As Introduced

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S. B. No. 243

Senators Lehner, Tavares

Cosponsors: Senators Hite, Manning, Cafaro, Schiavoni, Yuko, Brown

A BILL

To enact sections 3901.82, 3901.821, 3901.822, 5164.7511, 5164.7512, and 5164.7513 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 sections 3901.82, 3901.821, 3901.822, 5164.7511, 5164.7512, and 5164.7513 of the Revised Code be enacted to read as follows:

Sec. 3901.82. As used in sections 3901.82 to 3901.822 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 the medical necessity and

appropriateness of health care services.

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

(D) "Step therapy exemption determination" means a determination, based on a patient's or prescriber's request for an exemption, along with supporting rationale and documentation, as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug.

(E) "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 appropriate for a particular patient are covered by a health plan issuer.

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

Sec. 3901.821. (A) A health plan issuer or a utilization review organization that implements a step therapy protocol shall implement clinical review criteria in relation to that step therapy protocol that do 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 an independent, multidisciplinary panel of experts not affiliated with a health plan issuer or utilization review organization;

(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 biases 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 and research.

(B) 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 meet the requirements set forth in division (A) of this section.

(C) A health plan issuer or utilization review organization shall submit proposed clinical review criteria in relation to each step therapy protocol 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) 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 and convenient process to request a step therapy exemption determination. A health plan issuer or utilization review organization may use its existing medical exceptions process to satisfy this requirement. 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) The health plan issuer or utilization review organization shall expeditiously grant a step therapy exemption determination request if:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient based on the medical history of the patient and known characteristics of the prescription drug.

(2) The required prescription drug is expected to be ineffective based on the known relevant physical or mental 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 insurance or 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 appropriateness.

(5) The patient is stable on a prescription drug selected by their health care provider for the medical condition under

consideration.

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

(D) This section shall not be construed to prevent any 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 appropriate.

(E) Each health plan issuer shall maintain written or electronic records and data sufficient to demonstrate compliance with the requirements of this section and on an annual basis submit to the superintendent of insurance the following information with respect to requests made under this section:

(1) The total number of requests received;

(2) The number of requests approved and denied;

(3) Any other information the superintendent of insurance may request.

Sec. 5164.7511. (A) As used in sections 5164.7511 to 5164.7513 of the Revised Code:

(1) "Clinical practice guidelines" means a systematically

developed statement to assist medicaid providers and medicaid recipients make 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 the medical necessity and appropriateness of health care services.

(3) "Step therapy protocol" means a protocol under which it is determined through a specific sequence whether the medicaid program will pay for a medically appropriate prescribed drug that a medicaid provider prescribes for a medicaid recipient's specified medical condition.

(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) In a manner consistent with section 5164.7512 of the Revised Code, establish and implement clinical review criteria for the step therapy protocol;

(2) In a manner consistent with section 5164.7513 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 a determination of whether the step therapy protocol should apply in a particular situation or should be overridden in favor of immediate coverage of the medicaid provider's selected prescribed drug.

Sec. 5164.7512. All of the following apply to clinical

review criteria established and implemented by the department of medicaid pursuant to division (B)(1) of section 5164.7511 of the Revised Code:

(A) The criteria shall be developed and endorsed by an independent, multidisciplinary panel of experts not affiliated with the medicaid program.

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

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

(1) Minimizes biases 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.

(D) The criteria shall be continually updated through a review of new evidence and research.

Sec. 5164.7513. (A) All of the following apply to the step therapy exemption process established and implemented by the department of medicaid pursuant to division (B)(2) of section 5164.7511 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 recipient, based on the medical history of the recipient and known characteristics of the prescription drug.

(ii) It is expected to be ineffective based on the known relevant physical or mental characteristics of the recipient and the known characteristics of the prescribed drug regimen.

(iii) The 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 recipient, based on medical appropriateness.

(b) The recipient is stable on the prescribed drug selected by the recipient's medicaid provider for the medical condition under consideration.

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

prescribed drug.

(B) 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.

Section 2. (A) The Ohio General Assembly finds all of the following:

(1) That health plans, including 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 heath care provider's right to make treatment decisions in the best interest of the patient.

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

(1) That health plan issuers and other, related organizations that make coverage or benefits determinations base step therapy protocols on appropriate clinical practice guidelines 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 appropriate.

Section 3. This act shall apply to the Department of Medicaid and 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, 2016.