1 LD 1115 2 (Filing No. S-Date:) HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES 3 4 Reproduced and distributed under the direction of the Secretary of the Senate. 5 STATE OF MAINE 6 **SENATE** 7 130TH LEGISLATURE 8 FIRST SPECIAL SESSION 9 COMMITTEE AMENDMENT " " to S.P. 378, L.D. 1115, "An Act To Improve 10 Access to HIV Prevention Medications" 11 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 12 13 1, paragraph B" 14 Amend the bill by striking out all of section 4. 15 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 16 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 drugs and commercially packaged legend drugs and devices; the participation in drug 21 22 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 23 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 Committee on Immunization Practices, or successor organization, for administration to 26 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 products approved by the United States Food and Drug Administration; the prescribing, 30 31 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 32 33 or to protocols developed by the board; and the offering or performing of those acts, 34 services, operations or transactions necessary in the conduct, operation, management and

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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: "<u>Dispensing</u>" and inserting the following: '<u>Prescribing</u>, <u>dispensing</u> 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;

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1 2 3	(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
4 5 6 7 8	(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.
9 10	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:
11 12 13	(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;
14 15 16 17	(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;
19 20 21 22	(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
23 24 25 26 27	(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.'
28 29	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:
30 31 32 33 34 35	'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.'
36	Amend the bill by striking out all of sections 7 and 8 and inserting the following:
37 38	'Sec. 7. Appropriations and allocations. The following appropriations and allocations are made.
39	PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF
40	Administrative Services - Professional and Financial Regulation 0094
41 42	Initiative: Allocates funds for technology-related costs associated with establishing one half-time Regulatory Health Compliance position to manage the anticipated increase in

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3	prevention drugs.		spense HIV
5	OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
4	All Other	\$2,729	\$3,347
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6	OTHER SPECIAL REVENUE FUNDS TOTAL	\$2,729	\$3,347
7	Licensing and Enforcement 0352		
8 9 10	Initiative: Allocates funds for one half-time Regulatory Homanage the anticipated increase in workload associated with 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
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16	OTHER SPECIAL REVENUE FUNDS TOTAL	\$41,110	\$52,328
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18 19	PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF		
20	DEPARTMENT TOTALS	2021-22	2022-23
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22	OTHER SPECIAL REVENUE FUNDS	\$43,839	\$55,675
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22	OTHER SPECIAL REVENUE FUNDS DEPARTMENT TOTAL - ALL FUNDS	\$43,839	\$55,675 \$55,675
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22 23 24 25 26 27	DEPARTMENT TOTAL - ALL FUNDS Amend the bill by relettering or renumbering any nonconnumber to read consecutively.	\$43,839	\$55,675 er or section
22 23 24 25 26 27 28 29 30	DEPARTMENT TOTAL - ALL FUNDS Amend the bill by relettering or renumbering any nonconnumber to read consecutively. SUMMARY	\$43,839 Insecutive Part letters The amendment	\$55,675 er or section
22 23 24 25 26 27 28 29 30 31	DEPARTMENT TOTAL - ALL FUNDS Amend the bill by relettering or renumbering any nonconnumber to read consecutively. SUMMARY This amendment is the minority report of the committee provisions of the bill relating to requirements for health prevention drugs. The amendment makes changes to the bill relating to the second results of the bill relating to requirements.	\$43,839 Insecutive Part letter The amendment insurance cover poill's provisions a	\$55,675 er or section removes the age of HIV uthorizing a
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COMMITTEE AMENDMENT