



**WISCONSIN LEGISLATIVE COUNCIL
AMENDMENT MEMO**

2019 Senate Bill 26	Senate Substitute Amendment 1
<i>Memo published: May 8, 2019</i>	<i>Contact: Steve McCarthy, Staff Attorney</i>

2019 SENATE BILL 26

Both Senate Bill 26 and Senate Substitute Amendment 1 set specifications on the development and use of, and exceptions to, step therapy protocols for prescription drug coverage. “Step therapy protocol” is defined under both the bill and the substitute amendment as 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.

As described below in more detail, the bill and the substitute amendment differ in how each: (1) sets clinical review criteria that apply to an insurer, pharmacy benefit manager, or utilization review organization that establishes a step therapy protocol; (2) mandates an exception process to a step therapy protocol; and (3) sets a time frame for an insurer, pharmacy benefit manager, or utilization review organization to make a decision on a step therapy exception request.

CLINICAL REVIEW CRITERIA

The Bill

The bill provides that, when establishing a step therapy protocol, an insurer, pharmacy benefit manager, or utilization review organization must use clinical review criteria¹ based on clinical practice guidelines² that meet all of the following criteria:

- The guidelines recommend that the prescription drugs be taken in the specific sequences required by the step therapy protocol.
- The guidelines are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among its members as specified by the bill or, in the absence of a multidisciplinary panel, the guidelines are based on peer reviewed publications.
- The guidelines are based on evidence-based, high quality studies, research, and medical practices.
- The guidelines are created in an explicit and transparent process that minimizes biases and conflicts of interest, explains the relationship between treatment options and outcomes, rates the quality of the evidence supporting recommendations, and considers relevant patient subgroups and preferences.
- The guidelines are continually updated through a review of new evidence and research and newly developed treatments.

The bill also requires the insurer, pharmacy benefit manager, or utilization review organization to consider the needs of atypical patient populations and diagnoses when establishing the clinical review criteria and clarifies that the bill does not require insurers, pharmacy benefit managers, or the state to create a new entity to develop clinical review criteria used for step therapy protocols.

The Substitute Amendment

The substitute amendment provides that, when establishing a step therapy protocol, an insurer, pharmacy benefit manager, or utilization review organization must 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

¹ Both the bill and the substitute amendment define “clinical review criteria” as written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by an insurer, pharmacy benefits manager, or utilization review organization to determine whether health care services are medically necessary and appropriate.

² Both the bill and the substitute amendment define a “clinical practice guideline” as a systemically developed statement to assist decision making by health care providers and patients about appropriate health care for specific clinical circumstances and conditions.

practice guidelines are unavailable, the insurer, pharmacy benefit manager, or utilization review organization must 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 is also required to 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.

The substitute amendment also provides that any individual involved in establishing a step therapy protocol must 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 must recuse himself or herself from voting on a decision regarding the step therapy protocol if he or she has a conflict of interest. Additionally, the substitute amendment requires an insurer, pharmacy benefit manager, or utilization review organization to describe on its Internet site the process and criteria used for selecting and evaluating clinical practice guidelines used to develop step therapy protocols.

The substitute amendment also contains the provisions of the bill that provide that no new entity need be created to develop clinical review criteria used for step therapy protocols.

STEP THERAPY EXCEPTIONS PROCESS

The Bill

The bill requires an insurer, pharmacy benefit manager, or utilization review organization to provide a clear, readily accessible and convenient process to request an exception to a step therapy protocol used when coverage of a prescription drug is restricted by the insurer, pharmacy benefit manager, or utilization review organization. An insurer, pharmacy benefit manager, or utilization review organization may use any existing medical exceptions process to satisfy this requirement, and the exception process must be made easily accessible on the entity's Internet site.

The bill also requires an insurer, pharmacy benefit manager, or utilization review organization to expeditiously grant an exception to a step therapy protocol if any of the following criteria are satisfied:

- The prescription drug required under the step therapy protocol is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient.
- The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen.
- 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 and the

patient's use of the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

- Based on an evaluation of medically necessary drugs for the patient's condition, the prescription drug required under the step therapy protocol is not in the best interest of the patient.
- 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.

The bill provides that an insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the prescription drug prescribed by the patient's treating health care provider upon granting an exception to a step therapy protocol and that an insured may appeal any request for an exception to the step therapy protocol that is denied.

The bill also clarifies that its provisions must not be construed to prevent either an insurer, pharmacy benefit manager, or utilization review organization from requiring a patient to try certain generic equivalent prescription drugs before providing coverage for the equivalent brand name drug, or a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

The Substitute Amendment

The substitute amendment contains the same provisions in the bill that require a clear, readily accessible and convenient step therapy protocol exception process, including use of any existing medical exceptions process to satisfy this requirement, and that the exception process must be made easily accessible on the Internet site of the insurer, pharmacy benefit manager, or utilization review organization.

However, the substitute amendment differs from the bill in its criteria under which an insurer, pharmacy benefit manager, or utilization review organization must grant an exception to a step therapy protocol. Specifically, the substitute amendment requires an insurer, pharmacy benefit manager, or utilization review organization to grant an exception to a 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:

- 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 cause a serious adverse reaction in the patient, decrease the ability to achieve or maintain reasonable functional ability in performing daily activities, or cause physical or psychiatric harm to the patient.
- The prescription drug required under the step therapy protocol is expected to be ineffective based on sound clinical evidence or medical and scientific evidence, the known clinical characteristics of the patient, and the known characteristics of the

prescription drug regimen as described in peer-reviewed literature or the manufacturer's prescribing information for the prescription drug.

- 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.³
- 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.

The substitute amendment contains the same provisions in the bill that require authorization of coverage for the prescription drug prescribed by the patient's treating health care provider upon the granting of a step therapy protocol exception and that an insured may appeal any request for an exception to the step therapy protocol that is denied. The substitute amendment also contains the provisions in the bill that allow for use of certain generic equivalent prescription drugs⁴ and clarify that a health care provider is not prevented from prescribing a prescription drug that is determined to be medically appropriate.

Additionally, the substitute amendment clarifies that its provisions do not allow the use of a pharmaceutical sample to satisfy a criterion for a step therapy protocol exception.

EXCEPTION REQUEST DECISION TIMING

The Bill

The bill provides that an insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for any exception to the step therapy protocol within 72 hours of receipt of the request or the request to appeal the previous decision. In exigent circumstances⁵, an insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception to the step therapy protocol within 24 hours of receipt

³ The substitute amendment provides that this specific criterion under which a step therapy protocol exception must be granted 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.

⁴ Note that the bill allows only for use of an "AB-rated" generic equivalent prescription drug before providing coverage for a brand name prescription drug, but the substitute amendment allows for use of an "A-rated" generic equivalent prescription drug or a biosimilar, as defined under federal law.

⁵ Both the bill and the substitute amendment define "exigent circumstances" as when a patient is suffering from a health condition that may seriously jeopardize the patient's life, health, or ability to regain maximum function.

of the request. If the insurer, pharmacy benefit manager, or utilization review organization does not grant or deny a request or an appeal under the time specified, the exception is considered granted.

The Substitute Amendment

The substitute amendment differs from the bill because it requires a decision within a certain number of business days, rather than a certain number of hours. Specifically, the substitute amendment provides that an insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for any exception to the step therapy protocol within three business days of receipt of the complete, clinically relevant written documentation required to support a step therapy exception request 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 must 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. If the insurer, pharmacy benefit manager, or utilization review organization does not grant or deny a request or an appeal under the time specified, the exception is considered granted.

OTHER PROVISIONS

Both the bill and the substitute amendment also require the commissioner of insurance to promulgate any rules necessary to implement or enforce step therapy protocol requirements, provide an effective date of the first day of the 4th month beginning after publication, and specify that the provisions of the bill or substitute amendment first applies to policies and plans inconsistent with the step therapy protocol requirements beginning on January 1st of the year following the year in which the provisions take effect.

BILL HISTORY

Senator Darling offered Senate Substitute Amendment 1 on March 26, 2019. On May 7, 2019, the Senate Committee on Health and Human Services recommended adoption of the amendment, and the bill as amended, on votes of Ayes, 5; Noes, 0.

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