LC002534

2023 -- S 0570

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2023

AN ACT

RELATING TO HEALTH AND SAFETY -- PREVENTION AND SUPPRESSION OF CONTAGIOUS DISEASES -- HIV/AIDS

Introduced By: Senators Miller, Valverde, Sosnowski, DiMario, Lawson, Mack, Euer, Lauria, and Murray Date Introduced: March 07, 2023

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

- 1 SECTION 1. Chapter 23-6.3 of the General Laws entitled "Prevention and Suppression of
- 2 Contagious Diseases HIV/AIDS" is hereby amended by adding thereto the following section:
- 3 **23-6.3-20. HIV prevention drug.**
- 4 (a) A licensed pharmacist may prescribe, dispense or administer HIV prevention drugs in
- 5 accordance with rules and regulations promulgated by the department of health in accordance with
- 6 <u>this section.</u>
- 7 (b) A licensed pharmacist may prescribe, dispense or administer HIV prevention drugs
- 8 according to the United States Food and Drug Administration guidance and product labeling if the
- 9 patient:
- 10 (1) Is HIV negative, as documented by a negative HIV test result obtained within the

11 previous seven (7) days from an HIV antigen and antibody test or antibody-only test or from a

12 rapid, point-of-care fingerstick blood test approved by the United States Food and Drug

- 13 Administration; provided, however, that if the patient does not provide evidence of a negative HIV
- 14 test in accordance with this subsection, the pharmacist may order an HIV test prior to prescribing,
- 15 dispensing or administering the drugs; provided further, that if the test results are not transmitted
- 16 directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction
- 17 prior to prescribing, dispensing or administering the drugs; and provided further, that if the patient
- 18 tests positive for HIV infection, the pharmacist or person administering the test shall direct the

- 1 patient to a primary care provider and provide the patient with a list of providers and clinics in the
- 2 region;
- 3 (2) Does not report any signs or symptoms of acute HIV infection on a self-reported
 4 checklist of acute HIV infection signs and symptoms; and
- 5 (3) Does not report taking any contraindicated medication.
- 6 (c) A licensed pharmacist that prescribes, dispenses or administers HIV prevention drugs
 7 shall:
- 8 (1) Provide counseling to the patient on the ongoing use of pre-exposure prophylaxis,
 9 which may include education about side effects, safety during pregnancy and breastfeeding,
- 10 <u>adherence to recommended dosing and the importance of timely testing and treatment, as</u>
- 11 applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted infections and
- 12 pregnancy for individuals of child-bearing capacity;
- 13 (2) Notify the patient that the patient is required to be seen by a primary care provider to
- 14 receive subsequent prescriptions for pre-exposure prophylaxis and that a pharmacist shall not
- 15 <u>furnish a sixty (60) day supply of pre-exposure prophylaxis to a single patient more than once every</u>
- 16 <u>two (2) years;</u>
- 17 (3) Document, to the extent possible, the services provided to the patient by the pharmacist
- 18 in the patient's record in the record system maintained by the pharmacy and maintain records of
- 19 pre-exposure prophylaxis furnished to each patient; and
- (4) Notify the patient's primary care provider that the pharmacist completed the
 requirements specified in this subsection; provided, however, that if the patient does not have a
 primary care provider or refuses to consent to notify the patient's primary care provider, the
- 23 pharmacist shall provide the patient a list of physicians and surgeons, clinics or other health care
- 24 service providers to contact regarding ongoing care for pre-exposure prophylaxis.
- 25 (d) The department of health shall promulgate rules and regulations to establish statewide
 26 drug therapy protocols for prescribing, dispensing and administering pre-exposure prophylaxis and
- and descript proceeds for presentang, aspensing and administering pre-enposite prophymics and
- 27 other HIV prevention drugs approved by the United States Food and Drug Administration that are
- 28 consistent with federal Centers for Disease Control and Prevention guidelines not later than six (6)
- 29 months after the effective date of this section. The regulations shall include, but not be limited to,
- 30 rules stating that a pharmacist shall not furnish a sixty (60) day supply of pre-exposure prophylaxis
- 31 to a single patient more than once every two (2) years.
- 32 SECTION 2. Section 23-6.3-2 of the General Laws in Chapter 23-6.3 entitled "Prevention
 33 and Suppression of Contagious Diseases HIV/AIDS" is hereby amended to read as follows:
- 34 **23-6.3-2. Definitions.**

As used in this chapter the following words shall have the following meanings:

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2 (1) "Agent" means a person empowered by the patient to assert or waive the confidentiality, 3 or to disclose or consent to the disclosure of confidential information, as established by chapter 37.3 of title 5, as amended, entitled "Confidentiality of Health Care Communications and 4 Information Act." 5

(2) "AIDS" means the medical condition known as acquired immune deficiency syndrome, 6 7 caused by infection of an individual by the human immunodeficiency virus (HIV).

8 (3) "Anonymous HIV testing" means an HIV test that utilizes a laboratory generated code 9 based system, which does not require an individual's name or other identifying information that 10 may reveal one's identity, including information related to the individual's health insurance policy, 11 to be associated with the test.

12 (4) "Antibody" means a protein produced by the body in response to specific foreign 13 substances such as bacteria or viruses.

14 (5) "Community-based organization" means an entity that has written authorization from 15 the department for HIV counseling, testing and referral services (HIV CTRS).

16 (6) "Confidential HIV testing" means an HIV test that requires the individual's name and 17 other identifying information including information related to the individual's health insurance 18 policy, as appropriate.

19 (7) "Consent" means an explicit exchange of information between a person and a 20 healthcare provider or qualified professional HIV test counselor through which an informed 21 individual can choose whether to undergo HIV testing or decline to do so. Elements of consent 22 shall include providing each individual with verbal or written information regarding an explanation 23 of HIV infection, a description of interventions that can reduce HIV transmission, the meanings of 24 positive and negative test results, the voluntary nature of the HIV testing, an opportunity to ask 25 questions and to decline testing.

26 (8) "Controlled substance" means a drug, substance, or immediate precursor in schedules 27 I-V listed in the provisions of chapter 28 of title 21 entitled, "Uniform Controlled Substances Act." 28

(9) "Department" means the Rhode Island department of health.

29 (10) "Diagnosis of AIDS" means the most current surveillance case definition for AIDS 30 published in the Centers for Disease Control & Prevention (CDC).

31 (11) "Diagnosis of HIV" means the most current surveillance case definition for HIV 32 infection published in the CDC's (MMWR).

33 (12) "Director" means the director of the Rhode Island department of health.

34 (13) "ELISA result" means enzyme-linked immunosorbent assay or EIA (enzyme

1 immunoassay) which is a serologic technique used in immunology to detect the presence of either 2 antibody or antigen.

3 (14) "Health benefits" include accident and sickness, including disability or health 4 insurance, health benefit plans and/or policies, hospital, health, or medical service plans, or any 5 health maintenance organization plan pursuant to title 27 or otherwise.

(15) "Healthcare facility" means those facilities licensed by the department in accordance 6 7 with the provisions of chapter 17 of this title.

8 (16) "Healthcare provider," as used herein, means a licensed physician, physician assistant, 9 certified nurse practitioner or midwife.

10 (17) "Healthcare settings" means venues offering clinical STD services including, but not 11 limited to, hospitals, urgent care clinics, STD clinics and other substance abuse treatment facilities, 12 mental health treatment facilities, community health centers, primary care and OB/GYN physician 13 offices, and family planning providers.

14 (18) "HIV" means the human immunodeficiency virus, the pathogenic organism 15 responsible for HIV infection and/or the acquired immunodeficiency syndrome (AIDS) in humans.

16 (19) "HIV CD4 T-lymphocyte test result" means the results of any currently medically 17 accepted and/or FDA approved test used to count CD4 T-lymphatic cells in the blood of an HIV-18 infected person.

19 (20) "HIV counseling" means an interactive process of communication between a person 20 and a healthcare provider or qualified professional HIV test counselor during which there is an 21 assessment of the person's risks for HIV infection and the provision of counseling to assist the 22 person with behavior changes that can reduce risks for acquiring HIV infection.

23 (21) "HIV prevention drug" means a drug approved by the United States Food and Drug

24 Administration for the prevention of HIV, including, but not limited to, pre-exposure prophylaxis.

25 (22) "HIV screening" means the conduct of HIV testing among those who do not show 26 signs or symptoms of an HIV infection.

27 (22)(23) "HIV test" means any currently medically accepted and/or FDA approved test for 28 determining HIV infection in humans.

29 (23)(24) "Occupational health representative" means a person, within a healthcare facility, 30 trained to respond to occupational, particularly blood borne, exposures.

31 (24)(25) "Opts out" means that a person who has been notified that a voluntary HIV test 32 will be performed, has elected to decline or defer testing. Consent to HIV testing is inferred unless 33 the individual declines testing.

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(25)(26) "Perinatal case report for HIV" means the information that is provided to the

department related to a child aged less than eighteen (18) months born to an HIV-infected mother
and the child does not meet the criteria for HIV infection or the criteria for "not infected" with HIV
as defined in the most current surveillance case definition for HIV infection published by the CDC.
(26)(27) "Person" means any individual, trust or estate, partnership, corporation (including
associations, joint stock companies), limited liability companies, state, or political subdivision or
instrumentality of a state.

7 (27)(28) "Persons at high risk for HIV infection" means persons defined as being high risk
8 in the CDC's most current recommendations for HIV testing of adults, adolescents and pregnant
9 women in healthcare settings or through authority and responsibilities conferred on the director by
10 law in protecting the public's health.

(28)(29) "Polymerase chain reaction (PCR) test" means a common laboratory method of
 creating copies of specific fragments of DNA or RNA.

13 (29)(30) "Pre-exposure prophylaxis" means a drug or drug combination that is taken or
 14 administered to reduce the risk of HIV acquisition and meets the same clinical eligibility
 15 recommendations provided in current guidelines of the federal Centers for Disease Control and

16 <u>Prevention.</u>

17 (31) "Qualified professional HIV test counselor" means: (i) A physician, physician 18 assistant, certified nurse practitioner, midwife, or nurse licensed to practice in accordance with 19 applicable state law; (ii) A medical student who is actively matriculating in a medical degree 20 program and who performs duties assigned to them by a physician; or (iii) A person who has 21 completed an HIV counseling training program, in accordance with regulations hereunder 22 promulgated.

(30)(32) "Sexually transmitted diseases (STD's)" means those diseases included in § 2311-1, as amended, entitled "Sexually Transmitted Diseases," and any other sexually transmitted
disease that may be required to be reported by the department.

26 SECTION 3. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO HEALTH AND SAFETY -- PREVENTION AND SUPPRESSION OF CONTAGIOUS DISEASES -- HIV/AIDS

1	This act would permit a licensed pharmacist to prescribe, dispense or administer HIV
2	prevention drugs once every two (2) years to an individual who is HIV negative, does not report
3	any signs or symptoms of acute HIV infection, and does not report taking any contraindicated
4	medication. A licensed pharmacist prescribing, dispensing or administering HIV prevention drugs
5	shall counsel the individual receiving the drug on the ongoing use of the drug and notify the patient
6	that they must be seen by a primary care provider to receive subsequent dosages.
7	This act would take effect upon passage.

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