MAINE STATE LEGISLATURE

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1	L.D. 140
2	Date: $6/9/2017$ (Filing No. S-245)
3	INSURANCE AND FINANCIAL SERVICES
4	Reproduced and distributed under the direction of the Secretary of the Senate.
5	STATE OF MAINE
6	SENATE
7	128TH LEGISLATURE
8	FIRST REGULAR SESSION
9 10	COMMITTEE AMENDMENT "A" to S.P. 485, L.D. 1407, Bill, "An Ac Regarding Prescription Drug Step Therapy"
11 12 13	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'
13 14 15 16	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'
17 18 19	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'
20 21	Amend the bill in section 1 in §4320-K in subsection 1 by striking out all or paragraph E (page 1, lines 22 to 25 in L.D.) and inserting the following:
22 23 24 25	'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.'
26 27 28	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'
9 0 1	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'
2 3 4	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'

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COMMITTEE AMENDMENT "A" to S.P. 485, L.D. 1407

1 2	Amend the bill in section 1 in §4320-K by striking out all of subsection 6 (page 2 lines 22 to 38 and page 3, lines 1 to 28 in L.D.) and inserting the following:
3 4 5 6 7	'6. Exceptions process. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier or utilization review organization through the use of a step therapy protocol, the enrollee and prescriber must have access to a clear, readily accessible and convenient process to request a step therapy override exception determination from that carrier or utilization review organization.
8 9 10 11	A. A carrier or utilization review organization may use its existing medical exceptions process to provide step therapy override exception determinations, and the process established must be easily accessible on the carrier's or utilization review organization's website.
12 13	B. A carrier or utilization review organization shall expeditiously grant a step therapy override exception determination if:
14 15	(1) The required prescription drug is contraindicated or will likely cause an adverse reaction in or physical or mental harm to the enrollee;
16 17 18	(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics of the prescription drug regimen;
19 20 21 22 23	(3) The enrollee has tried the required prescription drug while under the enrollee's current or previous health insurance or health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event;
24 25	(4) The required prescription drug is not in the best interest of the enrollee, based on medical necessity; or
26 27 28	(5) The enrollee is stable on a prescription drug selected by the enrollee's health care provider for the medical condition under consideration while on a current or previous health insurance or health plan.
29 30 31	C. Upon the granting of a step therapy override exception determination, the carrier or utilization review organization shall authorize coverage for the prescription drug prescribed by the prescriber.
32 33 34 35 36 37	D. A carrier or utilization review organization shall respond to a request for a step therapy override exception determination or an appeal of a determination in accordance with the requirements of section 4304 and Bureau of Insurance Rule Chapter 850, Health Plan Accountability. If a response by a carrier or utilization review organization is not received within the time required under this paragraph, the exception or appeal is granted.
38	E. An enrollee may appeal a step therapy override exception determination.

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F. This section does not prevent:

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COMMITTEE AMENDMENT "A" to S.P. 485, L.D. 1407

1	(1) A carrier or utilization review organization from requiring an enrollee to try a
2	generic drug, as defined in Title 32, section 13702-A, subsection 14, prior to
3	providing coverage for the equivalent brand-name prescription drug; or
4	(2) A health care provider from prescribing a prescription drug that is
5	determined to be medically necessary.'
6	Amend the bill in section 1 in §4320-K in subsection 7 in the first line (page 3, line
7	29 in L.D.) by striking out the following: "shall" and inserting the following: 'may'
8	Amend the bill in section 2 in the 3rd line (page 3, line 34 in L.D.) by striking out the
9	following: "2018" and inserting the following: '2019'
10	SUMMARY
11	This amendment does the following.
12	1. It clarifies that carriers must apply the utilization review standards under current
13	law when acting on a request for a step therapy override exception determination or an
14	appeal of a determination.
15	2. It replaces certain terminology used in the bill to be consistent with current law.
16	3. It changes the applicability of the bill's provisions from January 1, 2018 to January
17	1, 2019.

FISCAL NOTE REQUIRED (See attached)

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128th MAINE LEGISLATURE

LD 1407

LR 1195(02)

An Act Regarding Prescription Drug Step Therapy

Fiscal Note for Bill as Amended by Committee Amendment "\(\)" (\$-245)

Committee: Insurance and Financial Services

Fiscal Note Required: Yes

Fiscal Note

Potential future biennium cost - All Funds

Fiscal Detail and Notes

The bill has an effective date of January 1, 2019, so only contracts executed after January 1, 2019 will be required to meet the coverage in this bill. Thus, the State Employee Health Plan (SEHP) will have no General Fund appropriations or Highway Fund allocations in the current biennium. Drug step therapy is the practice of beginning drug therapy for a medical condition with the most cost-effective and safest drug and progressing to other more costly or risky therapies only if necessary, with the goal of controlling costs and minimizing risks. This bill adds an exception process that must be clear, readily accessible and convenient to the patient and prescriber. This could lead to additional or longer lasting exceptions from the drug step therapy process, which could potentially increase costs in future bienniums for insurers, including the SEHP. However, there is not enough information available to identify a fiscal impact at this time.