OHIO LEGISLATIVE SERVICE COMMISSION

Final Analysis

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Reps. Anielski, Blessing, Brown, Carfagna, Craig, Cupp, Fedor, Galonski, Ginter, Green, Holmes, Ingram, T. Johnson, Kent, Koehler, LaTourette, Leland, Lipps, Miller, O'Brien, Patterson, Patton, Perales, Reineke, Retherford, Riedel, Roegner, Rogers, Ryan, Schaffer, Scherer, Sheehy, K. Smith, T. Smith, Sprague, Strahorn, Sykes, West, Wiggam, R. Smith

Effective date: April 5, 2019

ACT SUMMARY

Pharmacist-provided services

- Authorizes health plan issuers to pay or reimburse pharmacists for all health services that a pharmacist is legally authorized to provide and that are covered by the health benefit plan.

- Explicitly authorizes pharmacists to provide certain types of services at multi-purpose senior centers, jails, state correctional institutions, ambulatory surgical facilities, hospices, and pediatric respite care programs.

- Explicitly authorizes health insuring corporations, health care practitioners, and organized health care groups to hire pharmacists.

- Allows pharmacists to enter into contracts with contracting entities under the Health Care Contract Law.

Step therapy

- 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 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

Pharmacist-provided services

Reimbursement for covered services

The act explicitly authorizes a health plan issuer to pay or reimburse a pharmacist for providing health care services if the pharmacist is legally authorized to provide the service and if the patient's health benefit plan covers the service. The act specifically authorizes payment for the following services that continuing law authorizes a pharmacist to perform:

- Managing drug therapy under a consult agreement with a physician;
- Administering immunizations;
- Administering the following injectable drugs:
    - An opioid antagonist used for treatment of drug addiction in a long-acting form;
    - An antipsychotic drug in a long-acting form;
    - Hydroxyprogesterone caproate;
    - Medroxyprogesterone acetate;
    - Cobalamin.

This authorization applies to health insuring corporations, sickness and accident insurers, public employee benefit plans, multiple employer welfare arrangements, and the Department of Medicaid.[1]

These provisions apply to non-Medicaid health benefit plans that are delivered, issued for delivery, or renewed in Ohio on or after the act's effective date (April 5, 2019).[2] In an apparent drafting error, the effective date provision omitted reference to health insuring corporations.

Pharmacist services

The act explicitly authorizes pharmacists to provide the following types of services:

- Preventative medical services and counseling on health matters provided at a multi-purpose senior center;[3]
- Necessary care in a jail or state correctional institution;[4]
- Services provided in an ambulatory surgical facility for which an ambulatory surgical facility fee may be charged;[5]
- Hospice services as a part of a hospice care program;[6]
- Pediatric respite services as a part of a pediatric respite care program.[7]

Hiring pharmacists

The act authorizes pharmacists to be hired by certain entities. Current law states that nothing in the Health Insuring Corporation Law is to be construed as prohibiting a health insuring corporation, health care practitioner, or organized health care group associated with a health insuring corporation from hiring certain medical providers,

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[1] R.C. 1739.05, 1751.91, 3923.89, 5164.14, and 5167.121; R.C. 4729.39, 4729.41, and 4729.45, not in the act.

[2] Section 3.

[3] R.C. 173.12(A)(1).

[4] R.C. 341.192(A)(2).

[5] R.C. 3702.30(A)(2)(c).

[6] R.C. 3712.06(H).

[7] R.C. 3712.061(B).

including nurses, physicians assistants, and dietitians. The act adds pharmacists to that list of personnel that those entities may hire.[8]

These provisions apply to health benefit plans that are delivered, issued for delivery, or renewed by a health insuring corporation in Ohio on or after the act's effective date.[9]

Contracting entities under the Health Care Contract Law

The act includes pharmacists in the definition of "provider" for the purposes of contracting entities and health care contracts. Contracting entities are entities that pool a group of health care providers for the purpose of contracting with a health plan issuer for the provision of health care services. In other words, contracting entities gather groups of health care providers and bring those providers to health plan issuers for the purpose of forming the plan issuer's network.[10]

This provision applies to health care contracts that are entered into, materially amended, or renewed on or after the act's effective date.[11]

Step therapy

Summary

The act 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 on 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 act applies to sickness and accident insurers, health insuring corporations, fraternal benefit societies, multiple employer welfare arrangements, and nonfederal, governmental health plans. The act also applies to any utilization review organization used by a health plan issuer to make coverage determinations, as well as the Department of Medicaid.[12] For the purposes of this analysis, unless otherwise specified "health plan issuer" includes all of these entities.

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[8] R.C. 1751.01(Y).

[9] Section 3.

[10] R.C. 3963.01(C) and (P).

[11] Section 3.

[12] R.C. 3901.83(C) and (F), 3901.831(A), and 5164.7512(A)(5) and (B)(1); R.C. 3922.01(P), not in the act.

Clinical practice guidelines

The act 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 act 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.[13]

Step therapy exemption

The act 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 act authorizes a non-Medicaid health plan issuer to use its existing medical exceptions process to meet these requirements.[14]

Decision

The act 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:

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

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

[13] R.C. 3901.83(A) and (B), 3901.831(A) and (C), and 5164.7512(A), (B)(3), and (C).

[14] R.C. 3901.832(A)(1) and (5), 5164.7512(B)(2), and 5164.7514(A)(1) to (4) and (B)(2).

- 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.[15]

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.[16] Any exemption request or appeal that is not replied to within this timeline is considered approved.[17] When a health plan issuer grants a step therapy exemption, the issuer must authorize coverage for the prescription drug in question.[18]

Appeals

The act imposes certain requirements specifically with regard to appeals. An appeal is to be between the health care provider in question and a clinical peer – a health care practitioner in the same or similar specialty that typically manages the medical condition, procedure, or treatment under review.[19]

The act also prescribes how appeals made to non-Medicaid health plan issuers are to interact with the External Review Law. Under the act, 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 imposing an additional level of appeal prior to seeking an external review.[20] A rejected step therapy exemption appeal under Medicaid may be further appealed under existing Medicaid appeal procedures.[21]

Disclosures

The act 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

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

[16] R.C. 3901.832(A)(4) and (5) and 5164.7514(B)(1).

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

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

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

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

[21] R.C. 5164.7514(C).

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.[22]

Unfair and deceptive practice

The act designates, for non-Medicaid health plan issuers, a series of violations of the act's requirements as an unfair and deceptive practice in the business of insurance.[23] 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;
- Fees for attorneys and other costs of any investigation into the violations committed by the person.[24]

Interpretation

The act specifies that it is not to be construed as preventing either:

- A health plan issuer from requiring a patient to try any pharmaceutical alternative, per the FDA's Orange Book, Purple Book, or their successors, prior to providing or renewing coverage for a prescribed drug;

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

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

[24] R.C. 3901.22, not in the act.

- A health care provider from prescribing a prescription drug that is determined to be medically necessary.[25]

Rules

The act permits the Superintendent of Insurance to adopt rules as necessary to implement the act's non-Medicaid requirements.[26]

Medicaid

Note that, with regard to the Department of Medicaid, the act's requirements are adapted slightly to conform to the requirements of the Medicaid program, but are functionally the same as those that apply to other health plan issuers.[27]

Application to non-Medicaid plans

The act's step therapy provisions apply to non-Medicaid health benefit plans issued or renewed on and after January 1, 2020. Not later than July 5, 2019 (90 days after the act'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 to implement the act.[28]

Definitions

The act defines the following terms for the step therapy portion of the act:

"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.

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

[26] R.C. 3901.833.

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

[28] 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. The term includes a sickness and accident insurer, a health insuring corporation, 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, 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 FDA;
- Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services;

- Any other comparable medical or scientific evidence.

"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.[29]

HISTORY

ACTION	DATE
Introduced	02-22-18
Reported, S. Insurance & Financial Institutions	11-28-18
Passed Senate (30-0)	11-28-18
Reported, H. Gov't Accountability & Oversight	12-13-18
Passed House (86-0)	12-13-18
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[29] R.C. 3901.83 and 5164.7512.