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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2023

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A N A C T

RELATING TO INSURANCE -- INSURANCE COVERAGE FOR PREVENTION OF HIV INFECTION

Introduced By: Senators Murray, Valverde, Lauria, Pearson, Euer, Lawson, Mack, Acosta, Miller, and Cano
Date Introduced: March 07, 2023

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Title 27 of the General Laws entitled "INSURANCE" is hereby amended by adding thereto the following chapter:

CHAPTER 38.3

INSURANCE COVERAGE FOR PREVENTION OF HIV INFECTION

27-38.3-1. Coverage for prevention of HIV infection.

(a) A group health plan and an individual or group health insurance plan shall provide coverage for the prevention treatment of HIV infection under the same terms and conditions as that coverage is provided for other illnesses and diseases.

(b) Coverage for the prevention treatment of HIV infection shall not impose any annual or lifetime dollar limitation.

(c) Financial requirements and quantitative treatment limitations on coverage for the prevention treatment of HIV infection shall be no more restrictive than the predominant financial requirements applied to substantially all coverage for medical conditions in each treatment classification.

(d) Coverage shall not impose non-quantitative treatment limitations for the prevention treatment of HIV infection unless the processes, strategies, evidentiary standards, or other factors used in applying the non-quantitative treatment limitation, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary

standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification.

(e) The following classifications shall be used to apply the coverage requirements of this chapter:

(1) Inpatient, in-network;

(2) Inpatient, out-of-network;

(3) Outpatient, in-network;

(4) Outpatient, out-of-network;

(5) Emergency care; and

(6) Prescription drugs.

(f) Payors shall rely upon the criteria of the Society of Infectious Diseases Pharmacists when developing coverage for levels of care for HIV prevention treatment.

27-38.3-2. Definitions.

As used in this section, unless the context otherwise indicates, the following terms have the following meanings:

(1) "CDC guidelines" means guidelines related to the nonoccupational exposure to potential HIV infection, or any subsequent guidelines, published by the federal Department of Health and Human Services, Centers for Disease Control and Prevention (CDC).

(2) "Financial requirements" means deductibles, copayments, coinsurance, or out-of-pocket maximums.

(3) "Group health plan" means an employee welfare benefit plan as defined in 29 U.S.C. § 1002(1) and 42 U.S.C. § 300gg-91 to the extent that the plan provides health benefits to employees or their dependents directly or through insurance, reimbursement, or otherwise. For purposes of this chapter, a group health plan shall not include a plan that provides health benefits directly to employees or their dependents, except in the case of a plan provided by the state or an instrumentality of the state.

(4) "Health insurance plan" means health insurance coverage offered, delivered, issued for delivery, or renewed by a health insurer.

(5) "Health insurers" means all persons, firms, corporations, or other organizations offering and assuring health services on a prepaid or primarily expense-incurred basis, including, but not limited to, policies of accident or sickness insurance, as defined by chapter 18 of this title; nonprofit hospital or medical service plans, whether organized under chapter 19 or 20 of this title or under any public law or by special act of the general assembly; health maintenance organizations, as defined by chapter 41 of this title, or any other entity that insures or reimburses for diagnostic,

therapeutic, or preventive services to a determined population on the basis of a periodic premium. Provided, this chapter does not apply to insurance coverage providing benefits for:

(i) Hospital confinement indemnity;

(ii) Disability income;

(iii) Accident only;

(iv) Long-term care;

(v) Medicare supplement;

(vi) Limited benefit health;

(vii) Specific disease indemnity;

(viii) Sickness or bodily injury or death by accident or both; and

(ix) Other limited benefit policies.

(6) "HIV prevention drug" means a preexposure prophylaxis drug, post-exposure prophylaxis drug or other drug approved for the prevention of HIV infection by the federal Food and Drug Administration.

(7) "Non-quantitative treatment limitations" means:

(i) Medical management standards;

(ii) Formulary design and protocols;

(iii) Network tier design;

(iv) Standards for provider admission to participate in a network;

(v) Reimbursement rates and methods for determining usual, customary, and reasonable charges; and

(vi) Other criteria that limit scope or duration of coverage for services in the prevention treatment of HIV infection, including restrictions based on geographic location, facility type, and provider specialty.

(8) "Post-exposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines following potential exposure to HIV infection.

(9) "Preexposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines to prevent HIV infection.

(10) "Quantitative treatment limitations" means numerical limits on coverage for the preventive treatment of HIV infection based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment.

27-38.3-3. Coverage required.

A health insurer offering a health plan in this state shall provide coverage for an HIV

prevention drug that has been prescribed by a provider. Each long-acting injectable drug with a different duration shall constitute a separate method of administration. Coverage under this section is subject to the following;

(1) If the federal Food and Drug Administration has approved one or more HIV prevention drugs that use the same method of administration, a health insurer is not required to cover all approved drugs as long as the insurer covers at least one approved drug for each method of administration with no out-of-pocket cost.

(2) A health insurer is not required to cover any preexposure prophylaxis drug or post-exposure prophylaxis drug dispensed or administered by an out-of-network pharmacy provider unless the enrollee's health plan provides an out-of-network pharmacy benefit.

(3) A health insurer shall not prohibit or permit a pharmacy benefits manager to prohibit a pharmacy provider from dispensing or administering any HIV prevention drugs.

27-38.3-4. Limits on prior authorization and step therapy requirements.

Notwithstanding any requirements to the contrary, a health insurer shall not subject any HIV prevention drug to any prior authorization or step therapy requirement except as provided in this section. If the federal Food and Drug Administration has approved one or more methods of administering HIV prevention drugs, an insurer is not required to cover all of the approved drugs without prior authorization or step therapy requirements as long as the insurer covers at least one approved drug for each method of administration without prior authorization or step therapy requirements. If prior authorization or step therapy requirements are met for a particular enrollee with regard to a particular HIV prevention drug, the insurer is required to cover that drug with no out-of-pocket cost to the enrollee.

27-38.3-5. Coverage for laboratory testing related to HIV prevention drugs.

A health insurer offering a health plan in this state shall provide coverage with no out-of-pocket cost for any ancillary or support service determined by the department of health that is necessary to:

(1) Ensure that such a drug is prescribed and administered to a person who is not infected with HIV and has no medical contraindications to the use of such drug; and

(2) Monitor such a person to ensure the safe and effective ongoing use of such a drug through:

(i) An office visit;

(ii) Laboratory testing;

(iii) Testing for a sexually transmitted infection;

(iv) Medication self-management and adherence counseling; or

(v) Any health service specified as part of comprehensive HIV prevention drug services by the United States Department of Health and Human Services, the United States Centers for Disease Control and Prevention or the United States Preventive Services Task Force.

27-38.3-6. Medical necessity and appropriateness of treatment.

(a) Upon request of the reimbursing health insurers, all providers of prevention treatment of HIV infection shall furnish medical records or other necessary data which substantiates that initial or continued treatment is at all times medically necessary and/or appropriate. When the provider cannot establish the medical necessity and/or appropriateness of the treatment modality being provided, neither the health insurer nor the patient shall be obligated to reimburse for that period or type of care that was not established. Exception to the preceding requirement can only be made if the patient has been informed of the provisions of this subsection and has agreed in writing to continue to receive treatment at their own expense.

(b) The health insurers, when making the determination of medically necessary and appropriate treatment, shall do so in a manner consistent with that used to make the determination for the treatment of other diseases or injuries covered under the health insurance policy or agreement.

(c) Any subscriber who is aggrieved by a denial of benefits provided under this chapter may appeal a denial in accordance with the rules and regulations promulgated by the department of health pursuant to chapter 18.9 of title 27.

27-38.3-7. Network coverage.

The healthcare benefits outlined in this chapter apply only to services delivered within the health insurer's provider network; provided that, all health insurers shall be required to provide coverage for those benefits mandated by this chapter outside of the health insurer's provider network where it can be established that the required services are not available from a provider in the health insurer's network.

SECTION 2. Chapter 5-19.1 of the General Laws entitled "Pharmacies" is hereby amended by adding thereto the following section:

5-19.1-31.1. Prescribing, dispensing and administering HIV prevention drugs.

(a) Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

(1) "CDC guidelines" means guidelines related to nonoccupational exposure to potential HIV infection, or any subsequent guidelines, published by the federal Department of Health and Human Services, Centers for Disease Control and Prevention (CDC).

(2) "HIV prevention drug" means a preexposure prophylaxis drug, post-exposure

prophylaxis drug or other drug approved for the prevention of HIV infection by the federal Food and Drug Administration.

(3)"Post-exposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines following potential exposure to HIV infection.

(4) "Preexposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations provided in CDC guidelines to prevent HIV infection.

(b) Authorization. Notwithstanding any provision of law to the contrary, and as authorized by the board in accordance with rules and regulations adopted under subsection (c) of this section, a pharmacist may prescribe, dispense and administer HIV prevention drugs pursuant to a standing order or collaborative practice agreement or to protocols developed by the board for when there is no prescription drug order, standing order or collaborative practice agreement in accordance with the requirements in this subsection and may also order laboratory testing for HIV infection as necessary.

(1) Before furnishing an HIV prevention drug to a patient, a pharmacist shall complete a training program approved by the board on the use of protocols developed by the board for prescribing, dispensing and administering an HIV prevention drug, on the requirements for any laboratory testing for HIV infection and on guidelines for prescription adherence and best practices to counsel patients prescribed an HIV prevention drug.

(2) A pharmacist shall dispense or administer a preexposure prophylaxis drug in at least a thirty (30) day supply, and up to a sixty (60) day supply, as long as all of the following conditions are met:

(i) The patient tests negative for HIV infection, as documented by a negative HIV test result obtained within the previous seven (7) days. If the patient does not provide evidence of a negative HIV test result, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of primary care providers and clinics within a reasonable travel distance of the patient's residence;

(ii) The patient does not report any signs or symptoms of acute HIV infection on a self-reporting checklist of acute HIV infection signs and symptoms;

(iii) The patient does not report taking any contraindicated medications;

(iv) The pharmacist provides counseling to the patient, consistent with CDC guidelines, on the ongoing use of a preexposure prophylaxis drug. The pharmacist shall notify the patient that the

patient shall be seen by a primary care provider to receive subsequent prescriptions for a preexposure prophylaxis drug and that a pharmacist shall not dispense or administer more than a sixty (60) day supply of a preexposure prophylaxis drug to a single patient once every two (2) years without a prescription;

(v) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the patient profile record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis drugs dispensed or administered to each patient;

(vi) The pharmacist does not dispense or administer more than a sixty (60) day supply of a preexposure prophylaxis drug to a single patient once every two (2) years, unless otherwise directed by a practitioner; and

(vii) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subsection. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care providers to contact regarding follow-up care.

(3) A pharmacist shall dispense or administer a complete course of a post-exposure prophylaxis drug as long as all of the following conditions are met:

(i) The pharmacist screens the patient and determines that the exposure occurred within the previous seventy-two (72) hours and the patient otherwise meets the clinical criteria for a postexposure prophylaxis drug under CDC guidelines;

(ii) The pharmacist provides HIV testing to the patient or determines that the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for a post-exposure prophylaxis drug under this subsection, the pharmacist may dispense or administer a post-exposure prophylaxis drug;

(iii) The pharmacist provides counseling to the patient, consistent with CDC guidelines, on the use of a post-exposure prophylaxis drug. The pharmacist shall also inform the patient of the availability of a preexposure prophylaxis drug for persons who are at substantial risk of acquiring HIV; and

(iv) The pharmacist notifies the patient's primary care provider of the dispensing or administering of the post-exposure prophylaxis drug. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care providers to contact regarding follow-up care.

(c) Rules, regulations and protocols. The board shall promulgate rules and regulations establishing standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs in accordance with subsection (b) of this section, including adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement.

SECTION 3. Section 23-6.3-2 of the General Laws in Chapter 23-6.3 entitled "Prevention and Suppression of Contagious Diseases — HIV/AIDS" is hereby amended to read as follows:

23-6.3-2. Definitions.

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

(1) "Agent" means a person empowered by the patient to assert or waive the confidentiality, 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 Information Act."

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

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

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

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

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

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

(8) "Controlled substance" means a drug, substance, or immediate precursor in schedules

I-V listed in the provisions of chapter 28 of title 21 entitled, "Uniform Controlled Substances Act."

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

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

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

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

(13) "ELISA result" means enzyme-linked immunosorbent assay or EIA (enzyme immunoassay) which is a serologic technique used in immunology to detect the presence of either antibody or antigen.

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

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

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

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

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

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

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

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

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

(23) “Occupational health representative” means a person, within a healthcare facility, trained to respond to occupational, particularly blood borne, exposures.

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

(25) “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) “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.

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

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

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

(30) “Sexually transmitted diseases (STD’s)” means those diseases included in § 23-11-1, as amended, entitled “Sexually Transmitted Diseases,” and any other sexually transmitted disease that may be required to be reported by the department.

SECTION 4. This act shall take effect on January 1, 2024.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO INSURANCE -- INSURANCE COVERAGE FOR PREVENTION OF HIV INFECTION

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This act would require coverage for the treatment of pre-exposure prophylaxis (PrEP) for the prevention of HIV and post-exposure prophylaxis (PEP) for treatment of HIV infection, commencing January 1, 2024.

This act would take effect on January 1, 2024.

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