EXHIBIT H

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: SPA #2019-002, Section 1004 of the SUPPORT Act

DESCRIPTION:

Statement of Necessity

The Centers for Medicare and Medicaid Services (CMS) has issued state guidance for a mandatory State Plan Amendment related to Drug Utilization Review (DUR) to reduce opioid-related fraud, misuse, and abuse. This change is in compliance with Section 1004 of the Substance-Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also referred to as the SUPPORT for Patients and Communities Act or the SUPPORT Act.

Rule Summary

CMS requires states to submit the State Plan Amendment (SPA) by December 31, 2019. The effective date for this promulgation will be July 1, 2020.

The purpose of this SPA is to meet the requirements of the SUPPORT Act and to provide documentation of compliance with opioid standards applicable to Fee For Service (FFS) recipients and PASSE recipients. These requirements have already been implemented in Arkansas. This Medicaid SPA reflects what is already in practice.

The purpose of this change is to address required implementation concerning:

- Opioid prescription claim reviews at the point of sale and retrospective reviews
- The monitoring and management of antipsychotic medication in children
- Identification of processes to detect fraud and abuse
- Mandatory DUR report updates
- Requirements for Medicaid Managed Care Organizations

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on April 20, 2020. The agency indicated it did not receive any public comments.

Lacey Johnson, an attorney with the Bureau of Legislative Research, asked the following questions and received the following responses:

QUESTION #1: Are the routine metabolic labs mentioned in section H.2(a) required by statute? **RESPONSE:** Continued monitoring on an outpatient basis for metabolic changes is required for antipsychotic agents for children < 18 years of age. This was announced in a June 5, 2012 memo, after the April 18th, 2012 DUR Board meeting. See *June 12, 2012 REMINDER* REGARDING REQUIREMENTS OF INFORMED

CONSENT AND METABOLIC MONITORING FOR *ORAL ANTIPSYCHOTIC AGENTS* FOR CHILDREN < 18 YRS. OF AGE:

QUESTION #2: Is CMS approval required for these rule changes? If so, what is the status on that approval? **RESPONSE:** Yes. CMS approved on 2/20/20.

The proposed effective date is July 1, 2020.

FINANCIAL IMPACT: The agency indicated that this rule does not have a financial impact.

LEGAL AUTHORIZATION: The Department of Human Services has the authority to administer assigned forms of public assistance and to make rules as necessary to carry out its duties. Ark. Code Ann. § 20-76-201(1), (12). The Department is specifically tasked with establishing and maintaining an indigent medical care program. Ark. Code Ann. § 20-77-107(a)(1). This includes promulgating rules to ensure compliance with federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Department of Human Services
DIVISION Division of Medical Services
DIVISION DIRECTOR Janet Mann
CONTACT PERSON Alexandra Rouse
ADDRESS PO Box 1437, Slot S295, Little Rock, AR 72203-1437
PHONE NO. 501-580-8875 **FAX NO.** 501-404-4619 **E-MAIL** Alexandra.Rouse@dhs.arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Janet Mann
PRESENTER E-MAIL Janet.Mann@dhs.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 C. Sutton
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? SPA # 2019-002, Section 1004 of the SUPPORT Act

2. What is the subject of the proposed rule? Drug Utilization Review (DUR) to reduce opiod related fraud, misuse, and abuse.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes x No _____

   If yes, please provide the federal rule, regulation, and/or statute citation. § 1004 of the SUPPORT Act (P.L. 115-271)

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes_____ No x

   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__X__ If yes, please provide a brief summary explaining the rule.

Does this repeal an existing rule? Yes_____ No__X__ 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__X__ 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.

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://medicaid.mmis.arkansas.gov/general/comment/comment.aspx

9. Will a public hearing be held on this proposed rule? Yes_____ No__X__
If yes, please complete the following:

Date:_____

Time:_____

Place:_____

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

April 20, 2020

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

July 1, 2020

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 Brian Jones
TELEPHONE NO. 501-5372064 **FAX NO.** 501-682-3889 **EMAIL:** brian.jones@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 SPA # 2019-002, Section 1004 of the SUPPORT Act

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes _____ No __x__

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 __x__ 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 __x__ 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

General Revenue 0
Federal Funds 0
Cash Funds
Special Revenue
Other (Identify)

Total 0

Next Fiscal Year

General Revenue 0
Federal Funds 0
Cash Funds
Special Revenue
Other (Identify)

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

$_____

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

$ 0

Next Fiscal Year

$ 0

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 X

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.

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 July 1, 2020:

Background: The Centers for Medicare and Medicaid Services (CMS) issued guidance to the states concerning Drug Utilization Review (DUR) requirements in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Also referred to as the SUPPORT for Patients and Communities Act or SUPPORT Act, it seeks to reduce opioid related fraud, misuse, and abuse. The Support Act required each state to implement the new requirements by October 1, 2019, but gave each state until December 31, 2019, to submit a state plan amendment in compliance with the new requirements. By meeting the requirements, states become eligible for enhanced federal funding around technology to assist efforts to reduce opioid fraud, misuse, and abuse.

State Plan Amendment: The Arkansas Department of Human Services, Division of Medical Services (DHS/DMS), intends to adopt a state plan amendment to meet the requirements of the SUPPORT Act. The state plan amendment reflects the practices implemented in Arkansas and documents compliance with the requirements. The requirements broadly fall into four categories: claims review limitations; programs to monitor antipsychotic medications by children; fraud and abuse identification; and Medicaid Managed Care Organization mandates. The plan also sets mandatory DUR reporting requirements.

The plan implements claim review requirements for opioid prescriptions by prospective reviews at the point of sale and retrospective reviews of the same, including duplicate fill and early fill alerts, quantity limits, dosage limits, and Morphine Milligram Equivalent limitations. It establishes concurrent utilization reviews of opioids and benzodiazepines, or opioids and antipsychotics. And, it describes all actions for these reviews that will occur. The plan establishes monitoring and management of antipsychotic medications by children by prospective reviews at the point of sale and retrospective reviews. The plan implements programs and audits to identify fraud and abuse by recipients, providers, and pharmacists, including the monitoring of use in other states. The plan requires Medicaid Managed Care Organizations (MCOs) to comply with applicable requirements through updated contracts. Finally, the plan includes mandatory DUR report updates.

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 on the Medicaid website at https://medicaid.mmis.arkansas.gov/General/Comment/Comment.aspx. 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 April 20, 2020. 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.

If you need this material in a different format, such as large print, contact the Office of Rules Promulgation at 501-320-6266.

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. 4501888131

Janet Mann, Director
Division of Medical Services

Statement of Necessity and Rule Summary

SPA # 2019-002, Section 1004 of the SUPPORT Act

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