



Michael Preston  
SECRETARY OF COMMERCE

Alan McClain  
COMMISSIONER,  
ARKANSAS INSURANCE  
DEPARTMENT

July 26, 2021

Arkansas Secretary of State  
State Capitol Building  
Little Rock, AR 72201  
Attn. Arkansas Register

Re: Proposed New Rule 107 "Regulation of Medication Step Therapy Protocols"

Dear Secretary:

Arkansas Act 1478 of 2003 adds to requirements for adoption and re-adoption of public agency rules and regulations. In that regard, the new Act:

- (a) Requires notice of Proposed New Rule 107 "Regulation of Medication Step Therapy Protocols," as well as the Public Rule Hearing at the Arkansas Insurance Department, to be published by the Arkansas Secretary Of State on the Internet for thirty (30) days pursuant to Ark. Code Ann. § 25-15-218 of the Arkansas Administrative Procedure Act, as amended; and
- (b) Requires DOI filing of its adopted and proposed rules and notices with the Arkansas Secretary Of State in an electronic format acceptable to the Secretary.

In that regard, the Department has scheduled a public hearing as to Proposed New Rule 107 "Regulation of Medication Step Therapy Protocols." Enclosed are the DOI Notices of Public Hearing and a copy of the proposed rule.

Please arrange to publish the information in a format acceptable to the Secretary for at least 30 days in advance. Can you send us confirmation that we can use in the transcript as a public hearing exhibit?

An electronic filing will be made within the statutorily required 7 days. Thanks for your help.

Sincerely,

Clara Mezza  
Insurance Administrative Coordinator  
[clara.mezza@arkansas.gov](mailto:clara.mezza@arkansas.gov)  
501-371-2820

Enclosures

# ARKANSAS REGISTER

## Proposed Rule Cover Sheet



Secretary of State  
John Thurston  
500 Woodlane Street, Suite 026  
Little Rock, Arkansas 72201-1094  
(501) 682-5070  
[www.sos.arkansas.gov](http://www.sos.arkansas.gov)



Name of Department \_\_\_\_\_

Agency or Division Name \_\_\_\_\_

Other Subdivision or Department, If Applicable \_\_\_\_\_

Previous Agency Name, If Applicable \_\_\_\_\_

Contact Person \_\_\_\_\_

Contact E-mail \_\_\_\_\_

Contact Phone \_\_\_\_\_

---

Name of Rule \_\_\_\_\_

Newspaper Name \_\_\_\_\_

Date of Publishing \_\_\_\_\_

Final Date for Public Comment \_\_\_\_\_

Location and Time of Public Meeting \_\_\_\_\_

# **PROPOSED RULE 107**

## **REGULATION OF MEDICATION STEP THERAPY PROTOCOLS**

1. PURPOSE
2. AUTHORITY
3. APPLICABILITY
4. DEFINITIONS
5. DEVELOPMENT OF CLINICAL REVIEW CRITERIA
6. ACCESS TO CLINICAL REVIEW CRITERIA
7. ACCESS TO STEP THERAPY PROTOCOL EXCEPTION PROCESS
8. RESPONSE TO REQUESTS FOR STEP THERAPY PROTOCOL EXCEPTIONS
9. APPEALING A DENIAL OF A REQUEST FOR EXCEPTION
10. ENFORCEMENT
11. EFFECTIVE DATE

### **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.

---

ALAN MCCLAIN  
INSURANCE COMMISSIONER

---

DATE

## **SUMMARY**

### **ARKANSAS INSURANCE DEPARTMENT PROPOSED RULE 107**

#### **Regulation of Medication Step Therapy Protocols**

=====

To: Arkansas Legislative Council & Arkansas Bureau of Legislative Research

From: Crystal Phelps, Associate Counsel, Arkansas Insurance Department

CC: Alan McClain, Arkansas Insurance Commissioner; Steve Porch, General Counsel, Arkansas Department of Commerce; Russ Galbraith, Deputy Insurance Commissioner; Jim Brader, General Counsel; Jennifer Bruce, Public and Legislative Affairs Director

Date: July 22, 2021

=====

#### **LEGISLATIVE AUTHORITY FOR RULE**

This proposed Rule implements Act 97 of 2021, Section 7(a), which requires the Arkansas Insurance Department to issue rules implementing Act 97.

#### **BACKGROUND AND PURPOSE OF RULE**

The purpose of this Rule is to implement Act 97 of 2021, which requires healthcare insurers to base medication step therapy protocols on appropriate clinical practice guidelines or published peer-reviewed medical literature and to offer a fair, transparent process for requesting a step therapy protocol exception.

#### **EXPLANATION OF THE PROPOSED RULE**

Health insurers often control healthcare costs through implementing medication step therapy protocols to encourage insureds to choose lower-priced medications before taking more expensive drugs. A health insurer may not cover the higher-priced medication until patient experience demonstrates that lower-priced options do not work for the patient. Sometimes requiring a person to follow a step therapy protocol may have adverse or dangerous consequences for a patient who may be forced to take an inappropriate drug prior to coverage of a more expensive drug. Step therapy protocols may also interfere with a health care provider's right to make treatment decisions.

These protocols are becoming more common and are not always applied consistently. This proposed Rule establishes standards for developing clinical review criteria for medication step therapy protocols. It also describes the process for requesting an exception to a step therapy protocol and the circumstances that require an insurer to grant an exception. The Rule provides a timeline for responding to exception requests and deems any insurer who fail to respond to a request within a specified time period to have approved the request for exception.

Violations of this rule are considered to be unfair or deceptive acts under Ark. Code Ann. § 23-66-206, the Trade Practices Act. 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, apply to violations of this Rule.



Michael Preston  
SECRETARY OF COMMERCE

Alan McClain  
COMMISSIONER,  
ARKANSAS INSURANCE  
DEPARTMENT

## NOTICE OF PUBLIC HEARING AND COMMENT

The Arkansas Insurance Department will host a Public Hearing on August 26, 2021, at 9:30 AM, in the Second Floor Diamond Mine Hearing Room, in the Arkansas Department of Commerce Building, One Commerce Way, Little Rock, Arkansas 72202. The Arkansas Insurance Commissioner is considering adopting proposed Rule 107, implementing Act 97 of 2021, which 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 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. The Rule also creates a mechanism for enforcement and establishes penalties for nonconformance. This Notice is required by the Arkansas Administrative Procedures Act in Ark. Code Ann. § 25-15-206. Copies of the proposed Rule may be obtained by writing or calling the Arkansas Insurance Department, or by visiting its Internet site at <https://www.insurance.arkansas.gov/pages/industry-regulation/legal/proposed-rules/>. Comments from the public will be accepted until August 26, 2021 and may be submitted to the Department in writing at the address above or electronically to the following email address: [insurance.legal@arkansas.gov](mailto:insurance.legal@arkansas.gov). For more information, please contact Ms. Clara Mezza, Legal Division, Arkansas Insurance Department at 501-371-2820.



Michael Preston  
SECRETARY OF COMMERCE

Alan McClain  
COMMISSIONER,  
ARKANSAS INSURANCE  
DEPARTMENT

DATE: JULY 23, 2021  
TO: ALL INTERESTED PARTIES  
FROM: ARKANSAS INSURANCE DEPARTMENT  
SUBJECT: RULE 107: "Regulation of Medication Step Therapy Protocols"

### **NOTICE OF PUBLIC HEARING**

Please find attached or available by electronic publication by the Arkansas Insurance Department ("AID") Proposed Rule 107, "Regulation of Medication Step Therapy Protocols".

Pursuant to Arkansas Administrative Procedures Act, and other applicable laws or rules, NOTICE is hereby given that a PUBLIC HEARING will be held on August 26, 2021 at 09:30 A.M., in the Second Floor Hearing Room ("Diamond Mine"), at the Arkansas Department of Commerce, 1 Commerce Way, Little Rock, AR 72202.

The Arkansas Insurance Commissioner is considering adopting proposed Rule 107, implementing Act 97 of 2021, which 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 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. The Rule also creates a mechanism for enforcement and establishes penalties for nonconformance.

This Notice is required by Ark. Code Ann. § 25-15-206 of the Arkansas Administrative Procedures Act. Copies of the proposed Rule may be obtained by writing or calling the Arkansas Insurance Department, or by visiting its Internet site at <https://www.insurance.arkansas.gov/pages/industry-regulation/legal/proposed-rules/>. Comments from the public will be accepted until 4:30 PM on August 27, 2021 and may be submitted to the Department in writing at the address above or electronically to the following email address: [insurance.legal@arkansas.gov](mailto:insurance.legal@arkansas.gov).

Sincerely,

Crystal Phelps,  
Associate Counsel  
Arkansas Insurance Department

## NOTICE OF PUBLIC HEARING AND COMMENT

The Arkansas Insurance Department will host a Public Hearing on August 26, 2021, at 9:30 AM, in the Second Floor Diamond Mine Hearing Room, in the Arkansas Department of Commerce Building, One Commerce Way, Little Rock, Arkansas 72202. The Arkansas Insurance Commissioner is considering adopting proposed Rule 107, implementing Act 97 of 2021, which 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 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. The Rule also creates a mechanism for enforcement and establishes penalties for nonconformance. This Notice is required by Ark. Code Ann. § 25-15-206 of the Arkansas Administrative Procedures Act. Copies of the proposed Rule may be obtained by writing or calling the Arkansas Insurance Department, or by visiting its Internet site at <https://www.insurance.arkansas.gov/pages/industry-regulation/legal/proposed-rules/>. Comments from the public will be accepted until 4:30 PM on August 27, 2021 and may be submitted to the Department in writing at the address above or electronically to the following email address: [insurance.legal@arkansas.gov](mailto:insurance.legal@arkansas.gov).

**ECONOMIC IMPACT STATEMENT  
OF PROPOSED RULES OR REGULATIONS  
EO 05-04: Regulatory Flexibility**

**Department:** Arkansas Insurance Department  
**Contact Person:** Crystal Phelps  
**Contact Phone:** (501) 371-2841

**Division:** Legal  
**Date:** July 22, 2021  
**Contact Email:** crystal.phelps@arkansas.gov

**Title or Subject:**

Proposed Rule 107: Regulation of Medication Step Therapy Protocols

**Benefits of the Proposed Rule or Regulation**

1. Explain the need for the proposed change(s). Did any complaints motivate you to pursue regulatory action? If so, please explain the nature of such complaints.

Proposed Rule 107 implements Act 97 of 2021 pertaining to medication step therapy protocols. The Arkansas Insurance Department is proposing this Rule to comply with Act 97's mandate instructing the Department to promulgate rules. The Department is unaware of any complaints.

2. What are the top three benefits of the proposed rule or regulation?

(1) The Proposed Rule requires consistent development of clinical review criteria used to establish medication step therapy protocols; (2) the Proposed Rule requires consistent treatment of patients requesting a step therapy protocol exception; and (3) the Proposed Rule establishes a timeframe for insurers to follow when responding to requests for exceptions.

See attached Summary.

3. What, in your estimation, would be the consequence of taking no action, thereby maintaining the status quo?

There would continue to be no uniformity in the establishment and administration of medication step therapy protocols. Patients forced to undergo step therapy before an insurer covers a more expensive medication could suffer harm as a result of delay or lack of coverage.



4. Describe market-based alternatives or voluntary standards that were considered in place of the proposed regulation and state the reason(s) for not selecting those alternatives.

None.

### **Impact of Proposed Rule or Regulation**

5. Estimate the cost to state government of collecting information, completing paperwork, filing, recordkeeping, auditing and inspecting associated with this new rule or regulation.

None.

6. What types of small businesses will be required to comply with the proposed rule or regulation? Please estimate the number of small businesses affected.

None.

7. Does the proposed regulation create barriers to entry? If so, please describe those barriers and why those barriers are necessary.

None.

8. Explain the additional requirements with which small business owners will have to comply and estimate the costs associated with compliance.

None.

9. State whether the proposed regulation contains different requirements for different sized entities, and explain why this is, or is not, necessary.

None.

10. Describe your understanding of the ability of small business owners to implement changes required by the proposed regulation.

The Proposed Rule does not require small business owners to implement changes.

11. How does this rule or regulation compare to similar rules and regulations in other states or the federal government?

Neighboring states have similar laws and rules regulating medication step therapy protocols. On the federal side, a bill referred to the Senate Health, Education, Labor, and Pensions Committee would amend the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide similar processes for medication step therapy protocols.

12. Provide a summary of the input your agency has received from small business or small business advocates about the proposed rule or regulation.

We have received no comments from small businesses at this time.

**QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS  
WITH THE ARKANSAS LEGISLATIVE COUNCIL**

**DEPARTMENT/AGENCY** Arkansas Insurance Department  
**DIVISION** Legal Division  
**DIVISION DIRECTOR** Jim Brader  
**CONTACT PERSON** Crystal Phelps  
**ADDRESS** 1200 West Third Street  
**PHONE NO.** (501) 371-2841 **FAX NO.** (501) 371-2618 **E-MAIL** crystal.phelps@arkansas.gov  
**NAME OF PRESENTER AT COMMITTEE MEETING** Crystal Phelps, Associate Counsel  
**PRESENTER E-MAIL** crystal.phelps@arkansas.gov

**INSTRUCTIONS**

- A. Please make copies of this form for future use.  
B. Please answer each question **completely** using layman terms. You may use additional sheets, if necessary.  
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.  
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Jessica Sutton, ESQ.  
Administrative Rules Review Section  
Arkansas Legislative Council  
Bureau of Legislative Research  
One Capitol Mall, 5<sup>th</sup> Floor  
Little Rock, AR 72201

\*\*\*\*\*

1. What is the short title of this rule? Rule 107 Regulation of Medication Step Therapy Protocols
2. What is the subject of the proposed rule? Proposed Rule 107 implements Act 97 of 2021 which provides uniform standards for development and administration of medication step therapy protocols.
3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No ☒  
If yes, please provide the federal rule, regulation, and/or statute citation. \_\_\_\_\_
4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes ☐ No ☒  
If yes, what is the effective date of the emergency rule? N/A
- When does the emergency rule N/A

expire?

---

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?

Yes ☐

No ☒

5. Is this a new rule? Yes ☒ No ☐

If yes, please provide a brief summary explaining the regulation. See Attached Summary

Does this repeal an existing rule? Yes ☐ No ☒

If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. \_\_\_\_\_

Is this an amendment to an existing rule? Yes ☐ No ☒

If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation.

Act 97 of 2021, Section 7(a), requires the Arkansas Insurance Department to issue rules for the regulation of step therapy protocols.

7. What is the purpose of this proposed rule? Why is it necessary?

Step therapy requires patients to try and fail one or more medications before an insurer will cover a more expensive medication. Medication step therapy protocols reduce health expenses, but the process for obtaining an exception to a protocol is often lengthy and unclear. Following a step therapy protocol may prolong ineffective treatment and delay access to more effective treatment, resulting in increased disease activity, loss of function, or progression of deteriorating conditions. This Rule implements Act 97 by setting transparent and fair standards for developing and administering medication step therapy protocols and requests for exceptions from step therapy protocols.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). <https://www.insurance.arkansas.gov/pages/industry-regulation/>

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐

If yes, please complete the following:

Date: August 26, 2021

Time: 9:30 A.M.

Arkansas Department of Commerce,  
Second Floor Hearing Room, 1  
Commerce Way , Little Rock, AR

Place: 72202

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

August 27, 2021 at 4:30 PM

---

11. What is the proposed effective date of this proposed rule? (Must provide a date.)

November 1, 2021

---

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. We will update this after we send out our NOPH (“Notice of Public Hearing”) and receive newspaper documentation from the Arkansas Democrat-Gazette.

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e).

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

The Department does not know at this time but will update BLR and ALC in the public comments summary following the close of the comment period and public hearing.

## FINANCIAL IMPACT STATEMENT

### PLEASE ANSWER ALL QUESTIONS COMPLETELY

**DEPARTMENT** Arkansas Insurance Department

**DIVISION** Legal Division

**PERSON COMPLETING THIS STATEMENT** Crystal Phelps

**TELEPHONE** (501) 371-2841 **FAX** (501) 371-2618 **EMAIL:** crystal.phelps@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

**SHORT TITLE OF THIS RULE** Rule 107 Regulation of Medication Step Therapy Protocols

1. Does this proposed, amended, or repealed rule have a financial impact?      Yes ☐      No ☒
2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?      Yes ☒      No ☐
3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered?      Yes ☒      No ☐

If an agency is proposing a more costly rule, please state the following:

(a) How the additional benefits of the more costly rule justify its additional cost;

\_\_\_\_\_

(b) The reason for adoption of the more costly rule;

\_\_\_\_\_

(c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

\_\_\_\_\_

(d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

\_\_\_\_\_

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

(a) What is the cost to implement the federal rule or regulation?

NONE or NOT APPLICABLE.

#### Current Fiscal Year

General Revenue \_\_\_\_\_  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_

#### Next Fiscal Year

General Revenue \_\_\_\_\_  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_

Other (Identify) \_\_\_\_\_  
Total \_\_\_\_\_

Other (Identify) \_\_\_\_\_  
Total \_\_\_\_\_

(b) What is the additional cost of the state rule?

NONE

**Current Fiscal Year**

General Revenue \_\_\_\_\_  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_  
Total \_\_\_\_\_

**Next Fiscal Year**

General Revenue \_\_\_\_\_  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_  
Total \_\_\_\_\_

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

This rule does not create any additional expense for private individuals, entities, or businesses.

**Current Fiscal Year**

\$ \_\_\_\_\_

**Next Fiscal Year**

\$ \_\_\_\_\_

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

NONE

**Current Fiscal Year**

\$ \_\_\_\_\_

**Next Fiscal Year**

\$ \_\_\_\_\_

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

NOT APPLICABLE

Yes ☐ No ☐

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
  - (a) justifies the agency's need for the proposed rule; and
  - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
  - (a) the rule is achieving the statutory objectives;
  - (b) the benefits of the rule continue to justify its costs; and
  - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.





Michael Preston  
SECRETARY OF COMMERCE

Alan McClain  
COMMISSIONER,  
ARKANSAS INSURANCE  
DEPARTMENT

July 26, 2021

Ms. Jessica Whittaker, ESQ.  
Arkansas Legislative Council  
Arkansas Bureau of Legislative Research  
State Capitol, Suite 315  
Little Rock, Arkansas 72201

RE: Proposed New Rule 107 "Regulation of Medication Step Therapy Protocols"

Dear Ms. Whittaker:

Enclosed for your review and for filing with the Arkansas Legislative Council is Proposed New Rule 107 "Regulation of Medication Step Therapy Protocols."

Pursuant to Arkansas Administrative Procedure Act, and other applicable laws or rules, NOTICE is hereby given that a PUBLIC HEARING will be held on August 26, 2021, at 09:30 A.M., in the Second Floor Hearing Room (Diamond Mine Room), at the Arkansas Department of Commerce, 1 Commerce Way, Little Rock, AR 72202.

The purpose of the Public Hearing will be to determine whether the Department should adopt the Proposed New Rule 107 "Regulation of Medication Step Therapy Protocols." The Arkansas Insurance Commissioner is considering adopting Proposed New Rule 107 "Regulation of Medication Step Therapy Protocols" to implement Act 357 of 2021, which describes circumstances under which health benefit plans are required to provide coverage for early refills of prescription eye drops. The Rule also creates a mechanism for enforcement and establishes penalties for nonconformance.

I have enclosed the proposed Rule, our Notice of Public Hearing, the standard Questionnaire, Financial Impact Statement as well as a summary of the proposed Rule.

Sincerely,

Crystal Phelps  
Associate Counsel/Legal Division  
[crystal.phelps@arkansas.gov](mailto:crystal.phelps@arkansas.gov)

cc: Brandy Wedsted, Administrative Analyst  
Clara Mezza, Insurance Administrative Coordinator

State of Arkansas  
93rd General Assembly  
Regular Session, 2021

# A Bill

SENATE BILL 446

By: Senator Bledsoe  
By: Representative Vaught

## For An Act To Be Entitled

AN ACT TO CLARIFY THE APPLICABILITY OF STEP THERAPY  
PROTOCOLS; TO AMEND THE DEFINITION OF "HEALTH BENEFIT  
PLAN" TO INCLUDE INDIVIDUAL QUALIFIED HEALTH  
INSURANCE PLANS; AND FOR OTHER PURPOSES.

## Subtitle

TO CLARIFY THE APPLICABILITY OF STEP  
THERAPY PROTOCOLS; AND TO AMEND THE  
DEFINITION OF "HEALTH BENEFIT PLAN" TO  
INCLUDE INDIVIDUAL QUALIFIED HEALTH  
INSURANCE PLANS.

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

SECTION 1. Arkansas Code § 23-79-2102(4), as enacted by Acts 2021, No.  
97, and concerning the definition of "health benefit plan" used in the  
regulation of step therapy protocols, is amended to read as follows:

(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.; and



(iii) Individual qualified health insurance plans under § 23-61-1001 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 it existed on January 1, 2021, as approved by the United States Secretary of Health and Human Services, excluding individual qualified health insurance plans under § 23-61-1001 et seq.;

APPROVED: 4/12/21

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

# A Bill

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



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

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

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

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

13  
14           23-79-2102. Definitions.

15           As used in this subchapter:

16                   (1) "Clinical practice guidelines" means a systematically  
17 developed statement derived from peer-reviewed published medical literature,  
18 evidence-based research, and widely accepted medical practice to assist  
19 decision-making by healthcare providers and patients about appropriate  
20 healthcare for specific clinical circumstances and conditions;

21                   (2) "Clinical review criteria" means the written screening  
22 procedures, decision abstracts, clinical protocols, and clinical practice  
23 guidelines used by a healthcare insurer, health benefit plan, or utilization  
24 review organization to determine the medical necessity and appropriateness of  
25 healthcare services;

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

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

33                   (B) "Health benefit plan" includes:

34                           (i) Indemnity and managed care plans; and

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

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

2 (i) A disability income plan;

3 (ii) A credit insurance plan;

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

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

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

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

13 (vii) An accident-only plan;

14 (viii) A specified disease plan;

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

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

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

24 (i) The insurance laws of this state;

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

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

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

31 (6) "Interchangeable biological product" means a biological  
32 product that is interchangeable, as "interchangeable" is defined by 42 U.S.C.  
33 § 262(i)(3), as it existed on January 1, 2021;

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

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

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

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

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

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

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

14 (i) A healthcare insurer;

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

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

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

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

26  
27 23-79-2103. Clinical review criteria.

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

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

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

36 (b) A member shall recuse himself or herself

1 from voting if the member has a conflict of interest;

2 (ii) Using a methodologist to work with writing  
3 groups to provide objectivity in data analysis and ranking of evidence  
4 through the preparation of evidence tables and facilitating consensus; and

5 (iii) Offering opportunities for public review and  
6 comments;

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

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

11 (i) Minimizes biases and conflicts of interest;

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

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

16 (iv) Considers relevant patient subgroups and  
17 preferences; and

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

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

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

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

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

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



1 behalf of an insured upon written request.

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

5  
6 23-79-2104. Exceptions – Transparency.

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

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

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

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

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

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

31 (2) A required prescription drug is expected to be ineffective  
32 based on the known clinical characteristics of the patient and the known  
33 characteristics of the prescription drug regimen;

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

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

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

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

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

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

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

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

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

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

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

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

1 appeal shall apply.

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

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

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

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

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

17 (A) A patient to try a generic equivalent or  
18 interchangeable biological product unless such a requirement meets § 23-79-  
19 2104(b) pursuant to a step therapy protocol exception request submitted under  
20 § 23-79-2104(b); or

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

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

25  
26 23-79-2105. Applicability.

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

31  
32 SECTION 3. Arkansas Code § 23-99-1103(15)(A), concerning the  
33 definition of "prior authorization" under the Prior Authorization  
34 Transparency Act, is amended to read as follows:

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

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

5  
6 SECTION 4. Arkansas Code § 23-99-1103(17), concerning the definition  
7 of "step therapy" under the Prior Authorization Transparency Act, is  
8 repealed.

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

13  
14 SECTION 5. Arkansas Code § 23-99-1114 is amended to read as follows:  
15 23-99-1114. Limitations on step therapy – Definition.

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

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

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

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

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

1 ~~repeat step therapy appropriate.~~

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

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

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

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

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

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

20  
21 SECTION 6. Arkansas Code § 23-99-1115(c)(1), concerning the process  
22 for appealing adverse determination and restriction or denial of healthcare  
23 service, is amended to read as follows:

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

30  
31 SECTION 7. TEMPORARY LANGUAGE. DO NOT CODIFY. Rules.

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

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

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

4                   (2) The commissioner shall file the proposed rule with the  
5 Legislative Council under § 10-3-309(c) sufficiently in advance of January 1,  
6 2022, so that the Legislative Council may consider the rule for approval  
7 before January 1, 2022.

8  
9           SECTION 8. DO NOT CODIFY. Effective date.

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

11  
12  
13                               /s/Bledsoe  
14

15  
16                               APPROVED: 2/10/21  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36