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In Senate, March 22, 2021

An Act To Improve Access to HIV Prevention Medications

Received by the Secretary of the Senate on March 18, 2021. Referred to the Committee on Health Coverage, Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed.

A handwritten signature in black ink, appearing to read 'D M Grant'.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator SANBORN of Cumberland.
Cosponsored by Speaker FECTEAU of Biddeford and
Senators: CLAXTON of Androscoggin, LIBBY of Androscoggin.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 22 MRSA §3174-M, sub-§1-A, ¶B**, as enacted by PL 2005, c. 386, Pt. X,
3 §1, is amended to read:

4 B. Be structured to maintain at least the same therapeutic categories and
5 pharmacological classes of drugs provided on the MaineCare preferred drug list in
6 effect on July 1, 2005; ~~and~~

7 **Sec. 2. 22 MRSA §3174-M, sub-§1-A, ¶C**, as enacted by PL 2005, c. 386, Pt. X,
8 §1, is amended by amending subparagraph (3) to read:

9 (3) Conform to national standards for the prescribing of atypical antipsychotic
10 drugs; ~~and~~

11 **Sec. 3. 22 MRSA §3174-M, sub-§1-A, ¶D** is enacted to read:

12 D. With respect to HIV prevention drugs as defined in Title 24-A, section 4317-D,
13 subsection 1, paragraph B:

14 (1) Ensure that preexposure prophylaxis drugs are available; and

15 (2) Ensure that post-exposure prophylaxis drugs are available in accordance with
16 national standards for the prescribing of post-exposure prophylaxis drugs.

17 **Sec. 4. 24-A MRSA §4317-D** is enacted to read:

18 **§4317-D. Coverage of HIV prevention drugs**

19 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
20 following terms have the following meanings.

21 A. "CDC guidelines" means guidelines related to the nonoccupational exposure to
22 potential HIV infection, or any subsequent guidelines, published by the federal
23 Department of Health and Human Services, Centers for Disease Control and
24 Prevention.

25 B. "HIV prevention drug" means a preexposure prophylaxis drug, post-exposure
26 prophylaxis drug or other drug approved for the prevention of HIV infection by the
27 federal Food and Drug Administration.

28 C. "Post-exposure prophylaxis drug" means a drug or drug combination that meets the
29 clinical eligibility recommendations provided in CDC guidelines following potential
30 exposure to HIV infection.

31 D. "Preexposure prophylaxis drug" means a drug or drug combination that meets the
32 clinical eligibility recommendations provided in CDC guidelines to prevent HIV
33 infection.

34 **2. Coverage required.** A carrier offering a health plan in this State shall provide
35 coverage for an HIV prevention drug that has been prescribed by a provider. Coverage
36 under this section is subject to the following.

37 A. If the federal Food and Drug Administration has approved one or more therapeutic
38 equivalents of an HIV prevention drug, a carrier is not required to cover all of the
39 therapeutically equivalent drugs as long as the carrier covers at least one therapeutically

1 equivalent drug at the tier with the lowest cost-sharing requirement on the carrier's
2 prescription drug formulary.

3 B. A carrier is not required to cover any preexposure prophylaxis drug or post-
4 exposure prophylaxis drug dispensed by an out-of-network pharmacy provider unless
5 the enrollee's health plan provides an out-of-network pharmacy benefit.

6 C. A carrier may not prohibit, or permit a pharmacy benefits manager to prohibit, a
7 pharmacy provider from dispensing any HIV prevention drugs.

8 **3. Limits on prior authorization and step therapy requirements.** Notwithstanding
9 any requirements in section 4304 or 4320-N to the contrary, a carrier may not subject any
10 HIV prevention drug to any prior authorization or step therapy requirement except as
11 provided in this subsection. If the federal Food and Drug Administration has approved one
12 or more therapeutic equivalents of an HIV prevention drug, a carrier is not required to cover
13 all of the therapeutically equivalent drugs without prior authorization or step therapy
14 requirements as long as the carrier covers at least one therapeutically equivalent drug
15 without prior authorization or step therapy requirements.

16 **Sec. 5. 32 MRSA §13702-A, sub-§28**, as amended by PL 2017, c. 185, §1, is
17 further amended to read:

18 **28. Practice of pharmacy.** "Practice of pharmacy" means the interpretation and
19 evaluation of prescription drug orders; the compounding, dispensing and labeling of drugs
20 and devices, except labeling by a manufacturer, packer or distributor of nonprescription
21 drugs and commercially packaged legend drugs and devices; the participation in drug
22 selection and drug utilization reviews; the proper and safe storage of drugs and devices and
23 the maintenance of proper records for these drugs and devices; the administration of
24 vaccines licensed by the United States Food and Drug Administration that are
25 recommended by the United States Centers for Disease Control and Prevention Advisory
26 Committee on Immunization Practices, or successor organization, for administration to
27 adults; the performance of collaborative drug therapy management; the responsibility for
28 advising, when necessary or regulated, of therapeutic values, content, hazards and use of
29 drugs and devices; the ordering and dispensing of over-the-counter nicotine replacement
30 products approved by the United States Food and Drug Administration; the dispensing of
31 an HIV prevention drug, as defined in section 13786-E, subsection 1, paragraph B, pursuant
32 to a standing order or to protocols developed by the board; and the offering or performing
33 of those acts, services, operations or transactions necessary in the conduct, operation,
34 management and control of a pharmacy.

35 **Sec. 6. 32 MRSA §13786-E** is enacted to read:

36 **§13786-E. Dispensing HIV prevention drugs**

37 **1. Definitions.** As used in this section, unless the context otherwise indicates, the
38 following terms have the following meanings.

39 A. "CDC guidelines" means guidelines related to nonoccupational exposure to
40 potential HIV infection, or any subsequent guidelines, published by the federal
41 Department of Health and Human Services, Centers for Disease Control and
42 Prevention.

1 B. "HIV prevention drug" means a preexposure prophylaxis drug, post-exposure
2 prophylaxis drug or other drug approved for the prevention of HIV infection by the
3 federal Food and Drug Administration.

4 C. "Post-exposure prophylaxis drug" means a drug or drug combination that meets the
5 clinical eligibility recommendations provided in CDC guidelines following potential
6 exposure to HIV infection.

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

10 **2. Authorization.** Notwithstanding any provision of law to the contrary and as
11 authorized by the board in accordance with rules adopted under subsection 3, a pharmacist
12 may dispense HIV prevention drugs pursuant to a standing order or to protocols developed
13 by the board in accordance with the requirements in this subsection and may also order
14 laboratory testing for HIV infection as necessary.

15 A. Before furnishing an HIV prevention drug to a patient, a pharmacist shall complete
16 a training program approved by the board on the use of protocols developed by the
17 board for dispensing an HIV prevention drug, on the requirements for any laboratory
18 testing for HIV infection and on guidelines for prescription adherence and best
19 practices to counsel patients prescribed an HIV prevention drug.

20 B. A pharmacist shall dispense a preexposure prophylaxis drug in at least a 30-day
21 supply, and up to a 60-day supply, as long as all of the following conditions are met:

22 (1) The patient tests negative for HIV infection, as documented by a negative HIV
23 test result obtained within the previous 7 days. If the patient does not provide
24 evidence of a negative HIV test result in accordance with this subparagraph, the
25 pharmacist shall order an HIV test. If the test results are not transmitted directly
26 to the pharmacist, the pharmacist shall verify the test results to the pharmacist's
27 satisfaction. If the patient tests positive for HIV infection, the pharmacist or person
28 administering the test shall direct the patient to a primary care provider and provide
29 a list of primary care providers and clinics within a reasonable travel distance of
30 the patient's residence;

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

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

34 (4) The pharmacist provides counseling to the patient, consistent with CDC
35 guidelines, on the ongoing use of a preexposure prophylaxis drug. The pharmacist
36 shall notify the patient that the patient must be seen by a primary care provider to
37 receive subsequent prescriptions for a preexposure prophylaxis drug and that a
38 pharmacist may not dispense more than a 60-day supply of a preexposure
39 prophylaxis drug to a single patient once every 2 years without a prescription;

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

1 (6) The pharmacist does not dispense more than a 60-day supply of preexposure
2 prophylaxis to a single patient once every 2 years, unless otherwise directed by a
3 practitioner; and

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

9 C. A pharmacist shall dispense a complete course of a post-exposure prophylaxis drug
10 as long as all of the following conditions are met:

11 (1) The pharmacist screens the patient and determines that the exposure occurred
12 within the previous 72 hours and the patient otherwise meets the clinical criteria
13 for a post-exposure prophylaxis drug under CDC guidelines;

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

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

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

28 **3. Rules; protocols.** The board by rule shall establish standards for authorizing
29 pharmacists to dispense HIV prevention drugs in accordance with subsection 2, including
30 adequate training requirements and protocols for dispensing HIV prevention drugs. Rules
31 adopted under this subsection are routine technical rules as defined in Title 5, chapter 375,
32 subchapter 2-A.

33 **Sec. 7. Exemption from review.** Notwithstanding the Maine Revised Statutes,
34 Title 24-A, section 2752, this Act is enacted without review and evaluation by the
35 Department of Professional and Financial Regulation, Bureau of Insurance.

36 **Sec. 8. Application.** The requirements of this Act apply to all individual and group
37 health plans, as defined in the Maine Revised Statutes, Title 24-A, section 4301-A,
38 subsection 7, executed, delivered, issued for delivery, continued or renewed in this State
39 on or after January 1, 2022. For purposes of this Act, all contracts are deemed to be
40 renewed no later than the next yearly anniversary of the contract date.

41 SUMMARY

42 This bill makes the following changes to improve access to HIV prevention drugs.

1 The bill requires that any drug formulary used in the MaineCare program must ensure
2 that HIV prevention drugs are available to members covered by MaineCare.

3 The bill requires health insurance carriers to provide coverage for an enrollee for HIV
4 prevention drugs that have been determined to be medically necessary by a health care
5 provider. A carrier is not required to cover a preexposure prophylaxis drug, also known as
6 PrEP, in excess of a 60-day supply to a single enrollee every 2 years. If the federal Food
7 and Drug Administration has approved one or more therapeutic equivalents of an HIV
8 prevention drug, a carrier is not required to cover all of the therapeutically equivalent drugs
9 as long as the carrier covers at least one therapeutically equivalent drug at the tier with the
10 lowest cost-sharing requirement on the carrier's prescription drug formulary. The bill also
11 prohibits a carrier from imposing prior authorization or step therapy requirements on any
12 HIV prevention drug, except that, if the federal Food and Drug Administration has
13 approved one or more therapeutic equivalents of an HIV prevention drug, a carrier is
14 required to cover at least one therapeutically equivalent drug without prior authorization or
15 step therapy requirements. The bill's requirements with regard to health insurance carriers
16 apply to health plans issued or renewed on or after January 1, 2022.

17 The bill also authorizes a pharmacist to dispense HIV prevention drugs under certain
18 conditions without a prescription subject to rules for dispensing and protocols adopted by
19 the Maine Board of Pharmacy.