OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

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H.B. 72

132nd General Assembly
(As Introduced)

Reps. T. Johnson and Antonio, Blessing, Boccieri, Brenner, Fedor, Ginter, Hill, LaTourette, Sheehy

BILL SUMMARY

- Imposes requirements on health plan issuers that implement a step therapy protocol with regard to prescription drugs.
- Requires health plan issuers to provide a process by which an individual can request a step therapy exemption.
- Specifies specific circumstances in which a step therapy exemption must be granted.
- Applies these requirements with regard to the Department of Medicaid.

CONTENT AND OPERATION

Summary

The bill imposes requirements on health plan issuers that implement a step therapy protocol with regard to prescription drugs. A step therapy protocol is any coverage of a group of prescription drugs used to treat an illness that is dependent upon the drugs being tried in a specific order. For example, a health plan issuer may refuse to cover a more expensive drug until a less expensive, pharmaceutically equivalent drug is tried first. The bill applies to sickness and accident insurers, health insuring corporations, fraternal benefit societies, multiple employer welfare arrangements, and nonfederal governmental health plans. The bill also applies to any utilization review organization used by a health plan issuer to make coverage determinations, as well as the Department of Medicaid.[1]

[1] R.C. 3901.821(A) and 5164.7512; R.C. 3922.01(P), not in the bill.

Clinical practice guidelines

The bill requires a health plan issuer that uses a step therapy protocol to implement that protocol via clinical review criteria that are based on clinical practice guidelines meeting certain criteria. Clinical review criteria are the screening procedures, protocols, and practice guidelines that a health plan issuer uses to make coverage decisions. Clinical practice guidelines are recommendations made by a panel of doctors or other health care professionals on how to treat specified conditions after a review of relevant evidence and research. Under the bill, clinical practice guidelines must meet all of the following criteria:

- Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;
- Be based on high quality studies, research, and medical practice;
- Be continually updated through a review of new evidence, research, and newly developed treatments.[2]

The clinical practice guidelines must also meet certain transparency requirements. The guidelines must be created by an explicit and transparent process that does all of the following:

- Minimizes bias and conflicts of interest;
- Explains the relationship between treatment options and outcomes;
- Rates the quality of the evidence supporting recommendations;
- Considers relevant patient subgroups and preferences.[3]

The guidelines must be developed and endorsed by a multidisciplinary panel of experts that manage conflicts of interest by implementing all of the following safeguards:

- A requirement that each member disclose any potential conflict of interest with health services entities, including health plan issuers and pharmaceutical manufacturers;

[2] R.C. 3901.821(A)(1), (3), and (5).

[3] R.C. 3901.821(A)(4).

- The use of a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus;

- A requirement that the public be offered opportunity for review and comment.[4]

A health plan issuer must certify that its clinical review criteria and clinical practice guidelines meet these standards via rate filing documents submitted to the Superintendent of Insurance. Additionally, a health plan issuer must submit proposed clinical review criteria in relation to a step therapy protocol to the Superintendent and must not implement these criteria prior to approval from the Superintendent.[5]

In the absence of clinical practice guidelines that meet these criteria, a health plan issuer may base its step therapy protocol clinical review criteria on peer-reviewed publications.[6] Any step therapy protocol that is implemented must take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.[7]

The bill specifies that its provisions are not to be interpreted as requiring either a health plan issuer or the state to set up a new entity for the purpose of establishing clinical review criteria for step therapy protocols.[8]

Step therapy exemption

The bill imposes requirements with regard to requesting and receiving exemptions to step therapy protocols. A health plan issuer must provide a clear, accessible, and convenient process to request a step therapy exemption, and any exemption request that is denied may be appealed. Additionally, an individual must be able to make a step therapy exemption request online. Any request for a step therapy exemption must be accompanied by supporting rationale and documentation. The bill authorizes a health plan issuer to use its existing adverse benefit determination appeal process to meet these requirements.[9]

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[4] R.C. 3901.821(A)(2).

[5] R.C. 3901.821(E) and (F).

[6] R.C. 3901.821(B).

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

[8] R.C. 3901.821(D).

[9] R.C. 3901.822(A).

The bill requires a health plan issuer to grant a step therapy exemption if any of the following apply to the individual in question:

- The required prescription drug in question is contraindicated or will likely cause an adverse reaction by, or physical or mental harm to, the patient;
- The required prescription drug 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 required prescription drug while under their current, or a previous, health benefit plan, or another prescription drug in the same pharmacologic class and the use of such prescription drug was discontinued due to ineffectiveness;
- The required prescription drug is not in the best interest of the patient, based on medical necessity;
- The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration, regardless of whether or not the drug was prescribed when the patient was covered under the current or a previous health benefit plan.[10]

A health plan issuer must respond to a request for a step therapy exemption within 72 hours or, in the case of exigent circumstances, within 24 hours. Any exemption request that is not replied to within this timeline is considered approved.[11] When a health plan issuer grants a step therapy exemption, the issuer must authorize coverage for the prescription drug in question.[12]

The bill specifies that it is not to be construed as preventing either of the following:

- A health plan issuer from requiring a patient to try a generic equivalent drug prior to providing coverage for the branded prescription drug;

[10] R.C. 3901.822(B).

[11] R.C. 3901.822(D).

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

- A health care provider from prescribing a prescription drug that is determined to be medically necessary.[13]

Rules

The bill requires the Superintendent to adopt rules as necessary to implement the bill's requirements.[14]

Medicaid

The bill also applies to the Department of Medicaid. The requirements that the bill applies with regard to Medicaid are adapted slightly to conform to the requirements of the Medicaid program, but are functionally the same as those that apply to health plan issuers.[15]

Effective date

The bill applies to health benefit plans issued or renewed, as well as prescription drug coverage offered by the Department of Medicaid, on and after January 1, 2018.[16]

Definitions

The bill defines the following terms:

"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.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health plan issuer or utilization review organization to determine whether or not health care services or drugs are appropriate and medically necessary.

"Health benefit plan" means a policy, contract, certificate, or agreement offered by a health plan issuer to cover the cost of health care services. "Health benefit plan" does not include certain specified limited benefit plans.

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

[14] R.C. 3901.823.

[15] R.C. 5164.7512, 5164.7513, 5164.7514, and 5167.12.

[16] Section 4.

"Health plan issuer" means any entity subject to Ohio insurance laws and rules, or subject to the jurisdiction of the Superintendent of Insurance, that covers any of the costs of health care services under a health benefit plan. The term includes a sickness and accident insurer, a fraternal benefit society, a self-funded multiple employer welfare arrangement, or a nonfederal government health plan. It also includes a third-party administrator.

"Medically necessary" means a determination that a health care service or drug is, under the applicable standard of care, appropriate for any of the following:

- To improve or preserve health, life, or function;
- To slow the deterioration of health, life, or function;
- For the screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

"Step therapy exemption" means an overriding of a step therapy protocol in favor of immediate coverage of the health care provider's selected prescription drug.

"Step therapy protocol" means a protocol or program that establishes a specific sequence in which prescription drugs that are for a specified medical condition and that are medically necessary for a particular patient are covered, under either a medical or prescription drug benefit, by a health benefit plan, including both self-administered and physician-administered drugs.

"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. "Utilization review" is a process used to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.[17]

HISTORY

ACTION	DATE
Introduced	02-21-17

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[17] R.C. 3901.82 and 5164.7512.