Ohio Legislative Service Commission

Bill Analysis

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H.B. 443

131st General Assembly
(As Introduced)

Reps. T. Johnson and Antonio, LaTourette, Bishoff, Duffey, Blessing, Boccieri, Perales, Phillips, Ginter

BILL SUMMARY

- Establishes requirements regarding the implementation of step therapy protocols by health plan issuers, utilization review organizations, and the Medicaid program.
- Requires those entities that implement step therapy protocols to implement clinical review criteria on which the protocols are to be based.
- Requires health plan issuers and utilization review organizations to seek approval from the Superintendent of Insurance before implementing the clinical review criteria.
- Requires health plan issuers, utilization review organizations, and the Medicaid program to implement a process through which patients and health care providers can request an exemption from the step therapy protocols.
- Specifies situations in which an exemption must be granted.
- Specifies the findings and intent of the General Assembly regarding the use of step therapy protocols.

CONTENT AND OPERATION

Step therapy protocols

The bill establishes requirements regarding the implementation of step therapy protocols by health plan issuers, utilization review organizations, and the Medicaid program. A step therapy protocol is a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition are covered by a

health plan issuer or Medicaid.[1] Under such a protocol, a patient might be required to try one or more prescription drugs before coverage is provided for another drug selected by the patient's health care provider.[2]

Clinical review criteria

Under the bill, if a health plan issuer, a utilization review organization, or the Medicaid program implements a step therapy protocol, that entity must also implement clinical review criteria on which the protocol will be based.[3] Clinical review criteria are the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health plan issuer, utilization review organization, or Medicaid to determine the medical necessity and appropriateness of health care services.[4]

Standards for clinical review criteria

The bill establishes requirements that the clinical review criteria must satisfy. The clinical review criteria must be developed and endorsed by an independent, multidisciplinary panel of experts that is not affiliated with a health plan issuer, utilization review organization, or Medicaid. The clinical review criteria must be based on high quality studies, research, and medical practice and created through 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 the recommendation, and considers relevant patient subgroups and preferences. The clinical review criteria must be continually updated through a review of new evidence and research.[5]

For health plan issuers and utilization review organizations, the bill requires that the clinical review criteria recommend that prescription drugs be taken in the specific sequence required by the step therapy protocol.[6]

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[1] R.C. 3901.82(E) and 5164.7511(A)(3).

[2] Section 2(A)(1).

[3] R.C. 3901.821(A) and 5164.7511(B).

[4] R.C. 3901.82(B) and 5164.7511(A)(2).

[5] R.C. 3901.821(A) and 5164.7512.

[6] R.C. 3901.821(A)(1).

Superintendent of Insurance review

The bill requires health plan issuers and utilization review organizations to submit to the Superintendent of Insurance proposed clinical review criteria for each planned step therapy protocol. The clinical review criteria may not be implemented before they are approved or accredited by the Superintendent. Additionally, the bill requires that health plan issuers and utilization review organizations annually certify, in rate filing documents submitted to the Superintendent, that the clinical review criteria used in step therapy protocols satisfy the requirements described above.[7]

Exemptions from step therapy protocols

Under the bill, if a health plan issuer, utilization review organization, or the Medicaid program uses a step therapy protocol to restrict coverage of a prescription drug, that entity must provide the patient and prescriber access to a process to request an exemption. The process must be clear, convenient, and easily accessible on the entity's website. The bill permits a health plan issuer or utilization review organization to satisfy this requirement by using its existing adverse benefit determination process.[8]

With respect to the Medicaid program's exemption process, it must require that supporting rationale and documentation be submitted with each exemption request.[9]

When exemptions are granted

The bill requires that an exemption from a step therapy protocol be expeditiously granted in the following circumstances:

(1) The drug that would otherwise be required under the step therapy protocol is contraindicated or is likely to cause an adverse reaction or physical or mental harm to the patient.

(2) The drug is expected to be ineffective based on the patient's known relevant physical or mental characteristics and the drug regimen's known characteristics.

(3) The patient has tried the drug while under the current or a previous health insurance or health benefit plan, or another drug in the same pharmacologic class or with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction.

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[7] R.C. 3901.821(B) and (C).

[8] R.C. 3901.822(A), 5164.7511(B)(2), and 5164.7513(A).

[9] R.C. 5164.7513(A)(3).

(4) The drug is not in the patient's best interest, based on medical appropriateness.

(5) The patient is stable on a prescription drug selected by the patient's health care provider for the medical condition under consideration.[10]

When an exemption is granted, the bill requires the health plan issuer, utilization review organization, or the Department of Medicaid to authorize coverage or payment for the drug prescribed by the patient's health care provider if the drug is covered by the patient's policy or contract or by Medicaid.[11]

Demonstration of compliance

The bill requires health plan issuers to maintain written or electronic records and data sufficient to demonstrate compliance with the exemption process requirements. A health plan issuer must also submit annually to the Superintendent of Insurance the total number of exemption requests received, the number of requests approved and denied, and any other information the Superintendent requests.[12]

Limits on exemption process requirements

The bill clarifies that the exemption process requirements neither (1) prevent a health plan issuer, utilization review organization, or Medicaid from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug nor (2) prevent a health care provider from prescribing a drug that is determined to be medically appropriate.[13]

Date of application

The bill specifies that its provisions apply to the Department of Medicaid and to health benefit plans delivered, issued for delivery, modified, or renewed on or after January 1, 2016.[14]

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[10] R.C. 3901.822(B) and 5164.7513(A)(4).

[11] R.C. 3901.822(C) and 5164.7513(A)(5).

[12] R.C. 3901.822(E).

[13] R.C. 3901.822(D) and 5164.7513(B).

[14] Since this date has already passed, it will need to be updated in later amendments to the bill. Section 3.

Legislative findings and intent

Findings

The bill specifies that the General Assembly makes the following findings:

(1) Health plans are increasingly making use of step therapy protocols.

(2) Step therapy protocols can play an important role in controlling health care costs when the protocols are based on well-developed scientific standards and are administered in a flexible manner that takes the individual needs of patients into account.

(3) Requiring a patient to follow a step therapy protocol may have adverse consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug.

(4) Without uniform policies for step therapy protocols, patients may not receive the best and most appropriate treatment.

(5) It is imperative that step therapy protocols preserve the health care provider's right to make treatment decisions in the patient's best interest.[15]

Intent

The bill specifies that, because of these findings, the General Assembly intends all of the following by enacting the bill:

(1) That health plan issuers and related organizations base step therapy protocols on appropriate clinical practice guidelines developed by independent experts;

(2) That patients be exempt from step therapy protocols when those protocols are inappropriate or otherwise not in the patients' best interests.

(3) That patients have access to a fair, transparent, and independent process for requesting an exemption from a step therapy protocol.[16]

Definitions

The bill defines the following terms:

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[15] Section 2(A).

[16] Section 2(B).

- "Clinical practice guidelines" means a systematically developed statement to assist health care provider and patient decisions with regard to appropriate health care for specific clinical circumstances and conditions.[17]

- "Health plan issuer" means an entity subject to Ohio Insurance Laws and Rules, or subject to the jurisdiction of the Superintendent of Insurance, that contracts, or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services under a health benefit plan. "Health plan issuer" includes a licensed third party administrator to the extent that the benefits that it is contracted to administer under a health benefit plan are subject to Ohio Insurance Laws and Rules or subject to the jurisdiction of the Superintendent.[18]

- "Step therapy exemption determination" means a determination, based on a patient's or prescriber's request for an exemption, along with supporting rationale and documentation, 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 health care provider's selected prescription drug.[19]

- "Utilization review organization" means an entity that conducts utilization review, other than a health insuring corporation performing a review of its own health care plans.[20]

HISTORY

ACTION	DATE
Introduced	02-02-16

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[17] R.C. 3901.82(A) and 5164.7511(A)(1).

[18] R.C. 3901.82(C) and R.C. 3922.01, not in the bill.

[19] R.C. 3901.82(D).

[20] R.C. 3901.82(F) and R.C. 1751.77, not in the bill.