

2023 -- H 6150

LC002548

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2023

A N A C T

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

Introduced By: Representatives Potter, Baginski, Kazarian, Cruz, Donovan, Kislak, Giraldo, McNamara, Voas, and Morales

Date Introduced: March 10, 2023

Referred To: House Health & Human Services

It is enacted by the General Assembly as follows:

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

3 CHAPTER 38.3

4 INSURANCE COVERAGE FOR PREVENTION OF HIV INFECTION

5 **27-38.3-1. Coverage for prevention of HIV infection.**

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

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

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

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

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

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

5 (1) Inpatient, in-network;

6 (2) Inpatient, out-of-network;

7 (3) Outpatient, in-network;

8 (4) Outpatient, out-of-network;

9 (5) Emergency care; and

10 (6) Prescription drugs.

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

13 **27-38.3-2. Definitions.**

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

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

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

21 (3) "Group health plan" means an employee welfare benefit plan as defined in 29 U.S.C. §
22 1002(1) to the extent that the plan provides health benefits to employees or their dependents directly
23 or through insurance, reimbursement, or otherwise. For purposes of this chapter, a group health
24 plan shall not include a plan that provides health benefits directly to employees or their dependents,
25 except in the case of a plan provided by the state or an instrumentality of the state.

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

28 (5) "Health insurers" means all persons, firms, corporations, or other organizations offering
29 and assuring health services on a prepaid or primarily expense-incurred basis, including, but not
30 limited to, policies of accident or sickness insurance, as defined by chapter 18 of this title; nonprofit
31 hospital or medical service plans, whether organized under chapter 19 or 20 of this title or under
32 any public law or by special act of the general assembly; health maintenance organizations, or any
33 other entity that insures or reimburses for diagnostic, therapeutic, or preventive services to a
34 determined population on the basis of a periodic premium. Provided, this chapter does not apply to

- 1 insurance coverage providing benefits for:
- 2 (i) Hospital confinement indemnity;
- 3 (ii) Disability income;
- 4 (iii) Accident only;
- 5 (iv) Long-term care;
- 6 (v) Medicare supplement;
- 7 (vi) Limited benefit health;
- 8 (vii) Specific disease indemnity;
- 9 (viii) Sickness or bodily injury or death by accident or both; and
- 10 (ix) Other limited benefit policies.
- 11 (6) "HIV prevention drug" means a preexposure prophylaxis drug, post-exposure
- 12 prophylaxis drug or other drug approved for the prevention of HIV infection by the federal Food
- 13 and Drug Administration.
- 14 (7) "Non-quantitative treatment limitations" means:
- 15 (i) Medical management standards;
- 16 (ii) Formulary design and protocols;
- 17 (iii) Network tier design;
- 18 (iv) Standards for provider admission to participate in a network;
- 19 (v) Reimbursement rates and methods for determining usual, customary, and reasonable
- 20 charges; and
- 21 (vi) Other criteria that limit scope or duration of coverage for services in the prevention
- 22 treatment of HIV infection, including restrictions based on geographic location, facility type, and
- 23 provider specialty.
- 24 (8) "Post-exposure prophylaxis drug" means a drug or drug combination that meets the
- 25 clinical eligibility recommendations provided in CDC guidelines following potential exposure to
- 26 HIV infection.
- 27 (9) "Preexposure prophylaxis drug" means a drug or drug combination that meets the
- 28 clinical eligibility recommendations provided in CDC guidelines to prevent HIV infection.
- 29 (10) "Quantitative treatment limitations" means numerical limits on coverage for the
- 30 preventive treatment of HIV infection based on the frequency of treatment, number of visits, days
- 31 of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment.

32 **27-38.3-3. Coverage required.**

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

34 prevention drug that has been prescribed by a provider. Coverage under this section is subject to

1 the following:

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

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

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

11 **27-38.3-4. Limits on prior authorization and step therapy requirements.**

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

21 **27-38.3-5. Coverage for laboratory testing related to HIV prevention drugs.**

22 A health insurer offering a health plan in this state shall provide coverage with no out-of-
23 pocket cost for laboratory testing recommended by a provider related to the ongoing monitoring of
24 an enrollee who is taking an HIV prevention drug covered by this chapter.

25 **27-38.3-6. Medical necessity and appropriateness of treatment.**

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

34 (b) The health insurers, when making the determination of medically necessary and

1 appropriate treatment, shall do so in a manner consistent with that used to make the determination
2 for the treatment of other diseases or injuries covered under the health insurance policy or
3 agreement.

4 (c) Any subscriber who is aggrieved by a denial of benefits provided under this chapter
5 may appeal a denial in accordance with the rules and regulations promulgated by the department
6 of health pursuant to chapter 17.12 of title 23.

7 **27-38.3-7. Network coverage.**

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

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

15 **5-19.1-31.1. Prescribing, dispensing and administering HIV prevention drugs.**

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

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

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

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

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

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

1 necessary.

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

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

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

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

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

20 (D) The pharmacist provides counseling to the patient, consistent with CDC guidelines, on
21 the ongoing use of a preexposure prophylaxis drug. The pharmacist shall notify the patient that the
22 patient shall be seen by a primary care provider to receive subsequent prescriptions for a
23 preexposure prophylaxis drug and that a pharmacist shall not dispense or administer more than a
24 sixty (60) day supply of a preexposure prophylaxis drug to a single patient once every two (2) years
25 without a prescription;

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

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

33 (G) The pharmacist notifies the patient's primary care provider that the pharmacist
34 completed the requirements specified in this subsection. If the patient does not have a primary care

1 provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall
2 provide the patient a list of physicians, clinics or other health care providers to contact regarding
3 follow-up care.

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

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

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

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

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

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

27 SECTION 3. 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

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

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