As Reported by the Senate Health, Human Services and Medicaid Committee

132nd General Assembly

Regular Session **Sub. S. B. No. 56**

2017-2018

Senators Lehner, Tavares

Cosponsors: Senators Thomas, Beagle, Brown, Terhar, Williams, Schiavoni, Yuko, Hottinger, Gardner, Sykes

A BILL

To amend section 5167.12 and to enact sections 3901.83, 3901.831, 3901.832, 3901.833, 5164.7512, and 5164.7514 of the Revised Code to adopt requirements related to step therapy protocols implemented by health plan issuers and the Department of Medicaid.

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

Section 1. That section 5167.12 be amended and sections 3901.83, 3901.831, 3901.832, 3901.833, 5164.7512, and 5164.7514 of the Revised Code be enacted to read as follows:

Sec. 3901.83. As used in sections 3901.83 to 3901.833 of the Revised Code:

(A) "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.

(B) "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.

(C) "Health benefit plan" and "health plan issuer" have the same meanings as in section 3922.01 of the Revised Code.

(D) "Medical or scientific evidence" has the same meaning as in section 3922.01 of the Revised Code.

(E) "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.

(F) "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.

(G) "Urgent care services" has the same meaning as in section 3923.041 of the Revised Code.

(H) "Utilization review organization" has the same meaning as in section 1751.77 of the Revised Code.

Sec. 3901.831. (A) If a health plan issuer or a utilization review organization implements a step therapy protocol, that protocol shall be implemented via clinical review criteria that are based on clinical practice guidelines or medical or scientific evidence.

(B) When establishing a step therapy protocol, a health plan issuer and a utilization review organization shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(C) This section shall not be construed as requiring either a health plan issuer or the state to set up a new entity to develop clinical review criteria for step therapy protocols.

Sec. 3901.832. (A)(1)(a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health plan issuer or utilization review organization through the use of a step therapy protocol, the health plan issuer or utilization review organization shall provide the prescribing health care provider access to a clear, easily accessible, and convenient process to request a step therapy exemption on behalf of a covered individual. A health plan issuer or utilization review organization may use its existing medical exceptions process to satisfy this requirement.

(b) A step therapy exemption request shall include supporting documentation and rationale.

(2)(a) A health plan issuer shall make available, to all health care providers, a list of all drugs covered by the issuer that are subject to a step therapy protocol. If the health plan issuer offers more than one health benefit plan, and the covered drugs subject to a step therapy protocol vary from one plan to another, then the health plan issuer shall issue a separate list for each plan.

(b) Along with the information required under division (A)(2)(a) of this section, a health plan issuer shall indicate what information or documentation must be provided to the issuer or

organization for a step therapy exemption request to be considered complete. Such information shall be provided for each drug, if the requirements vary according to the drug, plan, or protocol in question.

(3)(a) The list required under division (A)(2)(a) of this section, along with the required information or documentation described in division (A)(2)(b) of this section, shall be made available on the issuer's web site or provider portal.

(b) A utilization review organization shall, for each health benefit plan it oversees that implements a step therapy protocol, similarly make the list and information required under divisions (A)(2)(a) and (b) of this section available on its web site or provider portal.

(4) From the time a step therapy exemption request is received by a health plan issuer or utilization review organization, the issuer or organization shall either grant or deny the request within the following time frames:

(a) Forty-eight hours for a request related to urgent care services;

(b) Ten calendar days for all other requests.

(5)(a) A provider may, on behalf of the covered individual, appeal any exemption request that is denied.

(b) From the time an appeal is received by a health plan issuer or utilization review organization, the issuer or organization shall either grant or deny the appeal within the following time frames:

(i) Forty-eight hours for appeals related to urgent care services;

(ii) Ten calendar days for all other appeals.

(c) The appeal shall be between the health care provider requesting the service in question and a clinical peer, as defined in section 3923.041 of the Revised Code.

(d)(i) The appeal shall be considered an internal appeal for purposes of section 3922.03 of the Revised Code.

(ii) A health plan issuer shall not impose a step therapy exemption appeal as an additional level of appeal beyond what is required under section 3922.03 of the Revised Code, unless otherwise permitted by law.

(e)(i) If the appeal does not resolve the disagreement, the covered individual, or the covered individual's authorized representative, may request an external review under Chapter 3922. of the Revised Code to the extent Chapter 3922. of the Revised Code is applicable.

(ii) As used in division (A)(5)(e) of this section, "authorized representative" has the same meaning as in section 3922.01 of the Revised Code.

(6) If a health plan issuer or utilization review organization does not either grant or deny an exemption request or an appeal within the time frames prescribed in division (A)(4) or (5) of this section, then such an exemption request or appeal shall be deemed to be granted.

(B) Pursuant to a step therapy exemption request initiated under division (A)(1) of this section or an appeal made under division (A)(5) of this section, a health plan issuer or utilization review organization shall grant a step therapy exemption if any of the following are met:

(1) The required prescription drug is contraindicated for that specific patient, pursuant to the drug's United States food and drug administration prescribing information.

(2) The patient has tried the required prescription drug while under their current, or a previous, health benefit plan, or another United States food and drug administration approved AB-rated prescription drug, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(3) The patient is stable on a prescription drug selected by the patient's 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 has already gone through a step therapy protocol. However, a health benefit plan may require a stable patient to try a pharmaceutical alternative, per the federal food and drug administration's orange book, purple book, or their successors, prior to providing coverage for the prescribed drug.

(C) Upon the granting of a step therapy exemption, the health plan issuer or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

(D) This section shall not be construed to prevent either of the following:

(1) A health plan issuer or utilization review organization from requiring a patient to try any new or existing pharmaceutical alternative, per the federal food and drug administration's orange book, purple book, or their successors,

prior to providing or renewing coverage for the prescribed drug;

(2) A health care provider from prescribing a prescription drug, consistent with medical or scientific evidence.

(E) Committing a series of violations of this section that, taken together, constitute a practice or pattern shall be considered an unfair and deceptive practice under sections 3901.19 to 3901.26 of the Revised Code.

Sec. 3901.833. The superintendent of insurance may adopt rules as necessary to enforce sections 3901.83 to 3901.833 of the Revised Code.

Sec. 5164.7512. (A) As used in sections 5164.7512 to 5164.7514 of the Revised Code:

(1) "Clinical practice guidelines" means a systematically developed statement to assist providers and medicaid recipients in making decisions about appropriate health care for specific clinical circumstances and conditions.

(2) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by the medicaid program to determine whether or not a health care service or drug is appropriate and consistent with medical or scientific evidence.

(3) "Medical or scientific evidence" has the same meaning as in section 3922.01 of the Revised Code.

(4) "Step therapy exemption" means an overriding of a step therapy protocol in favor of immediate coverage of a medicaid provider's selected prescription drug.

(5) "Step therapy protocol" means a protocol under which it is determined through a specific sequence whether the

medicaid program, under either a pharmacy or medical benefit, will pay for a prescribed drug that a medicaid provider, consistent with medical or scientific evidence, prescribes for a medicaid recipient's specified medical condition, including both self-administered and physician-administered drugs.

(6) "Urgent care services" has the same meaning as in section 3922.041 of the Revised Code.

(B) If the department of medicaid utilizes a step therapy protocol for the medicaid program under which it is recommended that prescribed drugs be taken in a specific sequence, the department shall do all of the following:

(1) Implement that step therapy protocol using clinical review criteria that are based on clinical practice guidelines or medical or scientific evidence. The department shall take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(2) In a manner consistent with section 5164.7514 of the Revised Code, establish and implement a step therapy exemption process under which medicaid recipients and medicaid providers who prescribe prescribed drugs for medicaid recipients may request and receive a step therapy exemption;

(3)(a) Make available, to all medicaid providers, a list of all drugs covered by the medicaid program that are subject to a step therapy protocol;

(b) Along with the information required under division (B)(3)(a) of this section, the department of medicaid shall indicate what information or documentation must be provided to the department for a step therapy exemption request to be considered complete. Such information shall be provided for each

drug, if the requirements vary according to the drug or protocol in question.

(c) The list required under division (B)(3)(a) of this section, along with all of the required information or documentation described in division (B)(3)(b) of this section, shall be made available on the department of medicaid's web site or provider portal.

(C) This section shall not be construed as requiring the department to set up a new entity to develop clinical review criteria for step therapy protocols.

Sec. 5164.7514. (A) All of the following shall apply to the step therapy exemption process established and implemented by the department of medicaid pursuant to division (B)(2) of section 5164.7512 of the Revised Code:

(1) The process shall be clear and convenient.

(2) The process shall be easily accessible on the department's web site.

(3) The process shall require that a medicaid provider initiate a step therapy exemption request on behalf of a medicaid recipient.

(4) The process shall require supporting documentation and rationale be submitted with each request for a step therapy exemption.

(5) The process shall, pursuant to a step therapy exemption request made under division (B)(2) of section 5164.7512 of the Revised Code or an appeal made under division (B)(2) of this section, require the department to grant a step therapy exemption if either of the following applies:

(a) Either of the following apply to the prescribed drug that would otherwise have to be used under the step therapy protocol:

(i) The required prescription drug is contraindicated for that specific medicaid recipient, pursuant to the drug's United States food and drug administration prescribing information.

(ii) The medicaid recipient tried the required prescription drug while enrolled in medicaid or other health care coverage, or another United States food and drug administration approved AB-rated prescription drug, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(b) The medicaid recipient is stable on the prescribed drug selected by the recipient's medicaid provider for the medical condition under consideration, regardless of whether or not the drug was prescribed while the individual in question was a medicaid recipient, or has already gone through a step therapy protocol. However, the department may require a stable medicaid recipient to try a pharmaceutical alternative, per the federal food and drug administration's orange book, purple book, or their successors, prior to providing coverage for the prescribed drug.

(6) On granting a step therapy exemption, the department shall authorize payment for the prescribed drug prescribed by the medicaid recipient's medicaid provider.

(B)(1) From the time a step therapy exemption request is received, the department shall either grant or deny the request within the following time frames:

(a) Forty-eight hours for requests related to urgent care

services;

(b) Ten calendar days for all other requests.

(2)(a) If an exemption request is denied, a medicaid provider may appeal the denial on behalf of the medicaid recipient.

(b) From the time a step therapy appeal is received, the department shall either grant or deny the appeal within the following time frames:

(i) Forty-eight hours for appeals related to urgent care services;

(ii) Ten calendar days for all other appeals.

(3) The appeal shall be between the medicaid provider making the appeal and a clinical peer appointed by or contracted by the department or the department's designee.

(4) If the department does not either grant or deny an exemption request or an appeal within the time frames prescribed in division (B)(1) or (2) of this section, then such an exemption request or appeal shall be deemed to be granted.

(C) If an appeal is rejected, the medicaid recipient in question may make a further appeal in accordance with section 5160.31 of the Revised Code.

(D) This section shall not be construed to prevent either of the following:

(1) The department from requiring a medicaid recipient to try any new or existing pharmaceutical alternative, per the federal food and drug administration's orange book, purple book, or their successors, before authorizing a medicaid payment for

the prescribed drug;

(2) A medicaid provider from prescribing a prescribed drug that is determined to be consistent with medical or scientific evidence.

Sec. 5167.12. (A) When contracting under section 5167.10 of the Revised Code with a managed care organization that is a health insuring corporation, the department of medicaid shall require the health insuring corporation to provide coverage of prescribed drugs for medicaid recipients enrolled in the health insuring corporation. In providing the required coverage, the health insuring corporation may use strategies for the management of drug utilization, but any such strategies are subject to ~~divisions (B) and (E)~~ the limitations and requirements of this section and the department's approval.

(B) The department shall not permit a health insuring corporation to impose a prior authorization requirement in the case of a drug to which all of the following apply:

(1) The drug is an antidepressant or antipsychotic.

(2) The drug is administered or dispensed in a standard tablet or capsule form, except that in the case of an antipsychotic, the drug also may be administered or dispensed in a long-acting injectable form.

(3) The drug is prescribed by any of the following:

(a) A physician who is allowed by the health insuring corporation to provide care as a psychiatrist through its credentialing process, as described in division (C) of section 5167.10 of the Revised Code;

(b) A psychiatrist who is practicing at a location on

behalf of a community mental health services provider whose mental health services are certified by the department of mental health and addiction services under section 5119.36 of the Revised Code;

(c) A certified nurse practitioner, as defined in section 4723.01 of the Revised Code, who is certified in psychiatric mental health by a national certifying organization approved by the board of nursing under section 4723.46 of the Revised Code;

(d) A clinical nurse specialist, as defined in section 4723.01 of the Revised Code, who is certified in psychiatric mental health by a national certifying organization approved by the board of nursing under section 4723.46 of the Revised Code.

(4) The drug is prescribed for a use that is indicated on the drug's labeling, as approved by the federal food and drug administration.

(C) Subject to division (E) of this section, the department shall authorize a health insuring corporation to develop and implement a pharmacy utilization management program under which prior authorization through the program is established as a condition of obtaining a controlled substance pursuant to a prescription.

(D) The department shall require a health insuring corporation to comply with ~~section~~ sections 5164.091, 5164.7511, 5164.7512, and 5164.7514 of the Revised Code ~~with respect to medication synchronization~~, as if the health insuring corporation were the department.

~~(E) The department shall require a health insuring corporation to comply with section 5164.091 of the Revised Code as if the health insuring corporation were the department.~~

Section 2. That existing section 5167.12 of the Revised Code is hereby repealed.

Section 3. This act shall apply to health benefit plans, as defined in section 3922.01 of the Revised Code, delivered, issued for delivery, modified, or renewed on or after January 1, 2020. Not later than ninety days after the effective date of this act, the Medicaid Director shall submit to the United States Secretary of Health and Human Services a Medicaid state plan amendment as necessary for the implementation of this act.