeutic equivalents of a drug, device, or product for the prevention of HIV and AIDS, paragraph (1) of this 7 8 subsection shall not be construed to require the contract to cover all 9 therapeutically equivalent versions without prior authorization or 10 step therapy, if at least one version is covered without prior 11 authorization or step therapy. 12 b. The State Health Benefits Commission shall not: 13 (1) prohibit, or permit a delegated pharmacy benefits manager to 14 prohibit, a pharmacist from dispensing HIV preexposure 15 prophylaxis or HIV postexposure prophylaxis; and 16 (2) be required to cover HIV preexposure prophylaxis that has 17 been furnished by a pharmacist without an individual prescription pursuant to pursuant to section 2 of P.L., c. (C.) (pending 18 19 before the Legislature as this bill) in excess of a 60-day supply for a 20 single patient within a given two year period. 21 c. Nothing in this section shall be construed to require the State Health Benefits Commission to provide coverage for HIV 22 23 preexposure prophylaxis or HIV postexposure prophylaxis 24 furnished by a pharmacist at an out-of-network pharmacy, unless 25 the contract has an out-of-network pharmacy benefit. 26 d. The benefits shall be provided to the same extent as for any 27 other medical condition under the contract. e. As used in this section: 28 29 "HIV preexposure prophylaxis" means the same as that term is 30 defined in section 1 of P.L., c. (C.) (pending before the 31 Legislature as this bill). 32 "HIV postexposure prophylaxis" means the same as that term is defined in section 1 of P.L., c. (C.) (pending before the 33 34 Legislature as this bill). "Step therapy" means requiring that a lower-cost alternative to 35 36 HIV preexposure prophylaxis or HIV postexposure prophylaxis be 37 shown to have been ineffective as a condition of providing prescription benefits.¹ 38 39 40 ¹<u>13. The Commissioner of Human Services shall apply for such</u> 41 State plan amendments or waivers as may be necessary to 42 implement the provisions of section 11 of this act and to secure federal financial participation for State Medicaid expenditures 43 44 under the federal Medicaid program.¹ 45 46 ¹14. a. Within 90 days after the date of enactment of this act, 47 and notwithstanding the provisions of the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) to the 48

1 contrary, the State Board of Pharmacy, in consultation with the 2 Department of Health, immediately upon filing proper notice with 3 the Office of Administrative Law, shall adopt rules and regulations 4 as may be necessary to implement the provisions of this act. 5 b. The rules and regulations adopted pursuant to subsection a. 6 of this section shall be in effect for a period not to exceed one year 7 from the date of filing. These rules and regulations shall thereafter 8 be adopted, amended, or readopted by the board, in consultation 9 with the Department of Health, in accordance with the requirements of the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-10 1 et seq.).¹ 11 12

13 1 [9.] <u>15.</u>¹ This act shall take effect immediately.