As Introduced

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Senators Lehner, Tavares

Cosponsors: Senators Thomas, Beagle, Brown, Terhar, Williams, Schiavoni, Yuko

A BILL

To amend section 5167.12 and to enact sections 3901.82, 3901.821, 3901.822, 3901.823, 5164.7512, 5164.7513, 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 3901.82, 3901.821, 3901.822, 3901.823, 5164.7512, 5164.7513, and 5164.7514 of the Revised Code be enacted to read as follows:

Sec. 3901.82. As used in sections 3901.82 to 3901.823 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 medically necessary.

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

(D) "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:

(1) To improve or preserve health, life, or function;

(2) To slow the deterioration of health, life, or function;

(3) For the screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

(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 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.

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

Sec. 3901.821. (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 that

meet all of the following:

(1) Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;

(2) Are developed and endorsed by a multidisciplinary panel of experts that manage conflicts of interest of the writing and review groups by implementing all of the following:

(a) A requirement that each member disclose any potential conflict of interest with entities, including health plan issuers and pharmaceutical manufacturers, and recuse the member's self from voting if the member has a conflict of interest;

(b) 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;

(c) A requirement that the public be offered opportunity for review and comment.

(3) Are based on high quality studies, research, and medical practice;

(4) Are created by an explicit and transparent process that does all of the following:

(a) Minimizes bias and conflicts of interest;

(b) Explains the relationship between treatment options and outcomes;

(c) Rates the quality of the evidence supporting recommendations;

(d) Considers relevant patient subgroups and preferences.

(5) Are continually updated through a review of new evidence, research, and newly developed treatments.

(B) In the absence of clinical practice guidelines that meet the requirements of division (A) of this section, peer-reviewed publications may be used instead.

(C) 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.

(D) 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.

(E) A health plan issuer or utilization review organization shall certify, annually in rate filing documents submitted to the superintendent of insurance, that the clinical review criteria used in step therapy protocols for prescription drugs are based on clinical practice guidelines that meet the requirements set forth in division (A) of this section.

(F) A health plan issuer or utilization review organization shall submit proposed clinical review criteria in relation to each step therapy protocol that the health plan issuer or utilization review organization seeks to implement to the superintendent of insurance for review and shall not implement those criteria prior to receiving approval or accreditation from the superintendent.

Sec. 3901.822. (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 patient and prescribing practitioner access to a clear, easily accessible, and convenient process to request a step therapy exemption.

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

(2) A covered individual may appeal a step therapy exemption request that is denied.

(3) A health plan issuer or utilization review organization may use its existing adverse benefit determination process provided for under Chapter 3922. of the Revised Code to provide for step therapy exemption requests and appeals.

(4) The health plan issuer or utilization review organization shall make the process easily accessible on the health plan issuer or utilization review organization's web site.

(B) A health plan issuer or utilization review organization shall expeditiously grant a step therapy exemption if any of the following are met:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction by, or physical or mental harm to, the patient.

(2) 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.

(3) 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 or with the same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) The required prescription drug is not in the best interest of the patient, based on medical necessity.

(5) 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.

(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)(1)(a) A health plan issuer or utilization review organization shall respond to a step therapy exemption request or an appeal within seventy-two hours of receipt.

(b) In cases where exigent circumstances exist, a health plan issuer or a utilization review organization shall respond within twenty-four hours of receipt.

(2) Should a response by a health plan issuer or a utilization review organization not be received within this time, the exception or appeal shall be deemed granted.

(E) 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 an AB-rated generic

equivalent prior to providing coverage for the equivalent branded prescription drug;

(2) A health care provider from prescribing a prescription drug that is determined to be medically necessary.

Sec. 3901.823. The superintendent of insurance shall adopt rules as necessary to enforce sections 3901.82 to 3901.823 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 medically necessary.

(3) "Health plan issuer" has the same meaning as in section 3922.01 of the Revised Code.

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

(a) To improve or preserve health, life, or function;

(b) To slow the deterioration of health, life, or function;

(c) For the screening, prevention, evaluation, diagnosis,

or treatment of a disease, condition, illness, or injury.

(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 medically necessary prescribed drug that a medicaid provider prescribes for a medicaid recipient's specified medical condition, including both self-administered and physician-administered drugs.

(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 both of the following:

(1) Implement that step therapy program using clinical review criteria that are based on clinical practice guidelines that meet the requirements of section 5164.7513 of the Revised Code;

(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 under division (A)(4) of section 5164.7514 of the Revised Code.

Sec. 5164.7513. All of the following shall apply to clinical practice guidelines used to develop a step therapy program by the department of medicaid pursuant to division (B)(1) of section 5164.7512 of the Revised Code:

(A) The guidelines shall recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;

(B) The guidelines shall be developed and endorsed by a multidisciplinary panel of experts not affiliated with the medicaid program that manage conflicts of interest of the writing and review groups by implementing all of the following:

(1) A requirement that members disclose any potential conflict of interest with entities, including the department, health plan issuers, and pharmaceutical manufacturers, and recuse the member's self from voting if the member has a conflict of interest;

(2) 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;

(3) A requirement that the public be allowed to review the guidelines and provide comments.

(C) The criteria shall be based on high quality studies, research, and medical practice.

(D) The criteria shall be created by an explicit and transparent process that does all of the following:

(1) Minimizes bias and conflicts of interest;

(2) Explains the relationship between treatment options and outcomes;

(3) Rates the quality of the evidence supporting recommendations;

(4) Considers relevant medicaid recipient subgroups and preferences.

(E) The criteria shall be continually updated through a

review of new evidence, research, and newly developed treatments.

(F) In the absence of guidelines that meet the requirements of divisions (A) to (E) of this section, the department may use peer-reviewed publications instead.

(G) 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 supporting rationale and documentation be submitted with each request for an exemption.

(4) The process shall require the department to expeditiously grant an exemption if either of the following applies:

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

(i) It is contraindicated or will likely cause an adverse reaction by, or physical or mental harm to, the medicaid recipient.

(ii) It is expected to be ineffective based on the known

relevant clinical characteristics of the medicaid recipient and the known characteristics of the prescribed drug regimen.

(iii) The medicaid recipient tried it while enrolled in medicaid or other health care coverage, or another prescribed drug in the same pharmacologic class or with the same mechanism of action, and it or the other prescribed drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(iv) It is not in the best interest of the medicaid recipient, based on medical necessity.

(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.

(5) On granting an exemption, the department shall authorize payment for the prescribed drug prescribed by the medicaid recipient's medicaid provider.

(B)(1)(a) The department shall respond to a step therapy exemption request or an appeal within seventy-two hours of receipt.

(b) In cases where exigent circumstances exist, the department shall respond within twenty-four hours of receipt.

(2) Should a response by the department not be received within this time, the exemption or appeal shall be deemed granted.

(C) Any step therapy exemption request that is denied shall be eligible for appeal by a medicaid recipient.

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

(1) The department from requiring a medicaid recipient to try an AB-rated generic equivalent before authorizing a medicaid payment for the equivalent branded prescribed drug;

(2) A medicaid provider from prescribing a prescribed drug that is determined to be medically appropriate.

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 either of the following:

(a) A physician whom the health insuring corporation, pursuant to division (C) of section 5167.10 of the Revised Code,

has credentialed to provide care as a psychiatrist;

(b) A psychiatrist practicing at 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.

(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, 5164.7513, 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. (A) The Ohio General Assembly finds all of the following:

(1) That health plan issuers and Medicaid are increasingly making use of step therapy protocols under which patients are

required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider.

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

(3) That, in some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous 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) That, without uniform policies in the state for step therapy protocols, patients may not receive the best and most appropriate treatment.

(5) That it is imperative that step therapy protocols in the state preserve the health care provider's right to make treatment decisions in the best interest of the patient.

(B) Therefore, the General Assembly declares its intent in relation to the enactment of this act and the implementation of step therapy protocols all of the following:

(1) That the Department of Medicaid, health plan issuers, and other related organizations that use step therapy protocols make coverage or benefits determinations based on appropriate clinical practice guidelines or published, peer-reviewed data developed by independent experts with knowledge of the condition or conditions under consideration;

(2) That patients be exempt from step therapy protocols

when those protocols are inappropriate or otherwise not in the best interest of the patients;

(3) That patients have access to a fair, transparent, and independent process for requesting an exemption to a step therapy protocol when the patient's physician considers appropriate.

Section 4. This act shall apply to health benefits plans, as defined in section 3922.01 of the Revised Code, delivered, issued for delivery, modified, or renewed on or after January 1, 2018. This act shall apply to the Medicaid program's coverage of prescribed drugs on and after January 1, 2018.