

# MAINE STATE LEGISLATURE

The following document is provided by the  
**LAW AND LEGISLATIVE DIGITAL LIBRARY**  
at the Maine State Law and Legislative Reference Library  
<http://legislature.maine.gov/lawlib>



Reproduced from electronic originals  
(may include minor formatting differences from printed original)



# 129th MAINE LEGISLATURE

## FIRST REGULAR SESSION-2019

---

Legislative Document

No. 1009

---

H.P. 751

House of Representatives, February 26, 2019

### **An Act To Provide Protections for Maine Patients Facing Step Therapy**

---

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

A handwritten signature in cursive script that reads "Robert B. Hunt".

ROBERT B. HUNT  
Clerk

Presented by Representative WARREN of Hallowell.  
Cosponsored by Senator SANBORN, H. of Cumberland and  
Representatives: GRAMLICH of Old Orchard Beach, PIERCE of Falmouth, PRESCOTT of  
Waterboro, TEPLER of Topsham, Senators: FOLEY of York, ROSEN of Hancock,  
SANBORN, L. of Cumberland, VITELLI of Sagadahoc.

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

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

3 **§4320-L. 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 enrollee 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 a carrier or utilization  
11 review organization to determine the medical necessity and appropriateness of health  
12 care services.

13 C. "Medically necessary," with respect to health services and supplies, means  
14 appropriate, under the applicable standard of care, to improve or preserve health, life  
15 or 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. "Pharmaceutical sample" means a unit of a prescription drug that is not intended  
19 to be sold and is intended to promote the sale of the drug.

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

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

28 G. "Utilization review organization" means an entity that conducts a utilization  
29 review, other than a carrier performing a utilization review for its own health benefit  
30 plans.

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

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

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

37 (1) Requiring members to disclose any potential conflicts of interest with  
38 entities, including carriers and pharmaceutical manufacturers, and recuse  
39 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 carriers or the State  
20                  to set up a new entity to develop clinical review criteria used for step therapy protocols.

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

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

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

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

34                  (2) The required prescription drug is expected to be ineffective based on the  
35                  known clinical characteristics of the enrollee and the known characteristics of the  
36                  prescription drug regimen;

37                  (3) The enrollee has tried the required prescription drug while under the  
38                  enrollee's current or previous health insurance or health plan, or another

1 prescription drug in the same pharmacologic class or with the same mechanism  
2 of action, and the prescription drug was discontinued due to lack of efficacy or  
3 effectiveness, diminished effect or an adverse reaction;

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

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

9 Nothing in this paragraph may be construed to encourage the use of a pharmaceutical  
10 sample for the sole purpose of meeting the requirements for the granting of a step  
11 therapy override exception determination.

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

15 D. A carrier or utilization review organization shall grant or deny a request for a step  
16 therapy override exception determination or an appeal of a determination within 48  
17 hours after receipt of the request. If exigent circumstances exist, a carrier or  
18 utilization review organization shall grant or deny the request within 24 hours after  
19 receipt of the request. If a carrier or utilization review organization does not grant or  
20 deny the request within the time required under this paragraph, the exception or  
21 appeal is granted.

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

23 F. This section does not prevent:

24 (1) A carrier or utilization review organization from requiring an enrollee to try a  
25 generic drug, as defined in Title 32, section 13702-A, subsection 14, prior to  
26 providing coverage for the equivalent brand-name prescription drug; or

27 (2) A health care provider from prescribing a prescription drug that is  
28 determined to be medically necessary.

29 7. Rules. The superintendent may adopt rules to implement this section. The  
30 superintendent shall adopt a rule defining the circumstances under which a carrier or  
31 utilization review organization is required to grant or deny a request within 24 hours  
32 pursuant to subsection 6, paragraph D. Rules adopted pursuant to this subsection are  
33 routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

34 **Sec. 2. Application.** The requirements of this Act apply to all policies, contracts  
35 and certificates executed, delivered, issued for delivery, continued or renewed in this  
36 State on or after January 1, 2020. For purposes of this Act, all contracts are deemed to be  
37 renewed no later than the next yearly anniversary of the contract date.

## 38 SUMMARY

39 This bill requires health insurance carriers to establish a process for prescription drug  
40 step therapy exceptions.