State of Wisconsin
2019 - 2020 LEGISLATURE

LRBs0016/1
CMH:cjs

SENATE SUBSTITUTE AMENDMENT 1,

TO SENATE BILL 26

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.

Analysis by the Legislative Reference Bureau

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

SECTION 1. 632.866 of the statutes is created to read:

632.866 Step therapy protocols. (1) DEFINITIONS. In this section:

(a) "Clinical practice guideline" means a systematically developed statement to assist decision making by health care providers and patients about appropriate health care for specific clinical circumstances and conditions.

(b) "Clinical review criteria" means written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by an insurer,

pharmacy benefit manager, or utilization review organization to determine whether health care services are medically necessary and appropriate.

(c) "Exigent circumstances" means when a patient is suffering from a health condition that may seriously jeopardize the patient's life, health, or ability to regain maximum function.

(d) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

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

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

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

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

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

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

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

(b) An insurer, pharmacy benefit manager, or utilization review organization shall grant an exception to the step therapy protocol if the prescribing provider

submits complete, clinically relevant written documentation supporting a step therapy exception request and any of the following are satisfied:

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

a. Cause a serious adverse reaction in the patient.

b. Decrease the ability to achieve or maintain reasonable functional ability in performing daily activities.

c. Cause physical or psychiatric harm to the patient.

2. The prescription drug required under the step therapy protocol is expected to be ineffective based on all of the following:

a. Sound clinical evidence or medical and scientific evidence.

b. The known clinical characteristics of the patient.

c. The known characteristics of the prescription drug regimen as described in peer–reviewed literature or the manufacturer's prescribing information for the prescription drug.

3. The patient has tried the prescription drug required under the step therapy protocol, or another prescription drug in the same pharmacologic class or with the same mechanism of action, under the policy or plan or a previous policy or plan, the patient was adherent to the prescription drug regimen for a time that allows for a positive treatment outcome, and the patient's use of the prescription drug was discontinued by the patient's provider due to lack of efficacy or effectiveness, diminished effect, or adverse event. This subdivision does not prohibit an insurer, pharmacy benefit manager, or utilization review organization from requiring a

patient to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by clinical review criteria under sub. (2) (a).

4. The patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while covered under the policy or plan or a previous policy or plan.

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

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

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

(f) An insurer, pharmacy benefit manager, or utilization review organization shall grant or deny a request for any exception to the step therapy protocol within 3 business days of receipt of the complete, clinically relevant written documentation required under par. (b) to support a step therapy exception request under par. (b) or the receipt of a request to appeal a previous decision that includes the complete, clinically relevant written documentation supporting a step therapy exception request. In exigent circumstances, an insurer, pharmacy benefit manager, or utilization review organization shall grant or deny a request for an exception to the step therapy protocol by the end of the next business day after receipt of the complete,

clinically relevant written documentation supporting a step therapy exception request under par. (b). If the insurer, pharmacy benefit manager, or utilization review organization does not grant or deny a request or an appeal under the time specified under this paragraph, the exception is considered granted.

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

1. An insurer, pharmacy benefit manager, or utilization review organization from requiring a patient to try an A–rated generic equivalent prescription drug, as designated by the federal food and drug administration, or a biosimilar, as defined under 42 USC 262 (i) (2), before providing coverage for the equivalent brand name prescription drug.

2. A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

(4) RULES. The commissioner shall promulgate any rules necessary to implement or enforce this section.

SECTION 2. Initial applicability.

(1) For policies and plans containing provisions inconsistent with this act, the act first applies to policy or plan years beginning on January 1 of the year following the year in which this subsection takes effect.

SECTION 3. Effective date.

(1) This act takes effect on the first day of the 4th month beginning after publication.

(END)