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

Clara Mezza
Insurance Administrative Coordinator
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

Name of Department Arkansas Department of Commerce

Agency or Division Name Arkansas Insurance Department

Other Subdivision or Department, If Applicable Legal Division

Previous Agency Name, If Applicable

Contact Person Crystal Phelps, Associate Counsel

Contact E-mail crystal.phelps@arkansas.gov

Contact Phone 501-371-2841

Name of Rule Proposed New Rule 107 Regulation of Medication Step Therapy Protocals

Newspaper Name Arkansas Democrat Gazette

Date of Publishing July 25, July 26 July 27

Final Date for Public Comment August 27, 2021

Location and Time of Public Meeting August 26, 2021 9:30 AM,Second Floor Diamond Mine Room, Arkansas Department of Commerce Building, One Commerce Way, Little Rock, Arkansas

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.

_____

ALAN MCCLAIN
INSURANCE COMMISSIONER

_____

DATE

SUMMARY

ARKANSAS INSURANCE DEPARTMENT PROPOSED RULE 107

Regulation of Medication Step Therapy Protocols

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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. 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.

Sincerely,

Crystal Phelps

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.

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

Department: Arkansas Insurance Department **Division:** Legal
Contact Person: Crystal Phelps **Date:** July 22, 2021
Contact Phone: (501) 371-2841 **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, 5th 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.
   Place: Arkansas Department of Commerce, Second Floor Hearing Room, 1 Commerce Way , Little Rock, AR 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		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	

Other (Identify)		Other (Identify)	
Total		Total	

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

NONE

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total		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**
$	$

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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**
$	$

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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

Crystal Phelps
Associate Counsel/Legal Division
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 **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