OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

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Sub. H.B. 72*

132nd General Assembly
(As Reported by H. Health)

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 a provider can request a step therapy exemption.
- Imposes deadlines by which a step therapy exemption request or appeal must either be granted or denied.
- Specifies specific circumstances in which a step therapy exemption must be granted.
- Requires health plan issuers to make disclosures with regard to a step therapy protocol.
- 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. A step therapy protocol is any coverage of a group of prescription drugs 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,

* This analysis was prepared before the report of the House Health Committee appeared in the House Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

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] For the purposes of this analysis, unless otherwise specified "health plan issuer" includes all of these entities.

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 or scientific evidence. 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.

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.[2]

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 for a prescribing health care provider to request a step therapy exemption, and any exemption request that is denied may be appealed. Additionally, a Medicaid provider 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 non-Medicaid health plan issuer to use its existing medical exceptions process to meet these requirements.[3]

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

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[1] R.C. 3901.83(C), 3901.831(A), and 5164.7512; R.C. 3922.01(P), not in the bill.

[2] R.C. 3901.83(A) and (B), 3901.831(C), and 5164.7512(C).

[3] R.C. 3901.832(A)(1), 5164.7512(B)(2), and 5164.7514(A).

- The required prescription drug in question is contraindicated for that specific patient, pursuant to the drug's United States Food and Drug Administration (USFDA) prescribing information;

- The patient has tried the required prescription drug while under their current, or a previous, health benefit plan, or another USFDA approved AB-rated prescription drug, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

- 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, or the patient has already gone through a step therapy protocol.[4]

A health plan issuer must either grant or deny a step therapy exemption or appeal within ten calendar days of receiving a request, or, when related to urgent care services, within 48 hours.[5] Any exemption request or appeal that is not replied to within this timeline is considered approved.[6] When a health plan issuer grants a step therapy exemption, the issuer must authorize coverage for the prescription drug in question.[7]

Appeals

The bill imposes certain requirements specifically with regard to appeals. An appeal is to be between the health care provider in question and a clinical peer, which is defined as being a health care practitioner in the same or similar specialty that typically manages the medical condition, procedure, or treatment under review.[8]

The bill also prescribes how appeals made to non-Medicaid health plan issuers are to interact with the External Review Law. Under the bill, a step therapy exemption appeal is to be considered an internal appeal, which is the final step prior to a person seeking an external review of a rejected claim, and prohibits health plan issuers from

[4] R.C. 3901.832(B) and 5164.7514(A)(5).

[5] R.C. 3901.832(A)(4) and (5) and 5164.7514(B).

[6] R.C. 3901.832(A)(6) and 5164.7514(B)(4).

[7] R.C. 3901.832(C) and 5164.7512(A)(6).

[8] R.C. 3901.832(A)(5)(c) and 5164.7514(B)(3).

imposing an additional level of appeal prior to seeking an external review.[9] A rejected step therapy exemption appeal under Medicaid may be further appealed under existing Medicaid appeal procedures.[10]

Disclosures

The bill requires health plan issuers to make disclosures regarding step therapy protocols. A health plan issuer is to make available to all health care providers a list of all drugs that the plan issuer subjects to a step therapy protocol. If a health plan issuer offers more than one plan, and the step therapy protocol varies according to plan, then the plan issuer is to provide a separate list for each plan. Along with this list, the plan issuer is to indicate what information or documentation must be provided for a step therapy exemption request or appeal to be considered complete. And if the requirements vary from drug to drug, then the health plan issuer is to provide this information for each drug. All of the required information is to be made available on the plan issuer's website or provider portal.[11]

Unfair and deceptive practice

The bill designates, for non-Medicaid health plan issuers, a series of violations of the bill's requirements as an unfair and deceptive practice in the business of insurance.[12] Under continuing law, a person who is found to have committed an unfair and deceptive practice in the business of insurance is subject to any or all of the following sanctions:

- Suspension or revocation of the person's license to engage in the business of insurance;
- Prohibition on an insurance company or insurance agency employing the person or permitting the person to serve the company or agency in any capacity for a period of time;
- Return of any payments received by the person as a result of the violation;

[9] R.C. 3901.832(A)(5)(d) and (e); R.C. 3922.03, not in the bill.

[10] R.C. 5164.7514(B)(4).

[11] R.C. 3901.832(A)(2) and (3) and 5164.7512(A)(3).

[12] R.C. 3901.832(E).

- Fees for attorneys and other costs of any investigation into the violations committed by the person.[13]

Interpretation

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 any pharmaceutical alternative, per the USFDA's Orange Book, Purple Book, or their successors, prior to providing or renewing coverage for a prescribed drug;

- A health care provider from prescribing a prescription drug that is determined to be medically necessary.[14]

Rules

The bill permits the Superintendent to adopt rules as necessary to implement the bill's non-Medicaid requirements.[15]

Medicaid

Note that, with regard to the Department of Medicaid, the bill's requirements 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.[16]

Effective date

The bill applies to health benefit plans issued or renewed on and after January 1, 2020. Not later than 90 days after the bill's effective date, the Medicaid Director must submit to the U.S. Secretary of Health and Human Services a Medicaid State Plan Amendment as necessary for the implementation of the bill.[17]

Definitions

The bill defines the following terms:

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[13] R.C. 3901.22, not in the bill.

[14] R.C. 3901.832(B)(3) and (D) and 5164.7514(A)(5) and (D).

[15] R.C. 3901.833.

[16] R.C. 5164.7512, 5164.7514, and 5167.12.

[17] Section 4.

"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 consistent with medical or scientific evidence.

"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.

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

"Medical or scientific evidence" means evidence found in any of the following sources:

- Peer-reviewed scientific studies published in, or accepted for publication by, medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

- Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for Indexing in Index Medicus and Elsevier Science Ltd. for indexing in Excerpta Medicus;

- Certain medical journals recognized by the U.S. Secretary of Health and Human Services;

- The following standard reference compendia:

    - The American Hospital Formulary Service Drug Information;

    - Drug Facts and Comparisons;

- The American Dental Association Accepted Dental Therapeutics;
- The U.S. Pharmacopoeia Drug Information.

- Findings, studies or research conducted by or under the auspices of a federal government agency or nationally recognized federal research institute, including any of the following:
  - The Federal Agency for Health Care Research and Quality;
  - The National Institutes of Health;
  - The National Cancer Institute;
  - The National Academy of Sciences;
  - The Centers for Medicare and Medicaid Services;
  - The USFDA;
  - Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services.
- Any other medical or scientific evidence that is comparable.

"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 consistent with medical or scientific evidence 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.[18]

[18] R.C. 3901.83 and 5164.7512.

HISTORY

ACTION	DATE
Introduced	02-21-17
Reported, H. Health	12-05-18

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