130th MAINE LEGISLATURE

FIRST REGULAR SESSION-2021

Legislative Document **No. 1115**

S.P. 378 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.

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.

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

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

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

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

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

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

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

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

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

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

§4317-D. Coverage of HIV prevention drugs

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

A. "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.

B. "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.

C. "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.

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

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

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

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

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

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

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

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

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

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

§13786-E. Dispensing HIV prevention drugs

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

A. "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.

B. "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.

C. "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.

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

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

A. 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 dispensing 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.

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

(1) The patient tests negative for HIV infection, as documented by a negative HIV test result obtained within the previous 7 days. If the patient does not provide evidence of a negative HIV test result in accordance with this subparagraph, 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;

(2) 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;

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

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

(5) 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 to each patient;

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

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this paragraph. 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. A pharmacist shall dispense a complete course of a post-exposure prophylaxis drug as long as all of the following conditions are met:

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

(2) 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 a post-exposure prophylaxis drug;

(3) 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

(4) The pharmacist notifies the patient's primary care provider of the dispensing 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.

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

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

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

SUMMARY

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

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

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

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