

**2019 Senate Bill 26 (LRB -1748)**

An Act to create 632.866 of the statutes; relating to: step therapy protocols for prescription drug coverage and requiring the exercise of rule-making authority.

**2019**

02-08.	S.	Introduced by Senators <b>Darling, Jacque, Roth, Johnson, Feyen, Marklein, Nass, Olsen, Ringhand, Wanggaard, Testin, Cowles, LeMahieu, Carpenter and Wirch</b> ; cosponsored by Representatives <b>Nygren, Oldenburg, Schraa, Kolste, Subeck, Rodriguez, Ballweg, Dittrich, Petersen, Horlacher, Vorpapel, Mursau, Kuglitsch, Spiros, Edming, Gundrum, Felzkowski, Kulp, Skowronski, Thiesfeldt, Brooks, Ramthun, Tittl, Swearingen, Novak, Jagler, VanderMeer, Zimmerman, Krug, Quinn, Rohrkaste, Duchow, Magnafici, Born, Kurtz, Brandtjen, Plumer, Summerfield, Loudenbeck, Ott and Knodl.</b> ....	59
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03-27.	S.	Representative Ohnstad added as a cosponsor .....	127
04-17.	S.	Public hearing held	
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05-07.	S.	Executive action taken	
05-07.	S.	Report adoption of Senate Substitute Amendment 1 recommended by Committee on Health and Human Services, Ayes 5, Noes 0 .....	179
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06-05.	S.	Read a third time and <b>passed</b> .....	233
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06-13.	A.	Placed on calendar 6-18-2019 by Committee on Rules	
06-18.	A.	Rules suspended to withdraw from calendar and take up	
06-18.	A.	Read a second time	
06-18.	A.	Ordered to a third reading	
06-18.	A.	Rules suspended	
06-18.	A.	Read a third time and <b>concurred in</b>	
06-18.	A.	Ordered immediately messaged	
06-18.	S.	Received from Assembly concurred in	

*MB*



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**ENROLLED BILL**

**Adopted Documents**

Original

Engrossed

Substitute Amdt

19 5001e, 1

Amendments:  None or  Listed below.

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Corrections:  None or  Listed by date below.

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Topic:  Same as relating clause or  Indicated below.

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*4/19/19*

*Case*

Date

Enrolling Drafter



State of Wisconsin  
2019 - 2020 LEGISLATURE

LRBs0016/1  
TJD:ah&kjf

SENATE SUBSTITUTE AMENDMENT 1,  
TO SENATE BILL 26

March 26, 2019 - Offered by Senator DARLING.

1     **AN ACT to create** 632.866 of the statutes; **relating to:** step therapy protocols for  
2           prescription drug coverage and requiring the exercise of rule-making  
3           authority.

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***Analysis by the Legislative Reference Bureau***

This bill sets specifications on the development and use of and exceptions to step therapy protocols for prescription drug coverage. A step therapy protocol, as defined in the bill, is a protocol that establishes the specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient are covered by a policy or plan. When establishing a step therapy protocol, an insurer, pharmacy benefit manager, or utilization review organization must use clinical review criteria based on clinical practice guidelines that meet certain criteria specified in the bill.

If an insurer, pharmacy benefit manager, or utilization review organization restricts the coverage of a prescription drug through a step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must provide access to a process to request an exception to the step therapy protocol, though an existing medical exceptions process may be used to satisfy this requirement. The insurer, pharmacy benefit manager, or utilization review organization must grant an exception to the step therapy protocol if the prescribing provider submits complete, clinically relevant written documentation supporting the request and any of the

circumstances specified in the bill apply, including when the drug is contraindicated for the patient or will likely cause a serious adverse event for the patient; the drug is expected to be ineffective based on certain evidence and the known characteristics of the patient and the drug regimen; the patient previously tried the drug or a similar drug and its use by the patient was discontinued under circumstances described in the bill; or the patient is stable on a different drug under this or a previous policy or plan. Upon granting an exception to the step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the drug prescribed by the patient's treating health care provider to the extent the drug is covered under the patient's policy or plan. An insured may appeal a denied request for an exception to the step therapy protocol. An insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception within three business days, or by the end of the next business day in exigent circumstances, of receipt of supporting documentation. If this deadline is not met, the exception is considered granted.

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*The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:*

- 1           **SECTION 1.** 632.866 of the statutes is created to read:
- 2           **632.866 Step therapy protocols. (1) DEFINITIONS.** In this section:
- 3           (a) "Clinical practice guideline" means a systematically developed statement
- 4           to assist decision making by health care providers and patients about appropriate
- 5           health care for specific clinical circumstances and conditions.
- 6           (b) "Clinical review criteria" means written screening procedures, decision
- 7           abstracts, clinical protocols, and clinical practice guidelines used by an insurer,
- 8           pharmacy benefit manager, or utilization review organization to determine whether
- 9           health care services are medically necessary and appropriate.
- 10          (c) "Exigent circumstances" means when a patient is suffering from a health
- 11          condition that may seriously jeopardize the patient's life, health, or ability to regain
- 12          maximum function.
- 13          (d) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

1 (e) “Step therapy protocol” means a protocol or program that establishes the  
2 specific sequence in which prescription drugs for a specified medical condition,  
3 whether self-administered or physician-administered, that are medically  
4 appropriate for a particular patient are covered under a policy or plan.

5 (f) “Utilization review organization” means an entity that conducts utilization  
6 review, other than an insurer or pharmacy benefit manager performing utilization  
7 review for its own policy or plan.

8 **(2) CLINICAL REVIEW CRITERIA.** (a) When establishing a step therapy protocol,  
9 an insurer, pharmacy benefit manager, or utilization review organization shall use  
10 clinical review criteria that are based on clinical practice guidelines that are derived  
11 from peer-review publications, evidence-based research, and widely accepted  
12 medical practice. If such clinical practice guidelines are unavailable, the insurer,  
13 pharmacy benefit manager, or utilization review organization shall derive clinical  
14 review criteria from peer-reviewed publications, evidence-based research, and  
15 widely accepted medical practice. The insurer, pharmacy benefit manager, or  
16 utilization review organization shall continually update the clinical review criteria  
17 based on an update to the clinical practice guidelines or a review of new evidence and  
18 research and newly developed treatments.

19 (b) Any individual involved in establishing a step therapy protocol under this  
20 subsection shall disclose to the insurer, pharmacy benefit manager, or utilization  
21 review organization any potential conflict of interest due to a financial or other  
22 relationship or payment from a pharmaceutical manufacturer and shall recuse  
23 himself or herself from voting on a decision regarding the step therapy protocol if he  
24 or she has a conflict of interest.

1 (c) An insurer, pharmacy benefit manager, or utilization review organization  
2 shall describe on its Internet site the process and criteria used for selecting and  
3 evaluating clinical practice guidelines used under par. (a) to develop step therapy  
4 protocols.

5 (d) Nothing in this subsection shall be construed to require insurers, pharmacy  
6 benefit managers, or the state to create a new entity to develop clinical review  
7 criteria used for step therapy protocols.

8 **(3) TRANSPARENCY OF EXCEPTIONS PROCESS.** (a) When coverage of a prescription  
9 drug for the treatment of any medical condition is restricted for use by an insurer,  
10 pharmacy benefit manager, or utilization review organization through the use of a  
11 step therapy protocol, the insurer, pharmacy benefit manager, or utilization review  
12 organization shall provide access to a clear, readily accessible and convenient process  
13 to request an exception to the step therapy protocol. An insurer, pharmacy benefit  
14 manager, or utilization review organization may use any existing medical exceptions  
15 process to satisfy the requirement under this paragraph. The exception process shall  
16 be made easily accessible on the Internet site of the insurer, pharmacy benefit  
17 manager, or utilization review organization.

18 (b) An insurer, pharmacy benefit manager, or utilization review organization  
19 shall grant an exception to the step therapy protocol if the prescribing provider  
20 submits complete, clinically relevant written documentation supporting a step  
21 therapy exception request and any of the following are satisfied:

22 1. The prescription drug required under the step therapy protocol is  
23 contraindicated or, due to a documented adverse event with a previous use or a  
24 documented medical condition, including a comorbid condition, is likely to do any of  
25 the following:

- 1           a. Cause a serious adverse reaction in the patient.
- 2           b. Decrease the ability to achieve or maintain reasonable functional ability in  
3 performing daily activities.
- 4           c. Cause physical or psychiatric harm to the patient.
- 5           2. The prescription drug required under the step therapy protocol is expected  
6 to be ineffective based on all of the following:
  - 7           a. Sound clinical evidence or medical and scientific evidence.
  - 8           b. The known clinical characteristics of the patient.
  - 9           c. The known characteristics of the prescription drug regimen as described in  
10 peer-reviewed literature or the manufacturer's prescribing information for the  
11 prescription drug.
- 12           3. The patient has tried the prescription drug required under the step therapy  
13 protocol, or another prescription drug in the same pharmacologic class or with the  
14 same mechanism of action, under the policy or plan or a previous policy or plan, the  
15 patient was adherent to the prescription drug regimen for a time that allows for a  
16 positive treatment outcome, and the patient's use of the prescription drug was  
17 discontinued by the patient's provider due to lack of efficacy or effectiveness,  
18 diminished effect, or adverse event. This subdivision does not prohibit an insurer,  
19 pharmacy benefit manager, or utilization review organization from requiring a  
20 patient to try another drug in the same pharmacologic class or with the same  
21 mechanism of action if that therapy sequence is supported by clinical review criteria  
22 under sub. (2) (a).
- 23           4. The patient is stable on a prescription drug selected by his or her health care  
24 provider for the medical condition under consideration while covered under the  
25 policy or plan or a previous policy or plan.

1 (c) Nothing in this subsection shall be construed to allow the use of a  
2 pharmaceutical sample to satisfy a criterion for an exception to a step therapy  
3 protocol.

4 (d) Upon granting an exception to the step therapy protocol under par. (b), the  
5 insurer, pharmacy benefit manager, or utilization review organization shall  
6 authorize coverage for the prescription drug prescribed by the patient's treating  
7 health care provider to the extent the prescribed drug is covered under the patient's  
8 policy or plan.

9 (e) An insured may appeal any request for an exception to the step therapy  
10 protocol that is denied.

11 (f) An insurer, pharmacy benefit manager, or utilization review organization  
12 shall grant or deny a request for any exception to the step therapy protocol within  
13 3 business days of receipt of the complete, clinically relevant written documentation  
14 required under par. (b) to support a step therapy exception request under par. (b) or  
15 the receipt of a request to appeal a previous decision that includes the complete,  
16 clinically relevant written documentation supporting a step therapy exception  
17 request. In exigent circumstances, an insurer, pharmacy benefit manager, or  
18 utilization review organization shall grant or deny a request for an exception to the  
19 step therapy protocol by the end of the next business day after receipt of the complete,  
20 clinically relevant written documentation supporting a step therapy exception  
21 request under par. (b). If the insurer, pharmacy benefit manager, or utilization  
22 review organization does not grant or deny a request or an appeal under the time  
23 specified under this paragraph, the exception is considered granted.

24 (g) Nothing in this subsection shall be construed to prevent any of the following:



