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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 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.'

**COMMITTEE AMENDMENT**

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

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

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

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

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

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

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

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

39 A. Before furnishing an HIV prevention drug to a patient, a pharmacist shall complete  
40 a training program approved by the board on the use of protocols developed by the  
41 board for prescribing, dispensing and administering an HIV prevention drug, on the  
42 requirements for any laboratory testing for HIV infection and on guidelines for  
43 prescription adherence and best practices to counsel patients prescribed an HIV  
44 prevention drug.

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

4                   (1) The patient tests negative for HIV infection, as documented by a negative HIV  
5                   test result obtained within the previous 7 days. If the patient does not provide  
6                   evidence of a negative HIV test result in accordance with this subparagraph, the  
7                   pharmacist shall order an HIV test. If the test results are not transmitted directly  
8                   to the pharmacist, the pharmacist shall verify the test results to the pharmacist's  
9                   satisfaction. If the patient tests positive for HIV infection, the pharmacist or person  
10                  administering the test shall direct the patient to a primary care provider and provide  
11                  a list of primary care providers and clinics within a reasonable travel distance of  
12                  the patient's residence;

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

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

16                  (4) The pharmacist provides counseling to the patient, consistent with CDC  
17                  guidelines, on the ongoing use of a preexposure prophylaxis drug. The pharmacist  
18                  shall notify the patient that the patient must be seen by a primary care provider to  
19                  receive subsequent prescriptions for a preexposure prophylaxis drug and that a  
20                  pharmacist may not dispense or administer more than a 60-day supply of a  
21                  preexposure prophylaxis drug to a single patient once every 2 years without a  
22                  prescription;

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

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

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

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

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

40                   (2) The pharmacist provides HIV testing to the patient or determines that the  
41                   patient is willing to undergo HIV testing consistent with CDC guidelines. If the  
42                   patient refuses to undergo HIV testing but is otherwise eligible for a post-exposure  
43                   prophylaxis drug under this subsection, the pharmacist may dispense or administer  
44                   a post-exposure prophylaxis drug;

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

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

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

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

18           Amend the bill by inserting after section 8 the following:

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

21           **PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF**

22           **Administrative Services - Professional and Financial Regulation 0094**

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

27 <b>OTHER SPECIAL REVENUE FUNDS</b>	<b>2021-22</b>	<b>2022-23</b>
28           All Other	\$2,729	\$3,347
29		
30           OTHER SPECIAL REVENUE FUNDS TOTAL	\$2,729	\$3,347

31           **Licensing and Enforcement 0352**

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

35 <b>OTHER SPECIAL REVENUE FUNDS</b>	<b>2021-22</b>	<b>2022-23</b>
36           POSITIONS - LEGISLATIVE COUNT	0.500	0.500
37           Personal Services	\$35,328	\$49,424
38           All Other	\$5,782	\$2,904
39		
40           OTHER SPECIAL REVENUE FUNDS TOTAL	\$41,110	\$52,328

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1	<b>PROFESSIONAL AND FINANCIAL</b>		
2	<b>REGULATION, DEPARTMENT OF</b>		
3	<b>DEPARTMENT TOTALS</b>	<b>2021-22</b>	<b>2022-23</b>
4			
5	<b>OTHER SPECIAL REVENUE FUNDS</b>	<b>\$43,839</b>	<b>\$55,675</b>
6			
7	<b>DEPARTMENT TOTAL - ALL FUNDS</b>	<b>\$43,839</b>	<b>\$55,675</b>

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

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### SUMMARY

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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.

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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.

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### FISCAL NOTE REQUIRED

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(See attached)