House Study Bill 26 - Introduced

HOUSE FILE _____
BY (PROPOSED COMMITTEE ON HUMAN RESOURCES BILL BY CHAIRPERSON FRY)

A BILL FOR

An Act relating to the use of step therapy protocols for prescription drugs by health carriers, health benefit plans, and utilization review organizations, and including applicability provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. LEGISLATIVE FINDINGS. The general assembly finds and declares the following:

1. Health carriers, health benefit plans, and utilization review organizations are increasingly making use of step therapy protocols under which covered persons are required to try one or more prescription drugs before coverage is provided for another prescription drug selected by the covered person's health care professional.

2. Such step therapy protocols, where they are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of covered persons, can play an important part in controlling health care costs.

3. In some cases, requiring a covered person to follow a step therapy protocol may have adverse and even dangerous consequences for the covered person, who may either not realize a benefit from taking a particular prescription drug or may suffer harm from taking an inappropriate prescription drug.

4. Without uniform policies in the state for step therapy protocols, all covered persons may not receive equivalent or the most appropriate treatment.

5. It is imperative that step therapy protocols in the state preserve the health care professional's right to make treatment decisions that are in the best interest of the covered person.

6. It is a matter of public interest that the general assembly require health carriers, health benefit plans, and utilization review organizations to base step therapy protocols on appropriate clinical practice guidelines or published peer review data developed by independent experts with knowledge of the condition or conditions under consideration; that covered persons be excepted from step therapy protocols when inappropriate or otherwise not in the best interest of the covered persons; and that covered persons have access to a fair, transparent, and independent process for allowing a covered person or a health care professional to request an

exception to a step therapy protocol when the covered person's health care professional deems appropriate.

Sec. 2. NEW SECTION. **514F.7 Use of step therapy protocols.**

1. *Definitions.* For the purposes of this section:

a. "Authorized representative" means the same as defined in section 514J.102.

b. "Clinical practice guidelines" means a systematically developed statement to assist health care professionals and covered persons in making decisions about appropriate health care for specific clinical circumstances and conditions.

c. "Clinical review criteria" means the same as defined in section 514J.102.

d. "Commissioner" means the commissioner of insurance.

e. "Covered person" means the same as defined in section 514J.102.

f. "Health benefit plan" means the same as defined in section 514J.102.

g. "Health care professional" means the same as defined in section 514J.102.

h. "Health care services" means the same as defined in section 514J.102.

i. "Health carrier" means the same as defined in section 514J.102.

j. "Medical necessity" means accepted health care services and supplies that, under the applicable standard of care, are appropriate to the evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

k. "Step therapy override exception determination" means a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the prescription drug selected by a health care professional. This determination is based on a review of the covered person's or health care professional's request for an override, along with supporting rationale and documentation.

1. "Step therapy protocol" means a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular covered person are covered by a health carrier, a health benefit plan, or a utilization review organization.

m. "Utilization review" means a program or process by which an evaluation is made of the necessity, appropriateness, and efficiency of the use of health care services, procedures, or facilities given or proposed to be given to an individual. Such evaluation does not apply to requests by an individual or provider for a clarification, guarantee, or statement of an individual's health insurance coverage or benefits provided under a health benefit plan, nor to claims adjudication. Unless it is specifically stated, verification of benefits, preauthorization, or a prospective or concurrent utilization review program or process shall not be construed as a guarantee or statement of insurance coverage or benefits for any individual under a health benefit plan.

n. "Utilization review organization" means an entity subject to the jurisdiction of the commissioner that performs utilization review, other than a health carrier performing utilization review for its own health benefit plans.

2. *Establishment of step therapy protocols.*

a. A health carrier, health benefit plan, or utilization review organization shall do all of the following when establishing a step therapy protocol:

(1) Use clinical review criteria based on clinical practice guidelines that meet all of the following requirements:

(a) Recommend that particular prescription drugs be taken in the specific sequence required by the step therapy protocol.

(b) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among members of the panel's writing and review groups by doing all of the following:

(i) Requiring members to disclose any potential conflicts

of interest with entities, including health carriers, health benefit plans, utilization review organizations, and pharmaceutical manufacturers, and requiring members to recuse themselves from voting if there is a conflict of interest.

(ii) Using a methodologist to work with the panel's writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and by facilitating consensus.

(iii) Offering opportunities for public review and comments.

(c) Are based on high-quality studies, research, and medical practice.

(d) Are created through an explicit and transparent process that does all of the following:

(i) Minimizes biases and conflicts of interest.

(ii) Explains the relationship between treatment options and outcomes.

(iii) Rates the quality of the evidence supporting the recommendations.

(iv) Considers relevant patient subgroups and preferences.

(e) Are continually updated through a review of new evidence, research, and newly developed treatments.

(2) Take into account the needs of atypical covered person populations and diagnoses when establishing clinical review criteria.

(3) Notwithstanding subparagraph (1), reviewed publications may be substituted for the use of clinical practice guidelines in establishing a step therapy protocol.

b. This subsection shall not be construed to require health carriers, health benefit plans, utilization review organizations, or the state to establish a new entity to develop clinical review criteria for step therapy protocols.

c. A health carrier, health benefit plan, or utilization review organization shall submit proposed clinical review criteria to the commissioner for review as required by the

commissioner by rules adopted under chapter 17A, and shall not utilize the clinical review criteria in establishing a step therapy protocol without prior approval or accreditation by the commissioner.

d. A health carrier, health benefit plan, or utilization review organization shall certify annually in rate filing documents or other certifications, as required by the commissioner by rules adopted pursuant to chapter 17A, that the clinical review criteria used to establish a step therapy protocol meet the requirements set forth in this section.

3. *Exceptions process transparency.*

a. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization through the use of a step therapy protocol, the covered person and the prescribing health care professional shall have access to a clear, readily accessible, and convenient process to request a step therapy override exception determination. A health carrier, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process used shall be easily accessible on the internet site of the health carrier, health benefit plan, or utilization review organization.

b. A request for a step therapy override exception shall be approved expeditiously if any of the following circumstances are determined to apply:

(1) The prescription drug required under the step therapy protocol is contraindicated or is likely to cause an adverse reaction or physical or mental harm to the covered person.

(2) The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person and the known characteristics of the prescription drug regimen.

(3) The covered person has tried the prescription drug

required under the step therapy protocol while under the covered person's current or a previous health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) The prescription drug required under the step therapy protocol is not in the best interest of the covered person, based on medical necessity.

(5) The covered person is stable on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while on the current or a previous health benefit plan.

c. Upon making a determination to approve a request for a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall expeditiously authorize coverage for the prescription drug selected by the covered person's prescribing health care professional.

d. A health carrier, health benefit plan, or utilization review organization shall make a determination to approve or deny a request for a step therapy override exception within seventy-two hours of receipt of the request. In cases where exigent circumstances exist, a health carrier, health benefit plan, or utilization review organization shall make a determination to approve or deny the request within twenty-four hours of receipt of the request. If a determination to approve or deny the request is not made within the applicable time period, the request shall be deemed to be approved.

e. If a determination is made to deny a request for a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall provide the covered person or the covered person's authorized representative and the covered person's prescribing health care professional with the reason for the denial and

information regarding the procedure to appeal the denial. Any determination to deny a request for a step therapy override exception may be appealed by a covered person or the covered person's authorized representative.

f. A health carrier, health benefit plan, or utilization review organization shall uphold or reverse a denial of a request for a step therapy override exception within seventy-two hours of receipt of an appeal of the denial. In cases where exigent circumstances exist as provided in paragraph "*d*", a health carrier, health benefit plan, or utilization review organization shall make a determination to uphold or reverse a denial of such request within twenty-four hours of receipt of an appeal of the denial. If the denial of a request for a step therapy override exception is not upheld or reversed on appeal within the applicable time period, the denial shall be deemed to be reversed and the request for an override exception shall be deemed to be approved.

g. If a denial of a request for a step therapy override exception is upheld on appeal, the health carrier, health benefit plan, or utilization review organization shall provide the covered person or the covered person's authorized representative and the patient's prescribing health care professional with the reason for upholding the denial on appeal and information regarding the procedure to request external review of the denial pursuant to chapter 514J. Any denial of a request for a step therapy override exception that is upheld on appeal shall be considered a final adverse determination for purposes of chapter 514J and is eligible for a request for external review by a covered person or the covered person's authorized representative pursuant to chapter 514J.

4. *Limitations.* This section shall not be construed to do either of the following:

a. Prevent a health carrier, health benefit plan, or utilization review organization from requiring a covered person to try an AB-rated generic equivalent prescription drug prior

to providing coverage for the equivalent branded prescription drug.

b. Prevent a health care professional from prescribing a prescription drug that is determined to be medically appropriate.

5. *Rules.* The commissioner of insurance shall adopt rules pursuant to chapter 17A to administer this section.

Sec. 3. APPLICABILITY. This Act is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2018.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to the use of step therapy protocols for prescription drugs by health carriers, health benefit plans, and utilization review organizations, and includes applicability provisions.

The bill includes legislative findings that step therapy protocols are increasingly being used by health carriers, health benefit plans, and utilization review organizations to control health care costs, that step therapy protocols that are based on well-developed scientific standards and flexibly administered can play an important role in controlling health care costs, but that in some cases use of such protocols can have adverse or dangerous consequences for the person for whom the drugs are prescribed. The bill includes findings that uniform policies for the use of such protocols that preserve a health care professional's right to make treatment decisions and that provide for exceptions to the use of such protocols are in the public interest.

The bill defines a "step therapy protocol" as a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular covered person are covered by a health carrier, a health benefit plan, or a

utilization review organization.

The bill requires that a step therapy protocol be established using clinical review criteria that are based on specified clinical practice guidelines. A step therapy protocol should take into account the needs of atypical populations and diagnoses. The bill does not require a health carrier, health benefit plan, utilization review organization, or the state to establish a new entity to develop clinical review criteria for such protocols. As required by rules adopted by the commissioner of insurance pursuant to Code chapter 17A, proposed clinical review criteria must be submitted to the commissioner for approval prior to being utilized, and a health carrier, health benefit plan, or utilization review organization must certify annually in rate filings with the commissioner that clinical review criteria being used meet the requirements of the bill.

The bill also provides that when a step therapy protocol is in use, the person participating in a health benefit plan or the person's prescribing health care professional must have access to a clear, readily accessible, and convenient process to request a step therapy override exception determination. A "step therapy override exception determination" is a determination made by a health carrier, a health benefit plan, or a utilization review organization as to whether a step therapy protocol should apply in a particular situation, or whether the protocol should be overridden in favor of immediate coverage of the prescription drug selected by the prescribing health care professional, based on a review of the request along with supporting rationale and documentation. The bill provides that the request for an exception shall be granted if specified circumstances are determined to exist and coverage for the drug selected by the prescribing health care professional shall be authorized.

A request for a step therapy override exception must be approved or denied by the health carrier, health benefit plan,

or utilization review organization utilizing the step therapy protocol within 72 hours of receipt of the request, or within 24 hours of receipt of the request where exigent circumstances exist. The health carrier, health benefit plan, or utilization review organization can use its existing medical exceptions procedure in making the determination. If a determination to approve or deny the request is not made within the applicable time period, the request is deemed to be approved.

If a determination is made to deny the request for a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall provide the person making the request with the reason for the denial and information about the procedure to appeal the denial. Any denial of such a request is eligible for appeal.

Upon appeal, the health carrier, health benefit plan, or utilization review organization shall make a determination to uphold or reverse the denial within 72 hours, or within 24 hours in the case of exigent circumstances, of receiving the appeal. If the denial is not upheld or reversed on appeal within the applicable time period, the denial is deemed to be reversed and the request for an exception is deemed to be approved.

If a denial of a request for a step therapy override exception is upheld on appeal, the person making the appeal shall be provided with the reason for upholding the denial on appeal and information regarding the procedure to request external review of the denial pursuant to Code chapter 514J. A denial of a request for such an exception that is upheld on appeal shall be considered a final adverse determination for purposes of Code chapter 514J and is eligible for a request for external review pursuant to Code chapter 514J.

The bill shall not be construed to prevent a health carrier, health benefit plan, or utilization review organization from requiring a person to try an AB-rated generic equivalent prescription drug prior to providing coverage for the

equivalent branded prescription drug, or to prevent a health care professional from prescribing a prescription drug that is determined to be medically appropriate.

The commissioner of insurance is required to adopt rules pursuant to Code chapter 17A to administer the provisions of the bill.

The bill is applicable to a health benefit plan that is delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2018.