

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Pharmacy 2-21 and Medicaid State Plan Amendment (SPA) 2021-0009, based on Act 758

DESCRIPTION:

Statement of Necessity

The 93rd General Assembly enacted Act 758. Act 758 allows six (6) prescription refills per month for adult Medicaid clients. In addition, the act includes additions to the list of prescription medications that do not count against the monthly prescription benefit cap. The medications added include prescriptions for high blood pressure, hypercholesterolemia, blood modifiers, diabetes, or respiratory inhalers. The Division of Medical Services is revising Section II of the Pharmacy Provider Manual as well as updating the Medicaid State Plan Amendment (SPA) to reflect the changes in Act 758.

Rule Summary

Pharmacy Provider Manual Section II: Replaced the term “beneficiary” with “client” identified in each revised section.

Section 213.100 Monthly Prescription Limits (B)

- Replaced three (3) with six (6)
- Added, “6. Prescriptions for the treatment of high blood pressure.”
- Added, “7. Prescriptions for the treatment of hypercholesterolemia.”
- Added, “8. Blood modifier medications.”
- Added, “9. Prescriptions for the treatment of diabetes.”
- Added, “10. Inhalers to treat respiratory illness.”
- Added, “C. Living Choices Assisted Living Program clients are eligible for up to nine (9) medically necessary prescriptions per month.”
- Added, “D. After the client has received the maximum monthly benefit or the maximum monthly extended benefit, they will be responsible for paying for their own medications for the remainder of the month.”

Deleted Section 213.110 - Extension of Benefits

Section 213.200 - Prescription Refill Limit

- Added, “Refills shall be in accordance with federal and state laws.”
- Deleted, “In no event is any prescription to be refilled more than five (5) times or beyond six (6) months after the date of the original issue, whichever comes first. Renewals or continuation of drug therapy beyond five refills or six months requires a new, original prescription.”

Section 215.000 – Child Health Services/Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program

- Deleted, “B. No refills are reimbursable after the five (5) refills or the six month period specified in Section 213.200 of this manual.”

Section 216.201 – Prescription Benefits for Hospice Patients in Long-Term Care Facilities

- Added, “Please refer to section 213.100 for monthly prescription limits.”
- Deleted, “These beneficiaries are only allowed three (3) prescriptions per month. If additional prescriptions are needed, an extension of drug benefits may be requested for up to a total of six (6) maintenance medications per month.”

Section 216.202 – Regulations governing Cycle-Fill and Pharmacy Notifications for Long-Term Care Facilities

- Deleted, “Per Section 213.200, the six (6) month prescription renewal is required for LTC eligible beneficiaries residing in LTC facilities. However, for those drugs that can be cycle filled as stated above, the five (5) refill limit does not apply.”

Arkansas Medicaid State Plan

SPA page 31A5a – Categorically Needy

- Deleted, “The first three (3) prescriptions do not require prior authorization. The three (3) additional prescriptions must be prior authorized.”
- Added, “..., EPSDT, high blood pressure, hypercholesterolemia, blood modifiers, diabetes, and respiratory illness inhaler...”

SPA page 31B4g - Medically Needy

- Deleted, “The first three (3) prescriptions do not require prior authorization. The three (3) additional prescriptions must be prior authorized.”
- Added, “..., EPSDT, high blood pressure, hypercholesterolemia, blood modifiers, diabetes, and respiratory illness inhaler...”

PUBLIC COMMENT: A public hearing was held on this rule on October 20, 2021. The public comment period expired on November 8, 2021. The agency indicated that it received no public comments.

The proposed effective date is January 1, 2022.

FINANCIAL IMPACT: The agency indicated that this rule has a financial impact. Per the agency, the total cost to implement this rule is \$30,537,600 for the current fiscal year (\$8,666,571 in general revenue and \$21,871,029 in federal funds) and \$61,075,200 for the next fiscal year (\$17,333,142 in general revenue and \$43,742,058 in federal funds). The total estimated cost to state, county, and municipal government to implement this rule is \$8,666,571 for the current fiscal year and \$17,333,142 for the next fiscal year.

The agency indicated that there is a new or increased cost or obligation of at least \$100,000 per year to a private individual, private entity, private business, state

government, county government, municipal government, or to two or more of those entities combined. Accordingly, the agency provided the following written findings:

(1) a statement of the rule's basis and purpose;

The 93rd General Assembly enacted Act 758. Act 758 allows six (6) prescription refills per month for adult Medicaid clients. In addition, the Act includes additional medications to the list of prescriptions that do not count against the monthly prescription benefit cap. The medications added include prescriptions for high blood pressure, hypercholesterolemia, blood modifiers, diabetes, or respiratory inhalers. The Division of Medical Services is revising Section II of the Pharmacy Provider Manual as well as updating the Medicaid State Plan Amendment (SPA) to reflect the changes in Act 758.

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

We are making this change to align the State Plan with Act 758.

(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;

We are making this change to align the State Plan with Act 758.

(3) 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;

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(4) 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;

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(5) 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

We are making this change to align the State Plan with Act 758.

(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.*

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LEGAL AUTHORIZATION: The Department of Human Services has the responsibility to administer assigned forms of public assistance and is specifically authorized to maintain an indigent medical care program (Arkansas Medicaid). *See* Ark. Code Ann. §§ 20-76-201(1), 20-77-107(a)(1). The Department has the authority to make rules that are necessary or desirable to carry out its public assistance duties. Ark. Code Ann. § 20-76-201(12). The Department and its divisions also have the authority to promulgate rules as necessary to conform their programs to federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

These rules implement Act 758 of 2021. The Act, sponsored by Representative Lee Johnson, clarified and expanded the prescription limitations in the Arkansas Medicaid Program and exempted long-term medication from being counted towards a prescription limit in the Arkansas Medicaid Program. Per the Act, “[o]n or before January 1, 2022, the Department of Human Services shall submit and apply for any federal waivers, Medicaid state plan amendments, or other authority necessary to implement this section.” Act 758, § 1(d), *codified at* Ark. Code Ann. § 20-77-406(d).

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

DEPARTMENT/AGENCY Department of Human Services
DIVISION Division of Medical Services
DIVISION DIRECTOR Elizabeth Pitman
CONTACT PERSON Mac Golden
ADDRESS P. O. Box 1437, Slot S295 Little Rock, AR 72203-1437
PHONE NO. 501-563-7634 FAX NO. 501-404-4619 E-MAIL Mac.E.Golden@dhs.arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING _____
PRESENTER E-MAIL _____

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 C. Sutton
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201**

- Pharmacy 2-21 and Medicaid State Plan Amendment (SPA)
1. What is the short title of this rule? 2021-0009, based on Act 758.

 2. What is the subject of the proposed rule? See Attached.

 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? _____
When does the emergency rule 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. _____

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."**

See attached.

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Arkansas Code §§ 20-76-201, 20-77-107, and 25-10-129

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

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://humanservices.arkansas.gov/do-business-with-dhs/proposed-rules/>

9. Will a public hearing be held on this proposed rule? Yes No
If yes, please complete the following:

Date: October 20th, 2021

Time: 11:00

Zoom meeting -
<https://us02web.zoom.us/j/87044183305>

Place: Webinar ID: 87044183305

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

November 8th, 2021

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

1/1/2022

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. See Attached.

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

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. Unknown

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services

DIVISION Division of Medical Services

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 2-21 and Medicaid State Plan Amendment (SPA) 2021-0009, based on Act 758.

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?

<u>Current Fiscal Year</u>		<u>Next Fiscal Year</u>	
General Revenue	<u>\$8,666,571</u>	General Revenue	<u>\$17,333,142</u>
Federal Funds	<u>\$21,871,029</u>	Federal Funds	<u>\$43,742,058</u>
Cash Funds	_____	Cash Funds	_____
Special Revenue	_____	Special Revenue	_____

Other (Identify) _____

Other (Identify) _____

Total \$30,537,600

Total \$61,075,200

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

Current Fiscal Year

Next Fiscal Year

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

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.

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.

Current Fiscal Year

Next Fiscal Year

\$ 8,666,571

\$ 17,333,142

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;

The 93rd General Assembly enacted Act 758. Act 758 allows six (6) prescription refills per month for adult Medicaid clients. In addition, the Act includes additional medications to the list of prescriptions that do not count against the monthly prescription benefit cap. The medications added include prescriptions for high blood pressure, hypercholesteriolema, blood modifiers, diabetes, or respiratory inhalers. The Division of Medical Services is revising Section II of the Pharmacy Provider Manual as well as updating the Medicaid State Plan Amendment (SPA) to reflect the changes in Act 758.

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Statement of Necessity and Rule Summary
Pharmacy 2-21 and Medicaid State Plan Amendment (SPA) 2021-0009, based on Act 758

Why is this change necessary? Please provide the circumstances that necessitate the change.

The 93rd General Assembly enacted Act 758. Act 758 allows six (6) prescription refills per month for adult Medicaid clients. In addition, the act includes additions to the list of prescription medications that do not count against the monthly prescription benefit cap. The medications added include prescriptions for high blood pressure, hypercholesterolemia, blood modifiers, diabetes, or respiratory inhalers. The Division of Medical Services is revising Section II of the Pharmacy Provider Manual as well as updating the Medicaid State Plan Amendment (SPA) to reflect the changes in Act 758.

What is the change? Please provide a summary of the change.

Pharmacy Provider Manual Section II: Replaced the term beneficiary with client identified in each revised section.

Section 213.100 Monthly Prescription Limits (B)

- Replaced three (3) with six (6)
- Added, "6. Prescriptions for the treatment of high blood pressure."
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- Added, "C. Living Choices Assisted Living Program clients are eligible for up to nine (9) medically necessary prescriptions per month."
- Added, "D. After the client has received the maximum monthly benefit or the maximum monthly extended benefit, they will be responsible for paying for their own medications for the remainder of the month."

Deleted Section 213.110 - Extension of Benefits

Section 213.200 - Prescription Refill Limit

- Added, "Refills shall be in accordance with federal and state laws."
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Arkansas Medicaid State Plan

SPA page 31A5a – Categorically Needy

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SPA page 31B4g - Medically Needy

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- Added, "..., EPSDT, high blood pressure, hypercholesterolemia, blood modifiers, diabetes, and respiratory illness inhaler..."

NOTICE OF RULE MAKING

The Director of the Division of Medical 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: 20-77-107, 25-10-129, and 20-76-201.

Effective January 1, 2022:

The Director of the Division of Medical Services (DMS) revises Section II of the Pharmacy Provider Manual. The 93rd General Assembly enacted Act 758 allowing six (6) prescription refills per month. Act 758 also included additional medications that do not count against the monthly prescription benefit cap. These medications are prescriptions for high blood pressure, hypercholesterolemia, blood modifiers, diabetes, and respiratory inhalers.

DMS amends Section II of the Pharmacy Provider Manual and the Medicaid State Plan to replace the term beneficiary with client. DMS changes sections that limited clients to three prescription refills per month to reflect the allowance of six (6) refills. DMS also adds prescriptions for treatment of high blood pressure, treatment of hypercholesterolemia, treatment of diabetes, blood modifier medications, and inhalers to treat respiratory illness to the list of medications that do not count against the monthly prescription cap. DMS adds that Living Choices Assisted Living Program clients are eligible for up to nine (9) medically necessary prescriptions per month. DMS adds that the client is responsible for paying for their own medications for the remainder of the month when the client has received the maximum monthly benefit or the maximum monthly extended benefit and deletes the "Extension of Benefits" section. Lastly, DMS deletes language requiring a new, original prescription to continue drug therapy beyond five refills or six months and adds that refills shall be in accordance with federal and state laws.

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 November 8th, 2021. 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 20th, 2021 at 11:00 a.m. and public comments may be submitted at the hearing. Individuals can access this public hearing at <https://us02web.zoom.us/j/87044183305>. The webinar ID is 870 4418 3305. 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 501-396-6428.

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. 4502035775

Elizabeth Pitman, Director
Division of Medical Services