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Date: (Filing No. S- )

**INSURANCE AND FINANCIAL SERVICES**

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**STATE OF MAINE  
SENATE  
128TH LEGISLATURE  
FIRST REGULAR SESSION**

COMMITTEE AMENDMENT “ ” to S.P. 485, L.D. 1407, Bill, “An Act Regarding Prescription Drug Step Therapy”

Amend the bill in section 1 in §4320-K in subsection 1 in paragraph A in the 2nd line (page 1, line 7 in L.D.) by striking out the following: "patient" and inserting the following: 'enrollee'

Amend the bill in section 1 in §4320-K in subsection 1 in paragraph B in the 2nd line (page 1, line 10 in L.D.) by striking out the following: "an insurer, health plan" and inserting the following: 'a carrier'

Amend the bill in section 1 in §4320-K in subsection 1 in paragraph D in the 2nd line (page 1, line 19 in L.D.) by striking out the following: "a patient's" and inserting the following: 'an enrollee's'

Amend the bill in section 1 in §4320-K in subsection 1 by striking out all of paragraph E (page 1, lines 22 to 25 in L.D.) and inserting the following:

'E. "Step therapy protocol" means a protocol that establishes a specific sequence in which prescription drugs for a specified medical condition are medically necessary for a particular enrollee and are covered under a pharmacy or medical benefit by a carrier, including self-administered and physician-administered drugs.'

Amend the bill in section 1 in §4320-K in subsection 1 in paragraph F in the 2nd line (page 1, line 27 in L.D.) by striking out the following: "an insurer or health plan" and inserting the following: 'a carrier'

Amend the bill in section 1 in §4320-K in subsection 2 in paragraph B in subparagraph (1) in the 2nd line (page 1, line 36 in L.D.) by striking out the following: "insurers, health plans" and inserting the following: 'carriers'

Amend the bill in section 1 in §4320-K in subsection 5 in the first line (page 2, line 19 in L.D.) by striking out the following: "insurers, health plans" and inserting the following: 'carriers'

**COMMITTEE AMENDMENT**

1 Amend the bill in section 1 in §4320-K by striking out all of subsection 6 (page 2,  
2 lines 22 to 38 and page 3, lines 1 to 28 in L.D.) and inserting the following:

3 '6. Exceptions process. When coverage of a prescription drug for the treatment of  
4 any medical condition is restricted for use by a carrier or utilization review organization  
5 through the use of a step therapy protocol, the enrollee and prescriber must have access to  
6 a clear, readily accessible and convenient process to request a step therapy override  
7 exception determination from that carrier or utilization review organization.

8 A. A carrier or utilization review organization may use its existing medical  
9 exceptions process to provide step therapy override exception determinations, and the  
10 process established must be easily accessible on the carrier's or utilization review  
11 organization's website.

12 B. A carrier or utilization review organization shall expeditiously grant a step  
13 therapy override exception determination if:

14 (1) The required prescription drug is contraindicated or will likely cause an  
15 adverse reaction in or physical or mental harm to the enrollee;

16 (2) The required prescription drug is expected to be ineffective based on the  
17 known clinical characteristics of the enrollee and the known characteristics of the  
18 prescription drug regimen;

19 (3) The enrollee has tried the required prescription drug while under the  
20 enrollee's current or previous health insurance or health plan, or another  
21 prescription drug in the same pharmacologic class or with the same mechanism  
22 of action, and the prescription drug was discontinued due to lack of efficacy or  
23 effectiveness, diminished effect or an adverse event;

24 (4) The required prescription drug is not in the best interest of the enrollee, based  
25 on medical necessity; or

26 (5) The enrollee is stable on a prescription drug selected by the enrollee's health  
27 care provider for the medical condition under consideration while on a current or  
28 previous health insurance or health plan.

29 C. Upon the granting of a step therapy override exception determination, the carrier  
30 or utilization review organization shall authorize coverage for the prescription drug  
31 prescribed by the prescriber.

32 D. A carrier or utilization review organization shall respond to a request for a step  
33 therapy override exception determination or an appeal of a determination in  
34 accordance with the requirements of section 4304 and Bureau of Insurance Rule  
35 Chapter 850, Health Plan Accountability. If a response by a carrier or utilization  
36 review organization is not received within the time required under this paragraph, the  
37 exception or appeal is granted.

38 E. An enrollee may appeal a step therapy override exception determination.

39 F. This section does not prevent:

