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Date: (Filing No. S-)

HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

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**STATE OF MAINE
SENATE
130TH LEGISLATURE
FIRST SPECIAL SESSION**

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

Amend the bill in section 3 in paragraph D in the first 2 lines (page 1, lines 12 and 13 in L.D.) by striking out the following: "as defined in Title 24-A, section 4317-D, subsection 1, paragraph B"

Amend the bill by striking out all of section 4.

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.'

COMMITTEE AMENDMENT

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

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

6 **'2. Authorization.** Notwithstanding any provision of law to the contrary and as
7 authorized by the board in accordance with rules adopted under subsection 3, a pharmacist
8 may prescribe, dispense and administer HIV prevention drugs pursuant to a standing order
9 or collaborative practice agreement or to protocols developed by the board for when there
10 is no prescription drug order, standing order or collaborative practice agreement in
11 accordance with the requirements in this subsection and may also order laboratory testing
12 for HIV infection as necessary.

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

19 B. A pharmacist shall dispense or administer a preexposure prophylaxis drug in at least
20 a 30-day supply, and up to a 60-day supply, as long as all of the following conditions
21 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 or administer more than a 60-day supply of a
39 preexposure prophylaxis drug to a single patient once every 2 years without a
40 prescription;

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

1 (6) The pharmacist does not dispense or administer more than a 60-day supply of
2 a preexposure prophylaxis drug to a single patient once every 2 years, unless
3 otherwise directed by a 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 or administer a complete course of a post-exposure
10 prophylaxis drug 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 or administer
18 a post-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 or administering of the post-exposure prophylaxis drug. If the patient does not
25 have a primary care provider, or refuses consent to notify the patient's primary care
26 provider, the pharmacist shall provide the patient a list of physicians, clinics or
27 other health care providers to contact regarding follow-up care.'

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

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

36 Amend the bill by striking out all of sections 7 and 8 and inserting the following:

37 '**Sec. 7. Appropriations and allocations.** The following appropriations and
38 allocations are made.

39 **PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF**
40 **Administrative Services - Professional and Financial Regulation 0094**

41 Initiative: Allocates funds for technology-related costs associated with establishing one
42 half-time Regulatory Health Compliance position to manage the anticipated increase in

1 workload associated with the regulation of pharmacists' authority to dispense HIV
 2 prevention drugs.

3	OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
4	All Other	\$2,729	\$3,347
5			
6	OTHER SPECIAL REVENUE FUNDS TOTAL	\$2,729	\$3,347

7 **Licensing and Enforcement 0352**

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

11	OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
12	POSITIONS - LEGISLATIVE COUNT	0.500	0.500
13	Personal Services	\$35,328	\$49,424
14	All Other	\$5,782	\$2,904
15			
16	OTHER SPECIAL REVENUE FUNDS TOTAL	\$41,110	\$52,328

18 **PROFESSIONAL AND FINANCIAL**
 19 **REGULATION, DEPARTMENT OF**
 20 **DEPARTMENT TOTALS**

21		2021-22	2022-23
22	OTHER SPECIAL REVENUE FUNDS	\$43,839	\$55,675
23			
24	DEPARTMENT TOTAL - ALL FUNDS	\$43,839	\$55,675

25 '
 26 Amend the bill by relettering or renumbering any nonconsecutive Part letter or section
 27 number to read consecutively.

28 **SUMMARY**

29 This amendment is the minority report of the committee. The amendment removes the
 30 provisions of the bill relating to requirements for health insurance coverage of HIV
 31 prevention drugs. The amendment makes changes to the bill's provisions authorizing a
 32 pharmacist to dispense HIV prevention drugs under certain conditions pursuant to a
 33 standing order or to protocols developed by the Maine Board of Pharmacy by authorizing
 34 a pharmacist to prescribe, dispense and administer HIV prevention drugs pursuant to a
 35 standing order or collaborative practice agreement or when there is no prescription drug
 36 order from a health care provider, subject to rules and protocols adopted by the board. The
 37 amendment also adds an appropriations and allocations section.

38 **FISCAL NOTE REQUIRED**
 39 **(See attached)**