L.D. 1115

Date: 6/9/24 **MAJORITY** (Filing No. S-239)

HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

Reproduced and distributed under the direction of the Secretary of the Senate.

STATE OF MAINE
SENATE
130TH LEGISLATURE
FIRST SPECIAL SESSION

COMMITTEE AMENDMENT " A " to S.P. 378, L.D. 1115, "An Act To Improve Access to HIV Prevention Medications"

Amend the bill in section 4 in §4317-D by striking out all of subsection 2 (page 1, lines 34 to 39 and page 2, lines 1 to 7 in L.D.) and inserting the following:

'**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 HIV prevention drugs that use the same method of administration, a carrier is not required to cover all approved drugs as long as the carrier covers at least one approved drug for each method of administration with no out-of-pocket cost.

B. A carrier 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.

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

Amend the bill in section 4 in §4317-D by striking out all of subsection 3 (page 2, lines 8 to 15 in L.D.) and inserting the following:

'**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 methods of administering HIV prevention drugs, a carrier is not required to cover all of the approved drugs without prior authorization or step therapy requirements as long as the carrier 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 carrier is required to cover that drug with no out-of-pocket cost to the enrollee.'

Amend the bill in section 4 in §4317-D by inserting after subsection 3 the following:

'**4. Coverage for laboratory testing related to HIV prevention drugs.** A carrier offering a health plan in this State shall provide coverage with no out-of-pocket cost for laboratory testing recommended by a provider related to the ongoing monitoring of an enrollee who is taking an HIV prevention drug covered by this section.'

Amend the bill by striking out all of section 5 and inserting the following:

'**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 prescribing, dispensing and administering of an HIV prevention drug, as defined in section 13786-E, subsection 1, paragraph B, pursuant to a standing order or collaborative practice agreement 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.'

Amend the bill in section 6 in §13786-E in the first line (page 2, line 36 in L.D.) by striking out the following: "**Dispensing**" and inserting the following: '**Prescribing, dispensing and administering**'

Amend the bill in section 6 in §13786-E by striking out all of subsection 2 (page 3, lines 10 to 43 and page 4, lines 1 to 27 in L.D.) and inserting the following:

'**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 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.

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 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.

B. A pharmacist shall dispense or administer 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 or administer 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 or administered to each patient;

(6) The pharmacist does not dispense or administer more than a 60-day supply of a preexposure prophylaxis drug 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 or administer 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 or administer a post-exposure prophylaxis drug;

A of S

(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 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.'

Amend the bill in section 6 in §13786-E by striking out all of subsection 3 (page 4, lines 28 to 32 in L.D.) and inserting the following:

'**3. Rules; protocols.** The board by rule shall establish standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs in accordance with subsection 2, including adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement. Rules adopted under this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.'

Amend the bill by inserting after section 8 the following:

'**Sec. 9. Appropriations and allocations.** The following appropriations and allocations are made.

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF

Administrative Services - Professional and Financial Regulation 0094

Initiative: Allocates funds for technology-related costs associated with establishing one half-time Regulatory Health Compliance position to manage the anticipated increase in workload associated with the regulation of pharmacists' authority to dispense HIV prevention drugs.

OTHER SPECIAL REVENUE FUNDS	**2021-22**	**2022-23**
All Other	$2,729	$3,347
OTHER SPECIAL REVENUE FUNDS TOTAL	$2,729	$3,347

Licensing and Enforcement 0352

Initiative: Allocates funds for one half-time Regulatory Health Compliance position to manage the anticipated increase in workload associated with the regulation of pharmacists' authority to dispense HIV prevention drugs.

OTHER SPECIAL REVENUE FUNDS	**2021-22**	**2022-23**
POSITIONS - LEGISLATIVE COUNT	0.500	0.500
Personal Services	$35,328	$49,424
All Other	$5,782	$2,904
OTHER SPECIAL REVENUE FUNDS TOTAL	$41,110	$52,328

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF DEPARTMENT TOTALS	2021-22	2022-23
OTHER SPECIAL REVENUE FUNDS	$43,839	$55,675
DEPARTMENT TOTAL - ALL FUNDS	$43,839	$55,675

Amend the bill by relettering or renumbering any nonconsecutive Part letter or section number to read consecutively.

SUMMARY

This amendment is the majority report of the committee. The amendment clarifies that health insurance carriers are not required to cover all of the drugs approved by the federal Food and Drug Administration for HIV prevention as long as the carrier covers at least one approved drug for each method of administration with no out-of-pocket cost to the enrollee. The amendment also clarifies that a carrier is required to cover at least one approved drug for each method of administration without prior authorization or step therapy requirements.

The amendment also makes changes to the bill's provisions authorizing a pharmacist to dispense HIV prevention drugs under certain conditions pursuant to a standing order or to protocols developed by the Maine Board of Pharmacy by authorizing a pharmacist to prescribe, dispense and administer HIV prevention drugs pursuant to a standing order or collaborative practice agreement or when there is no prescription drug order from a health care provider, subject to rules and protocols adopted by the board. The amendment also adds an appropriations and allocations section.

FISCAL NOTE REQUIRED

(See attached)

Approved: 05/04/21 mac

130th MAINE LEGISLATURE

LD 1115 **LR 1215(02)**

An Act To Improve Access to HIV Prevention Medications

Fiscal Note for Bill as Amended by Committee Amendment "A" (S-239)
Committee: Health Coverage, Insurance and Financial Services
Fiscal Note Required: Yes

Fiscal Note

	FY 2021-22	FY 2022-23	Projections FY 2023-24	Projections FY 2024-25
Appropriations/Allocations				
Other Special Revenue Funds	$43,839	$55,675	$58,640	$61,783
Transfers				
Other Special Revenue Funds	$0	$0	$0	$0

Fiscal Detail and Notes

The bill includes Other Special Revenue Funds allocations to the Department of Professional and Financial Regulation of $43,839 in fiscal year 2021-22 and $55,675 in fiscal year 2022-23 to implement the requirements of this legislation within the Office of Professional and Occupational Licensing, Maine Board of Pharmacy.

Of this amount, the bill includes Other Special Revenue Funds allocations to the Licensing and Enforcement program of $41,110 in fiscal year 2021-22 and $52,328 in fiscal year 2022-23 to establish one half-time Regulatory Health Compliance position and related All Other costs to manage the anticipated increase in workload associated with the regulation of pharmacists authority to dispense HIV prevention drugs. Additionally, the bill includes Other Special Revenue Funds allocations to the Administrative Services Division of $2,729 in fiscal year 2021-22 and $3,347 in fiscal year 2022-23 for technology-related costs associated with establishing the Regulatory Health Compliance position. The Office of Professional and Occupational Licensing will transfer funds from its Licensing and Enforcement program (which includes funds for the Maine Board of Pharmacy) to the Administrative Services Division to fund the allocations.

The Maine Board of Pharmacy within the Office of Professional and Occupational Licensing has sufficient resources available to support the cost of this legislation without raising fees through the 2022-2023 biennium. However, fees may need to be increased in future biennia if the current fee structure does not generate sufficient revenue to cover the cost of this legislation.