ARKANSAS REGISTER

Proposed Rule Cover Sheet

Secretary of State
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Name of Department Department of Human Services

Agency or Division Name Division of Medical Services

Other Subdivision or Department, If Applicable N/A

Previous Agency Name, If Applicable N/A

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Name of Rule Pharmacy (1-22) Provider Manual change for combining the DUR Board and DRC

Newspaper Name Arkansas Democrat Gazette

Date of Publishing September 25th - September 27th

Final Date for Public Comment October 24, 2022

Location and Time of Public Meeting October 5@10:30amhttps://us02web.zoom.us/j/88442714370

TOC not required

240.000 PRIOR AUTHORIZATION 8-1-21~~1-1-23~~

Prescription drugs may be reimbursed under the Arkansas Medicaid Program pursuant to an order from an authorized prescriber.

The prescriber must initiate the prior authorization (PA) for prescription drugs that require PA. The PA request must be completed and submitted by the prescriber.– All PA documentation must remain in the patient's chart and will be subject to audit by the Division of Medical Services or its authorized representatives.

In addition, clinical edits will be established through a system modification enhancement, as well as limits placed on drugs based on age, gender, quantity, and dosage, as approved by our Drug Utilization Review Board.– Lists of all drugs, subject to clinical editing and the criteria for reimbursement, are maintained by DHS or its contracted Pharmacy Vendor.– **View or print the DHS Contracted Pharmacy Vendor Help Desk contact information.**

Arkansas Medicaid Pharmacy Program will maintain a Preferred Drug List based on comparative evidence-based data from Clinical Evidence Reports (CER).– Arkansas Medicaid Pharmacy Program will use the CER to identify drug class or drug classes of medications that have similar indications, efficacy, and safety.– Arkansas Medicaid will negotiate state supplemental rebates with manufacturers for the identified medication(s), pursuant to a CMS approved State Supplemental Rebate Agreement.– A Drug Cost Committee (DCC) will review both State Supplemental and Federal rebates to determine the final net cost to the State ~~of the identified medication(s).– A Drug Review Committee (DRC)~~ The Drug Utilization Review (DUR) Board will review the CER to determine safety and efficacy of the identified medication(s).– The DCC and ~~DRC~~ DUR Board will provide recommendations to the State for preferred and non-preferred status for the identified medication(s).– Arkansas Medicaid will use these recommendations to establish and maintain a Preferred Drug List.

In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy may dispense up to a five-day supply of a drug that requires prior authorization.– This provision applies only in an ***emergency*** situation when the DHS Contracted Pharmacy Vendor Help Desk and the State Medicaid Pharmacy Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription.– The Emergency Supply Policy does not apply to drugs that are not covered by the State.– Frequency of the emergency override is limited to ~~once~~one (1) time per year per drug class for non-LTC beneficiaries and ~~once~~one (1) time per sixty (60) days per drug class for LTC beneficiaries.– To file a claim using this emergency provision, the pharmacy provider will submit a "03" in the Level of Service (418-DI) field.

Prior Authorization information is maintained by DHS or its contracted Pharmacy Vendor.– **View or print the DHS Contracted Pharmacy Vendor Help Desk contact information.**

The following information is available:

A. Prescription Drug Clinical Edits

B. Prescription Drug Claim Edits

C. Prescription Drug PA Forms

D. VRS System Brochure, and

E. Evidence-Based Prescription Drug Program.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services

DIVISION OFA – Medicaid Finance

PERSON COMPLETING THIS STATEMENT Jason Callan

TELEPHONE 501-320-6540 **FAX** _____ **EMAIL:** Jason.Callan@dhs.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 Pharmacy (1-22) Provider Manual change for combining the DUR Board and DRC

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?

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?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	$0	General Revenue	$0
Federal Funds	$0	Federal Funds	$0
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0	Total	$ 0

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.

Current Fiscal Year	**Next Fiscal Year**
$ 0	$ 0

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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.

Current Fiscal Year	**Next Fiscal Year**
$ 0	$ 0

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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?

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.

Statement of Necessity and Rule Summary

Pharmacy (1-22) Provider Manual Change for Combining the DUR Board and DRC

Why is this change necessary? Please provide the circumstances that necessitate the change.
Combining the Drug Utilization Review (DUR) Board and the Drug Review Committee (DRC) will streamline the Arkansas Medicaid drug review process. Currently, the DUR Board reviews new drugs to the market and drug classes for implementing clinical criteria for point-of-sale claim adjudication and for prior authorization review by the Arkansas Medicaid pharmacy program and the pharmacy vendor staff. The DRC reviews drug classes to be included in the preferred drug list with preferred and non-preferred options recommended based on clinical safety and efficacy information.

The combined board will continue to be known as the DUR board.

Many of the topics discussed during the DUR Board meeting are also discussed during the DRC meeting. Sometimes, this confuses Medicaid staff and the board or committee members. Criteria decided during the DUR Board meeting will sometimes not be applicable when the preferred drug list is recommended in the DRC meeting. Combining the DUR and DRC allows for criteria discussion at the same time as preferred drug list placement. Combining the committees also will decrease some of the confusion and make for a more efficient process. The Pharmacy Provider Manual is being revised to reflect this change.

What is the change? Please provide a summary of the change.
Pharmacy Provider Manual
Section 240.000 - Prior Authorization

- Replaced Drug Review Committee (DRC) with Drug Utilization Review (DUR) Board;
- Revised language from “once" to one (1) time when discussing frequency of emergency override.

Please attach additional documents if necessary

NOTICE OF RULE MAKING

The Director of the Division of Medical Services of the Department of Human Services announces for a public comment period of thirty (30) calendar days a notice of rulemaking for the following proposed rule under one or more of the following chapters, subchapters, or sections of the Arkansas Code: §§20-76-201, 20-77-107, and 25-10-129.

Effective January 1, 2023:

The Director of the Division of Medical Services amends Section 240.000 of the Pharmacy Provider Manual to combine the Drug Utilization Review (DUR) Board and the Drug Review Committee (DRC). The combined board will streamline the Arkansas Medicaid drug review process and allow for criteria discussion at the same time as preferred drug list placement.

The proposed rule is available for review at the Department of Human Services (DHS) Office of Rules Promulgation, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. You may also access and download the proposed rule at https://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/. Public comments must be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than October 24, 2022. Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

A public hearing by remote access only through a Zoom webinar will be held on October 5th, 2022 at 10:30am. and public comments may be submitted at the hearing. Individuals can access this public hearing at https://us02web.zoom.us/j/88442714370. The webinar ID is 884 4271 4370. If you would like the electronic link, "one-tap" mobile information, listening only dial-in phone numbers, or international phone numbers, please contact ORP at ORP@dhs.arkansas.gov.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-534-4138.

The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color or national origin. 4502100209

Elizabeth Pitman, Director
Division of Medical Services