State of Arkansas *As Engrossed: S1/25/21 S1/28/21*
93rd General Assembly **A Bill**
Regular Session, 2021 SENATE BILL 99

By: Senators Bledsoe, D. Wallace*, Irvin*
By: Representatives Vaught, *Lundstrum*

For An Act To Be Entitled

AN ACT TO REGULATE STEP THERAPY PROTOCOLS; AND FOR OTHER PURPOSES.

Subtitle

TO REGULATE STEP THERAPY PROTOCOLS.

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

SECTION 1. Arkansas Code § 23-61-804(a)(3)(B)(iii), concerning the duties of the Arkansas Health Insurance Marketplace, is repealed.

~~(iii) Step therapy requirements;~~

SECTION 2. Arkansas Code Title 23, Chapter 79, is amended to add an additional subchapter to read as follows:

Subchapter 21 — Regulation of Step Therapy Protocols

23-79-2101. Legislative findings and intent.

(a) The General Assembly finds that:

(1) Health benefit plans are increasingly making use of step therapy protocols under which patients are required to try one (1) or more prescription drugs before coverage is provided for a drug selected by the patient's healthcare provider;

(2) Such step therapy protocols, if the step therapy protocols are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of a patient, can play an important role in controlling healthcare *costs; and*

"*(3) Without uniform policies in the state for step therapy protocols, a patient may not receive the equivalent or most appropriate treatment.*

(b) It is the intent of the General Assembly that:

(1) To require healthcare insurers to base step therapy protocols on appropriate clinical practice guidelines or published peer-reviewed data developed by independent experts with knowledge of the *condition or conditions under consideration is a matter of public interest; and*

(2) Patients have access to a fair, transparent, and independent process for requesting a step therapy protocol exception when the patient's physician deems it appropriate.

23-79-2102. Definitions.

As used in this subchapter:

(1) "Clinical practice guidelines" means a systematically *developed statement derived from peer-reviewed published medical literature, evidence-based research, and widely accepted medical practice to assist decision-making by healthcare providers and* patients about appropriate healthcare 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 a healthcare insurer, health benefit plan, or utilization review organization to determine the medical necessity and appropriateness of healthcare services;

(3) "Generic equivalent" means an AB-rated drug that is pharmaceutically and therapeutically equivalent to the drug prescribed;

(4)(A) "Health benefit plan" means an individual, blanket, or any group plan, policy, or contract for healthcare services issued, renewed, or extended in this state by a healthcare insurer, health maintenance organization, hospital medical service corporation, or self-insured governmental or church plan in this state.

(B) "Health benefit plan" includes:

(i) Indemnity and managed care plans; and

(ii) Plans providing health benefits to state and public school employees under § 21-5-401 et seq.

(C) "Health benefit plan" does not include:

(i) A disability income plan;

(ii) A credit insurance plan;

(iii) Insurance coverage issued as a supplement to liability insurance;

(iv) Medical payments under an automobile or homeowners' insurance plan;

(v) A health benefit plan provided under Arkansas Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

(vi) A plan that provides only indemnity for hospital confinement;

(vii) An accident-only plan;

(viii) A specified disease plan;

(ix) A plan that provides only dental benefits or eye and vision care benefits; or

(x) A program or plan authorized and funded under 42 U.S.C. 1396a et seq. as approved by the United States Secretary of Health and Human Services;

(5)(A) "Healthcare insurer" means an insurance company, hospital and medical service corporation, or health maintenance organization that issues or delivers health benefit plans in this state and is subject to any of the following laws:

(i) The insurance laws of this state;

(ii) Section 23-75-101 et seq., pertaining to hospital and medical service corporations; or

(iii) Section 23-76-101 et seq., pertaining to health *maintenance organizations.*

(B) "Healthcare insurer" does not include an entity that provides only dental benefits or eye and vision care benefits;

(6) "Interchangeable biological product" means a biological product that is interchangeable, as "interchangeable" is defined by 42 U.S.C. § 262(i)(3), as it existed on January 1, 2021;

(7) "Medically necessary" means healthcare services and supplies that, under the applicable standard of care, are appropriate:

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

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

(C) For the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury;

(8) "Step therapy protocol" means a protocol, policy, or program that establishes the specific sequence in which prescription drugs for a specified medical condition and that are medically appropriate for a patient are covered by a healthcare insurer or health benefit plan;

(9) "Step therapy protocol exception" means that a step therapy protocol is overridden in favor of immediate coverage of the healthcare provider's selected prescription drug; and

(10)(A) "Utilization review organization" means an individual or entity that performs step therapy for at least one (1) of the following:

(i) A healthcare insurer;

(ii) A preferred provider organization or health maintenance organization; or

(iii) Any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits to a person treated by a healthcare provider in this state under a policy, health benefit plan, or contract.

(B) A healthcare insurer is a utilization review entity if the healthcare insurer performs step therapy.

(C) "Utilization review organization" does not include an insurer of automobile, homeowners, or casualty and commercial liability insurance or the insurer's employees, agents, or contractors.

23-79-2103. Clinical review criteria.

(a)(1) Clinical review criteria used to establish a step therapy protocol shall be based on clinical practice guidelines that:

(A) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(i)(a) Requiring members to disclose any potential conflicts of interest with entities, including healthcare insurers, health benefit plans, and pharmaceutical manufacturers.

(b) A member shall recuse himself or herself

from voting if the member has a conflict of interest;

(ii) Using 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; and

(iii) Offering opportunities for public review and comments;

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

(C) Are created by an explicit and transparent process that:

(i) Minimizes biases and conflicts of interest;

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

(iii) Rates the quality of the evidence supporting recommendations; and

(iv) Considers relevant patient subgroups and preferences; and

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

(2) Peer-reviewed published medical literature may be substituted for clinical practice guidelines to establish clinical review criteria if the peer-reviewed published medical literature meets the requirements of subdivisions (a)(1)(B) and (C) of this section, when those requirements apply to the available peer-reviewed published medical literature.

(3) If establishing a step therapy protocol, a utilization review agent shall take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(4) A healthcare insurer, pharmacy benefit manager, or utilization review organization shall:

(A) Upon written request, provide all specific written clinical review criteria relating to the particular condition or disease, including clinical review criteria relating to a step therapy protocol override determination; and

(B) Make available such clinical review criteria and other clinical information on its website and to a healthcare professional on

behalf of an insured upon written request.

(b) This section does not require healthcare insurers, health benefit plans, or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

23-79-2104. Exceptions — Transparency.

(a)(1) If coverage of a prescription drug for the treatment of any medical condition is restricted for use by a healthcare insurer, health benefit plan, or utilization review organization through the use of a step therapy protocol, a patient and prescribing healthcare provider shall have access to a clear, readily accessible, and convenient process to request a step therapy protocol exception.

(2)(A) A healthcare insurer, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy the requirement under subdivision (a)(1) of this section.

(B) The existing medical exceptions process shall be made easily accessible on the website of the healthcare insurer, health benefit plan, or utilization review organization.

(C) Upon request, a healthcare insurer, health benefit plan, or utilization review organization shall disclose to a prescribing healthcare provider all rules and clinical review criteria related to the step therapy protocol, including without limitation the specific information and documentation that is required to be submitted by a prescribing healthcare provider or patient to the healthcare insurer, health benefit plan, or utilization review organization to be considered a complete step therapy protocol exception request.

(b) A step therapy protocol exception shall be expeditiously granted if:

(1) A required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient;

(2) A 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) A patient has tried the required prescription drug while under the patient's current or previous health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism

of action and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) A required prescription drug is not in the best interest of the patient, based on medical necessity; or

(5) A patient is stable on a prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on a current or previous health benefit plan.

(c)(1) The healthcare insurer, health benefit plan, or utilization review organization shall grant or deny a request for a step therapy protocol exception within seventy-two (72) hours of receiving the request.

(2) In cases in which exigent circumstances exist, the healthcare insurer, health benefit plan, or utilization review organization shall grant or deny the request within twenty-four (24) hours of receiving the request.

(d)(1) A patient covered by a healthcare insurer under a health benefit plan may appeal the denial of a request for a step therapy protocol exception.

(2) The health benefit plan shall grant or deny the appeal within seventy-two (72) hours of receiving the appeal.

(3) In cases in which exigent circumstances exist, the health benefit plan shall grant or deny the appeal within twenty-four (24) hours of receiving the appeal.

(e) If a response by a healthcare insurer, health benefit plan, or utilization review organization is not received within the time allotted under this section, the request for a step therapy protocol exception or the appeal of a denial of such a request shall be deemed granted.

(f)(1) If a request for a step therapy protocol exception is incomplete or additional clinically relevant information is required, a healthcare insurer, health benefit plan, or utilization review organization shall notify the prescribing healthcare provider within seventy-two (72) hours of submission, or twenty-four (24) hours in exigent circumstances, of the additional or clinically relevant information that is required in order to approve or deny the step therapy protocol exception request or appeal as described under subdivision (a)(1) of this section.

(2) Once the requested information is submitted, the applicable time period to grant or deny a step therapy protocol exception request or

appeal shall apply.

(3) If a determination or notice of incomplete or clinically relevant information by a healthcare insurer, health benefit plan, or utilization review organization is not received by the prescribing healthcare provider within the time allotted, the step therapy protocol exception or appeal shall be deemed granted.

(4) In the event of a denial, a healthcare insurer, health benefit plan, or utilization review organization shall inform the patient of a potential appeal process.

(g) Upon the granting of a step therapy protocol exception, a healthcare insurer, health benefit plan, or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating healthcare provider.

(h) This section shall not be construed to prevent:

(1) A healthcare insurer, a health benefit plan, or a utilization review organization from requiring:

(A) A patient to try a generic equivalent or interchangeable biological product unless such a requirement meets § 23-79-2104(b) pursuant to a step therapy protocol exception request submitted under § 23-79-2104(b); or

(B) A pharmacist to effect substitutions of prescription drugs consistent with § 17-92-503; or

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

23-79-2105. Applicability.

This subchapter applies to a group health benefit plan or offered in connection with a group health plan that provides coverage of a prescription drug under a policy that meets the definition of a medication step therapy protocol whether or not the policy is described as a step therapy protocol.

SECTION 3. Arkansas Code § 23-99-1103(15)(A), concerning the definition of "prior authorization" under the Prior Authorization Transparency Act, is amended to read as follows:

(15)(A) "Prior authorization" means the process by which a utilization review entity determines the medical necessity of an otherwise

covered healthcare service before the healthcare service is rendered, including without limitation preadmission review, pretreatment review, utilization review, case management, and fail first protocol~~, and step therapy~~.

SECTION 4. Arkansas Code § 23-99-1103(17), concerning the definition of "step therapy" under the Prior Authorization Transparency Act, is repealed.

~~(17) "Step therapy" means a protocol requiring that a subscriber shall not be allowed coverage of a prescription drug ordered by the subscriber's healthcare provider until other less expensive drugs have been tried;~~

SECTION 5. Arkansas Code § 23-99-1114 is amended to read as follows:

23-99-1114. Limitations on step therapy — Definition.

~~(a) If a utilization review entity has required a healthcare provider to utilize step therapy for a specific prescription drug for a subscriber, the utilization review entity shall not require the healthcare provider to utilize step therapy a second time for that same prescription drug, even though the utilization review entity or healthcare insurer may change its prescribed drug formulary or change to a new or different pharmacy benefits manager or utilization review entity.~~

~~(b) In order to ensure compliance with this section, if a healthcare insurer or utilization review entity changes its pharmacy benefits manager, the healthcare insurer or utilization review entity shall provide the new pharmacy benefits manager with adequate historical claims data to identify all subscribers who have been required to utilize step therapy and the results of that step therapy.~~

~~(c) Except as provided in subsection (d) of this section, notwithstanding subsection (a) of this section, a utilization review entity may require the utilization of step therapy if:~~

~~(1) A new drug has been introduced to treat the patient's condition or an existing therapy is considered clinically appropriate for treatment of the patient's condition; or~~

~~(2) The patient's medical or physical condition has changed substantially since the step therapy was required that makes the use of~~

~~repeat step therapy appropriate.~~

~~(d)(1)~~(a) An insurance policy that provides coverage for the treatment of metastatic cancer shall not limit or exclude coverage under the health benefit plan for a drug approved by the United States Food and Drug Administration that is on the prescription drug formulary of the insurance policy by mandating that a covered person with metastatic cancer undergo step therapy unless the preferred drug is consistent with best practices that:

~~(A)~~(1) Are used for the treatment of metastatic cancer or associated conditions under:

~~(i)~~(A) The United States Food and Drug Administration-approved indication; or

~~(ii)~~(B) The National Comprehensive Cancer Network Drugs and Biologics Compendium indication; or

~~(B)~~(2) Use evidence-based, peer-reviewed, recognized medical literature.

~~(2)~~(b) As used in ~~subdivision (d)(1)~~ subsection (a) of this section, "metastatic cancer" means cancer that has spread from a primary or original site of the cancer to surrounding or nearby tissues, lymph nodes, or other parts of the body.

SECTION 6. Arkansas Code § 23-99-1115(c)(1), concerning the process for appealing adverse determination and restriction or denial of healthcare service, is amended to read as follows:

(c)(1) When a healthcare service for the treatment or diagnosis of any medical condition is restricted or denied in favor of ~~step therapy or~~ a fail first protocol preferred by the utilization review entity, the subscriber's healthcare provider shall have access to a clear and convenient process to expeditiously request an override of that restriction or denial from the utilization review entity or healthcare insurer.

SECTION 7. TEMPORARY LANGUAGE. DO NOT CODIFY. Rules.

(a) The *Insurance Commissioner* shall promulgate rules necessary to implement Section 2 of this act.

(b)(1) When adopting the initial rules to implement Section 2 of this act, the final rule shall be filed with the Secretary of State for adoption under § 25-15-204(f):

(A) On or before January 1, 2022; or

(B) If approval under § 10-3-309 has not occurred by January 1, 2022, as soon as practicable after approval under § 10-3-309.

(2) The *commissioner* shall file the proposed rule with the Legislative Council under § 10-3-309(c) sufficiently in advance of January 1, 2022, so that the Legislative Council may consider the rule for approval before January 1, 2022.

SECTION 8. DO NOT CODIFY. Effective date.

Section 2 of this act is effective on and after January 1, 2022.

/s/Bledsoe

APPROVED: 2/10/21