ARKANSAS REGISTER

Proposed Rule Cover Sheet

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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

Previous Agency Name, If Applicable

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

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Revision: HCFA-PM- (MB)

State/Territory: ARKANSAS

Citation

1927(g)(2)(C)
42 CFR 456.709(b)

F.2. The DUR program assesses data on drug use against explicit predetermined standards including but not limited to monitoring for:

-Therapeutic appropriateness
-Overutilization and underutilization
-Appropriate use of generic products
-Therapeutic duplication
-Drug-disease contraindications
-Drug-drug interactions
-Incorrect drug dosage/duration of drug treatment
-Clinical abuse/misuse

1927(g)(2)(D)
42 CFR 456.711

3. The DUR program through its State DUR Board, using data provided by the Board, provides active and ongoing educational outreach programs to educate practitioners on common drug therapy problems to improve prescribing and dispensing practices.

1927(g)(3)(A)
42 CFR 456.716(a)

G.1. The DUR program has established a State DUR Board either:

_X_ Directly, or
___ Under contract with a private organization

1927(g)(3)(B)
42 FR 456.716
(A) and (B)

2. The DUR Board membership includes health professionals (~~one-third licensed actively practicing pharmacists and one-third but no more than 51 percent licensed and actively practicing physicians~~at least 1/3 but no more than fifty-one percent (51%) licensed and actively practicing physicians and at least 1/3 licensed and actively practicing pharmacists) with knowledge and experience in one or more of the following:

-Clinically appropriate prescribing of covered outpatient drugs.
-Clinically appropriate dispensing and monitoring of covered outpatient drugs.
-Drug use review, evaluation and intervention.
-Medical quality assurance.

1927(g)(3)(C)
42 CFR 456.716(d)

3. The activities of the DUR Board include:

-Retrospective DUR,
-Application of Standards as defined in section 1927(g)(2)(C), and
-Ongoing interventions for physicians and pharmacists targeted toward therapy problems or individuals identified in the course of retrospective DUR.

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1927(g)(3)(C)
42 CFR 456.711
(a)-(d)

G.4. The interventions include in appropriate instances:

-Information dissemination
-Written, oral, and electronic reminders
-Face-to-Face discussions
-Intensified monitoring/review of prescribers/dispensers

~~1927(g)(3)(D)~~
~~42 CFR 456.712~~
~~and (B)~~

P.L. 115-271
Section 1004 of the
SUPPORT Act

H.1. The DUR program meets the requirements of Section 1004 of the SUPPORT Act for substance use-disorder prevention that promotes opioid recovery and treatment. Opioid claim review limitations for initial and subsequent refills require prospective safety edits and comprehensive retrospective claims review processes.

a) Prospective point-of-sale safety edits

- Therapeutic duplication edit
- Maximum daily quantity edit
- Maximum monthly quantity edit
- Morphine Milligram Equivalent edit
- Refill too soon logic
- Age edit
- Maximum days'supply edits for treatment naïve and treatment experienced

~~1927(h)(1)~~
~~42 CFR 456.722~~

b) Retrospective claims review

- Morphine Milligram Equivalent review per recipient and prescriber
- Concurrent opioid and benzodiazepine usage prompts prescriber or pharmacy provider notification by letter

~~1927(g)(2)(A)(i)~~
~~42 FR 456.705(b)~~

- Concurrent opioid and antipsychotic medication usage prompts prescriber or pharmacy provider notification by letter

~~1927(j)(2)~~
~~42 CFR 456.703(c)~~

- Review opioid use in adolescents
- Review prescribing and dispensing patterns on opioid claims
- Retrospective reviews on opioid prescriptions exceeding these above limitations on an ongoing basis

H.2. Program to monitor antipsychotic medication use by children

a) Prospective point-of-sale edits

- Age edits for recipients < 18 years old
- Therapeutic duplication edit
- Maximum dose edit
- Antipsychotic medication usage in children including those in foster care are monitored in monthly reports by a staff psychiatrist
- Routine metabolic labs required

b) Retrospective claims review

- Monitor antipsychotic use patterns in children including foster care
- Doses of antipsychotic medications monitored

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Citation

1927(g)(3)(D)
42 CFR 456.712
(A) and (B)

~~H~~.2. Program to monitor antipsychotic medication use by children
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b) Retrospective claims review
- Monitor antipsychotic use patterns in children including foster care
- Doses of antipsychotic medications monitored

1927(h)(1)
42 CFR 456.722

H.3. Fraud and Abuse Identification
a) Lock-in program for recipients identified by Retrospective DUR for possible abuse or misuse of controlled substances
b) Prescriber and pharmacy provider patterns of misuse/overprescribing
- Identified by Retrospective DUR
- Identified by contracted auditor(s)

c) Prescription Drug Monitoring programs enable prescribers and pharmacy providers to search the PDMP for monitoring narcotic use behavior including access to other states

~~H~~I. The State assures that it will prepare and submit an annual report to the Secretary, which incorporates a report from the State DUR Board, and that the State will adhere to the plans, steps, procedures as described in the report.

X

1927(g)(2)(A)(i)
42 FR 456.705(b)

1927(j)(2)
42 CFR 456.703(c)

~~I~~J.1. The State establishes, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system to perform on-line:

-real time eligibility verification
-claims data capture
-adjudication of claims
-assistance to pharmacists, etc. applying for and receiving payment.

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2. Prospective DUR is performed using an electronic point of sale drug claims processing system.

~~J~~K. Hospitals which dispense covered outpatient drugs are

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exempted from the drug utilization review requirements of this section when facilities use drug formulary systems and bill the Medicaid program no more than the hospital's purchasing cost for such covered outpatient drugs.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services
DIVISION Division of Medical Services
PERSON COMPLETING THIS STATEMENT Brian Jones
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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 **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**

$_____ $_____

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

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.

Statement of Necessity and Rule Summary

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

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 implementations concerning:

- Opioid prescription claim reviews at the point of sale (POS) 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 (MCOs).