



# 128th MAINE LEGISLATURE

## FIRST REGULAR SESSION-2017

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Legislative Document

No. 1407

S.P. 485

In Senate, April 11, 2017

### An Act Regarding Prescription Drug Step Therapy

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Reference to the Committee on Insurance and Financial Services suggested and ordered printed.

A handwritten signature in cursive script, reading 'Heather J.R. Priest'.

HEATHER J.R. PRIEST  
Secretary of the Senate

Presented by Senator ROSEN of Hancock.  
Cosponsored by Representative PIERCE of Dresden and  
Senators: CARSON of Cumberland, DOW of Lincoln, GRATWICK of Penobscot,  
Representatives: HARLOW of Portland, MALABY of Hancock, POULIOT of Augusta,  
SANBORN of Portland, VACHON of Scarborough.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 24-A MRSA §4320-K** is enacted to read:

3 **§4320-K. Step therapy**

4 **1. Definitions.** As used in this section, unless the context otherwise indicates, the  
5 following terms have the following meanings.

6 A. "Clinical practice guidelines" means a systematically developed statement to  
7 assist prescriber and patient decisions about appropriate health care for specific  
8 clinical circumstances and conditions.

9 B. "Clinical review criteria" means the written screening procedures, decision  
10 abstracts, clinical protocols and practice guidelines used by an insurer, health plan or  
11 utilization review organization to determine the medical necessity and  
12 appropriateness of health care services.

13 C. "Medically necessary" means health services and supplies that, under the  
14 applicable standard of care, are appropriate to improve or preserve health, life or  
15 function; to slow the deterioration of health, life or function; or for the early  
16 screening, prevention, evaluation, diagnosis or treatment of a disease, condition,  
17 illness or injury.

18 D. "Step therapy override exception determination" means a determination based on  
19 a review of a patient's or prescriber's request for an override, along with supporting  
20 rationale and documentation, that the step therapy protocol should be overridden in  
21 favor of immediate coverage of the health care provider's selected prescription drug.

22 E. "Step therapy protocol" means a protocol that establishes a specific sequence in  
23 which prescription drugs for a specified medical condition are medically necessary  
24 for a particular patient and are covered under a pharmacy or medical benefit by an  
25 insurer or health plan, including self-administered and physician-administered drugs.

26 F. "Utilization review organization" means an entity that conducts a utilization  
27 review, other than an insurer or health plan performing a utilization review for its  
28 own health benefit plans.

29 **2. Clinical review criteria.** Clinical review criteria used to establish a step therapy  
30 protocol must be based on clinical practice guidelines that:

31 A. Recommend that the prescription drugs be taken in the specific sequence required  
32 by the step therapy protocol;

33 B. Are developed and endorsed by a multidisciplinary panel of experts that manages  
34 conflicts of interest among the members of the writing and review groups by:

35 (1) Requiring members to disclose any potential conflicts of interest with  
36 entities, including insurers, health plans and pharmaceutical manufacturers, and  
37 recuse themselves from voting if they have a conflict of interest;

1                   (2) Using a methodologist to work with writing groups to provide objectivity in  
2                   data analysis and ranking of evidence through the preparation of evidence tables  
3                   and facilitating consensus; and

4                   (3) Offering opportunities for public review and comments;

5                   C. Are based on high-quality studies, research and medical practice;

6                   D. Are created by an explicit and transparent process that:

7                   (1) Minimizes biases and conflicts of interest;

8                   (2) Explains the relationship between treatment options and outcomes;

9                   (3) Rates the quality of the evidence supporting recommendations; and

10                  (4) Considers relevant patient subgroups and preferences; and

11                  E. Are continually updated through a review of new evidence, research and newly  
12                  developed treatments.

13                  **3. Absence of clinical practice guidelines.** In the absence of clinical practice  
14                  guidelines that meet the requirements in subsection 2, peer-reviewed publications may be  
15                  substituted.

16                  **4. Consideration of atypical populations and diagnoses.** When establishing a step  
17                  therapy protocol, a utilization review organization shall also take into account the needs  
18                  of atypical patient populations and diagnoses when establishing clinical review criteria.

19                  **5. Construction.** This section may not be construed to require insurers, health plans  
20                  or the State to set up a new entity to develop clinical review criteria used for step therapy  
21                  protocols.

22                  **6. Exceptions process.** When coverage of a prescription drug for the treatment of  
23                  any medical condition is restricted for use by an insurer, health plan or utilization review  
24                  organization through the use of a step therapy protocol, the patient and prescriber must  
25                  have access to a clear, readily accessible and convenient process to request a step therapy  
26                  override exception determination from that insurer, health plan or utilization review  
27                  organization.

28                  A. An insurer, health plan or utilization review organization may use its existing  
29                  medical exceptions process to provide step therapy override exception  
30                  determinations, and the process established must be easily accessible on the insurer's,  
31                  health plan's or utilization review organization's website.

32                  B. An insurer, health plan or utilization review organization shall expeditiously grant  
33                  a step therapy override exception determination if:

34                  (1) The required prescription drug is contraindicated or will likely cause an  
35                  adverse reaction in or physical or mental harm to the patient;

36                  (2) The required prescription drug is expected to be ineffective based on the  
37                  known clinical characteristics of the patient and the known characteristics of the  
38                  prescription drug regimen;

