PROPOSED RULE 107
REGULATION OF MEDICATION STEP THERAPY PROTOCOLS

SECTION 1. PURPOSE

This Rule implements Act 97 of 2021 and Act 645 of 2021, which amends a definition within Act 97. Act 97 requires healthcare insurers to base medication step therapy protocols on appropriate clinical practice guidelines or peer-reviewed data developed by independent experts with knowledge of the condition or conditions under consideration. Act 97 also ensures that 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.

SECTION 2. AUTHORITY

This Rule is issued pursuant to the authority granted the Arkansas Insurance Commissioner (“Commissioner”) by Act 97 of 2021, codified at Ark. Code Ann. § 23-79-2101 et seq., which provides the Commissioner with authority necessary to promulgate rules to implement Section 7 of Act 97 of 2021.

SECTION 3. APPLICABILITY

This subchapter applies to a group health benefit plan or health insurance coverage 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 4. DEFINITIONS

(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 a drug rated “A” or “B” by the United States Preventive Taskforce 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:

(1) Indemnity and managed care plans;

(2) Plans providing health benefits to state and public school employees under Ark. Code Ann. § 21-5-401 et seq.; and

(3) Individual qualified health insurance plans under Ark. Code Ann. § 23-61-1001 et seq.

(c) “Health benefit plan” does not include:

(1) A disability income plan;

(2) A credit insurance plan;

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

(4) Medical payments under an automobile or homeowner insurance plan;

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

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

(7) An accident-only plan;

(8) A specified disease plan;

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

(10) A program or plan authorized under 42 U.S.C. § 1396a et seq., as it existed on January 1, 2021, as approved by the United States Secretary of Health and Human Services, excluding individual qualified health plans under Ark. Code Ann. § 23-61-1001 et seq.

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

(1) The insurance laws of this state;

(2) Ark. Code Ann. § 23-75-101 et seq., pertaining to hospital and medical service corporations; or

(3) Ark. Code Ann. § 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 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.

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

(1) A healthcare insurer;

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

(3) 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, homeowner, or casualty and commercial liability insurance or the insurer's employees, agents, or contractors.

SECTION 5. DEVELOPMENT OF CLINICAL REVIEW CRITERIA

(a) Health insurers shall base clinical review criteria used to establish step therapy protocols on appropriate clinical practice guidelines or peer-reviewed published medical literature.

(b) For step therapy protocols based on clinical practice guidelines, such guidelines shall be:

(1) Developed and endorsed by a multidisciplinary panel of experts who manage conflicts of interest among the members of the writing and review groups by:

(A) Requiring members to disclose any potential conflicts of interest with entities, including healthcare insurers, health benefit plans, and pharmaceutical manufacturers, and to recuse from voting if the member has a conflict of interest;

(B) 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

(C) Offering opportunities for public review and comments;

(2) Based on high-quality studies, research, and medical practices;

(3) Created by an explicit and transparent process that:

(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; and

(D) Considers relevant patient subgroups and preferences; and

(4) Continually updated through a review of new evidence, research, and newly developed treatments.

(c) For step therapy protocols based on peer-reviewed published medical literature, such materials, when applicable, shall be:

(1) Based on high-quality studies, research, and medical practices; and

(2) Created by an explicit and transparent process that:

(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; and

(D) Considers relevant patient subgroups and preferences.

(d) 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.

(e) Healthcare insurers, health benefit plans, or the state are not required to set up a new entity to develop critical review criteria used for step therapy protocols.

SECTION 6. ACCESS TO CLINICAL REVIEW CRITERIA

(a) Upon written request, a healthcare insurer, pharmacy benefit manager, or utilization review organization shall 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) A healthcare insurer, pharmacy benefit manager, or utilization review organization shall make clinical review criteria and other clinical information available on its website and to a healthcare professional on behalf of an insured upon written request.

SECTION 7. ACCESS TO STEP THERAPY PROTOCOL EXCEPTION PROCESS

(a) 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.

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

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

(3) 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.

SECTION 8. RESPONSE TO REQUESTS FOR STEP THERAPY PROTOCOL EXCEPTIONS

(a) A healthcare insurer, health benefit plan, or utilization review organization shall expeditiously grant a step therapy protocol exception 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.

(b)(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) However, 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.

(c) 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 shall be deemed granted.

(d)(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.

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

(e) 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.

(f) 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) 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 Ark. Code Ann. § 23-79-2104(b) pursuant to a step therapy protocol exception request submitted under Ark. Code Ann. § 23-79-2104(b); or

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

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

SECTION 9. APPEALING A DENIAL OF A REQUEST FOR EXCEPTION

(a)(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.

(b) 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 appeal of a denial of a request shall be deemed granted.

(c)(1) If an appeal 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 appeal.

(2) Once the requested information is submitted, the applicable time period to grant or deny an 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 appeal shall be deemed granted.

SECTION 10. ENFORCEMENT

Violations of this Rule shall constitute an unfair or deceptive act under Ark. Code Ann. § 23-66-206. Therefore, the penalties, actions or orders, including but not limited to monetary fines, suspension, or revocation of license, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

SECTION 11. EFFECTIVE DATE

The effective date of this Rule is November 1, 2021.

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ALAN MCCLAIN
INSURANCE COMMISSIONER

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DATE