

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Medication Assisted Treatment including the following provider manuals: Federally Qualified Health Center-1-19, Hospital-5-19, Nurse Practitioner-3-19, Outpatient Behavioral Health Services-1-19, Physician-4-19 and Rural Health Clinic-119; Pharmacy-2-19; Section I-4-19; State Plan Amendment #2020-0013

DESCRIPTION:

Statement of Necessity

The Division of Medical Services (DMS) provider manuals and Arkansas Medicaid state plan are revised to comply with Act 964 of 2019. The purpose of the Act is to increase services and medications available to Arkansas Medicaid eligible beneficiaries diagnosed with Opioid Use Disorders. Act 964 mandates that Arkansas Medicaid may not require prior authorization (PA) nor impose other requirements other than a valid prescription and compliance with Medication-Assisted Treatment (MAT) guidelines by the Substance Abuse and Mental Health Services Administration (SAMHSA). The intent of the Act is to remove barriers to patients obtaining coverage for buprenorphine, naloxone, naltrexone, methadone, and their various formulations and combinations approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid addiction. This mandate to remove PA requirements pertains to prescription drugs for the treatment of opioid addiction designated as preferred on the evidence-based preferred drug list (PDL) provided there is at least one (1) of each of the drugs which has the preferred designation on the PDL, or available without PA. In addition, under Act 964, prescriptions for these drugs for this purpose may not count against any prescription limits imposed. An additional change was made to clarify that tobacco cessation products do not count toward the three-prescription limit.

SAMHSA defines MAT as the use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders. A combination of medication and behavioral therapies is effective in the treatment of substance use disorders and can help some people to sustain recovery. This definition and other MAT guidelines can be found at <https://www.integration.samhsa.gov/clinical-practice/mat/matoverview>. Only providers who have an X-DEA identification number on file with Arkansas Medicaid may prescribe medication required for the treatment of Opioid Use Disorder as part of a MAT program for Arkansas Medicaid beneficiaries. These MAT providers are responsible for coordinating all follow-up and referrals for counseling and other services in conjunction with prescribing medications. In support of building capacity for SAMHSA-compliant practices, Arkansas Medicaid is promulgating additional policy to recognize the importance of physician visits, counseling, and behavioral therapies in conjunction with prescribed medication by removing barriers to access. Visits to enrolled MAT practitioners will be excluded from the programmatic visit limits when the claim is coded with a specific Opioid Use Disorder (OUD) diagnosis. These services will also be excluded from the \$500 lab and x-ray limit.

Rule Summary

The proposed effective date for the rule revisions is September 1. The rule revisions are as follows:

- Physician: **Sections 201.500 through 201.520** are revised to reflect Arkansas Medicaid participation requirements for providers of MAT for Opioid Use Disorder; **Section 203.270** is revised to replace the word “Mental” with “Behavioral”; **Section 203.271** is added to explain the MAT Provider role in administering Opioid Use Disorder services; **Section 225.000** is revised to automatically extend the outpatient hospital visit benefit limit when services are rendered for Opioid Use Disorder once monthly by MAT providers; **Section 225.100** is revised to automatically override benefit limitations when one (1) Opioid Use Disorder test per month is ordered by a MAT provider; **Section 226.000** is revised to automatically extend the physician visit benefit limit when services are rendered for Opioid Use Disorder once monthly by MAT providers; **Sections 230.000 through 230.100** are added to explain coverage rules for MAT and minimum requirement compliance standards; **Section 263.000** is revised to clarify where to locate information regarding procedures for physician-administered drugs; **Section 263.100** is added to explain coverage for MAT prescription products; **Section 272.600** is added to explain special reimbursement rules for MAT may be available; **Section 292.920** is added to outline special billing procedures for MAT.
- Outpatient Behavioral Health Services: **Section 211.200** has a grammatical change; **Section 214.200** is added to explain coverage rules for MAT and minimum requirement compliance standards.
- Pharmacy: **Section 211.105** is added to explain coverage and limitations for MAT products in the pharmacy program; **Section 213.100** is revised to add prescriptions for Opioid Use Disorder and tobacco cessation products to the list of monthly prescription limits.
- Federally Qualified Health Center: **Section 212.220** is revised to add MAT for Opioid Use Disorders when furnished in collaboration with a physician; **Section 220.000** is revised to exempt MAT for Opioid Use Disorder from the twelve (12) FQHC core service encounters per state fiscal year limit; **Section 220.200** is revised to add Opioid Use Disorder when treated with MAT to the list of diagnoses for extension of benefits; **Section 262.430** is added to provide guidelines for MAT billing.
- Hospital: **Section 272.501** is revised to incorporate coverage of MAT and Opioid Use Disorder treatment drugs when provided according to rules promulgated into the Arkansas Medicaid Physician’s provider manual.
- Nurse Practitioner: **Section 252.448** is revised to incorporate coverage of MAT and Opioid Use Disorder treatment drugs when provided according to rules promulgated into the Arkansas Medicaid Physician’s provider manual.

- Rural Health Clinic: **Section 211.100** is revised to include MAT for Opioid Use Disorders as a core service; **Section 218.100** is revised to explain that the established benefit limit does not apply to individuals receiving MAT for Opioid Use Disorders when it is the primary diagnosis; **Section 252.400** has been added as a place holder for Special Billing Procedures; **Section 252.401** has been added to provide guidance for claims submitted for the Upper Respiratory Infection Acute Pharyngitis episode; **Section 252.402** has been added to provide guidance for MAT billing procedures.

- The Arkansas Medicaid State Plan: has been updated throughout to add MAT program guidelines.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired June 13, 2020. The agency indicated that it received the following public comment and it provided the following response to that comment.

Commenter's Name: Steven C. Anderson, President and Chief Executive Officer, National Association of Chain Drug Stores

COMMENT: On behalf our members operating chain pharmacies in the state of Arkansas, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the proposed rule regarding Medication Assisted Treatment (MAT). We want to express our support for the new regulations associated with Arkansas Act 964 of 2019, which expands the availability of Opioid Use Disorder (OUD) medications and services for Medicaid eligible members.

NACDS and our member companies are committed to supporting policies and other initiatives to aggressively combat the opioid epidemic. We believe holistic approaches are needed not only to prevent misuse, abuse, diversion, and addiction from taking root, but also to provide treatment options for individuals who are currently suffering from opioid use disorders.

Section 211.105 of the new regulation is specific to pharmacies. The removal of prior authorization for preferred oral drugs for OUD helps alleviate administrative burdens on our pharmacists and enables patients to receive their prescriptions in a timelier manner. Additionally, allowing MAT drugs to be exempt from the monthly prescription benefit limit and copay requirement are important provisions which will improve access to these important OUD therapies.

NACDS is an active partner in helping states to address the opioid epidemic. We urge all states to utilize pharmacists to provide OUD medications and services to Medicaid beneficiaries and we thank the Division of Medical Services for taking action to address this important public health issue. If you have any questions, please do not hesitate to contact Mary Staples at mstaples@nacds.org or 817-442-1155.

RESPONSE: Thank you for your support.

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

1. What is the status on CMS approval for the SPA? **RESPONSE:** The SPA was submitted on 5/14/20 and is currently pending. The 90th day is 8/12/20.
2. The hyperlink provided in Section 203.271 points to the Center of Excellence for Integrated Health Solutions' home page. Is this the correct link? **RESPONSE:** The link has changed. DMS is changing the language to include a hyperlink instead (see attached updated packet), which can be easily updated should this happen again. The correct link that will be attached to the hyperlink is: <https://store.samhsa.gov/product/TIP-63Medications-for-Opioid-Use-Disorder-Full-Documnet/PEP20-02-01-006>. The hyperlink in the policy will be activated when the rule becomes effective.
3. Where do the requirements in Section 230.000(D)(c) regarding maintenance treatment after the first year of treatment come from? **RESPONSE:** The guidelines were derived from TIP 63 in the SAMHSA guidelines and the state's objective for at least quarterly quality assurance to ensure that all persons on MAT are achieving objectives through treatment.

The proposed effective date is September 1, 2020.

FINANCIAL IMPACT: The agency indicated that this rule has a financial impact.

Per the agency, the additional cost of this rule is estimated at \$924,784 for the current fiscal year (\$265,017 in general revenue and \$659,767 in federal funds) and \$1,109,629 for the next fiscal year (\$316,355 in general revenue and \$793,274 in federal funds). The total estimated cost by fiscal year to state, county, and municipal government to implement this rule is \$265,017 for the current fiscal year and \$316,355 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;* To combat opioid use disorders.
- (2) *the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;*
To comply with Act 964, which mandates that Arkansas Medicaid not require prior authorization other than a valid prescription and compliance with MAT guidelines by the Substance Abuse and Mental Health Services Administration.
- (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;*

To combat opioid use disorders. To comply with Act 964, which mandates that Arkansas Medicaid not require prior authorization other than a valid prescription and compliance with Medication Assisted Treatment guidelines by the Substance Abuse and Mental Health Services Administration.

(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; No alternatives are proposed at this time.

(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; No comments have been received.

(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 Not applicable.

(7) an agency plan for review of the rule no less than every ten 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*

The agency monitors state and federal rules and policies for opportunities to reduce and control costs.

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).

This proposed rule implements Act 964 of 2019, sponsored by Representative Deborah Ferguson, which amended the Prior Authorization Transparency Act and prohibited prior authorization for medication-assisted treatment.

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 Janet Mann
CONTACT PERSON Alexandra Rouse
ADDRESS PO Box 1437, Slot S295, Little Rock, AR 72203-1437
PHONE NO. 501-508-8875 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

Medication Assisted Treatment including the following provider manuals: Federally Qualified Health Center-1-19, Hospital-5-19, Nurse Practitioner-3-19, Outpatient Behavioral Health Services-1-19, Physician-4-19, Rural Health Clinic-1-19, Pharmacy-2-19, Section I-4-19, State Plan Amendment #2020-0013

1. What is the short title of this rule? Section I-4-19, State Plan Amendment #2020-0013

The Medicaid provider manuals and Arkansas Medicaid state plan are being revised to comply with Act 964 of 2019. Act 964 mandates that Arkansas Medicaid may not require prior authorization nor impose other requirements other than a valid prescription and compliance with Medication Assisted Treatment guidelines by the Substance Abuse and Mental Health Services Administration.

2. What is the subject of the proposed rule? Abuse and Mental Health Services Administration.

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."**

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, 25-10-129, 23-99-1100 et seq.
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). <http://humanservices.arkansas.gov/resources/legal-notice>
9. Will a public hearing be held on this proposed rule? Yes No
If yes, please complete the following:
- Date: _____
- Time: _____
- Place: _____
10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
June 13, 2020
11. What is the proposed effective date of this proposed rule? (Must provide a date.)
September 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.

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 August 1, 2020:

Background: Arkansas Act 964 of 2019 increases access to medications for Arkansas Medicaid eligible members diagnosed with opioid use disorder (OUD). The Act mandates that Arkansas Medicaid may not require prior authorization (PA) nor impose other requirements other than a valid prescription and compliance with medication assisted treatment (MAT) guidelines issued by the Substance Abuse and Mental Health Services Administration (SAMHSA). The Act intends to remove barriers to patients obtaining coverage for buprenorphine, naloxone, naltrexone, methadone, and their various formulations and combinations approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid addiction. This mandate to remove PA requirements pertains to prescription drugs for treatment of opioid addiction designated as preferred on the evidence-based preferred drug list (PDL), if there is at least one of each of the drugs which has the preferred designation on the PDL or are available without PA. Also, prescriptions for preferred prescription products, including oral and injectable medications, will not count against the monthly prescription benefit limit and are not subject to co-payment requirements. An additional change was made to clarify that tobacco cessation products do not count toward the three-prescription limit for pharmacy.

SAMHSA defines MAT as the use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders. A combination of medication and behavioral therapies is effective in the treatment of substance use disorders and can help some people to sustain recovery. This definition and other MAT guidelines can be found at: <https://www.integration.samhsa.gov/clinical-practice/mat/mat-overview>. Only providers who have an X-DEA identification number and have obtained an Arkansas Medicaid Specialty designation for MAT may prescribe medication required for the treatment of opioid use disorder for Arkansas Medicaid beneficiaries in conjunction with coordinating all follow-up and referrals for counseling and other services. In support of building capacity for SAMHSA-compliant practices, Arkansas Medicaid is promulgating additional rules to recognize the importance of physician visits, counseling, and behavioral therapies in conjunction with prescribed medication by removing barriers to access. Visits to enrolled MAT practitioners will be excluded from the programmatic visit limits when the claim is coded with a specific Opioid Use Disorder (OUD) diagnosis. These services will also be excluded from the \$500 lab and x-ray limit.

Arkansas Medicaid State Plan Amendment: The Arkansas Department of Human Services (DHS), Division of Medical Services (DMS), intends to adopt a state plan amendment to meet the requirements of Act 964 of 2019. DMS added treatment for opioid use disorder when provided by an X-DEA waived practitioner and specified that preferred prescription drugs for treatment of opioid use disorder do not count against the prescription limit.

Provider Manuals: DMS intends to revise agency provider manuals to meet the requirements of Act 964 of 2019. The rule revisions are:

Physician: Sections 201.500 through 201.520 are revised to reflect Arkansas Medicaid participation requirements for providers of MAT for Opioid Use Disorder; Section 203.270 is revised to replace the

word "Mental" with "Behavioral;" Section 203.271 is added to explain the MAT Provider role for administering Opioid Use Disorder services; Section 225.000 is revised to automatically extend the outpatient hospital visit benefit limit when Opioid Use Disorder is rendered once monthly by MAT providers; Section 225.100 is revised to automatically override benefit limitations when one (1) Opioid Use Disorder test per month is ordered by a MAT provider; Section 226.000 is revised to automatically extend the physician visit benefit limit when services are rendered for Opioid Use Disorder once monthly by MAT providers; Sections 230.000 through 230.100 are added to explain coverage rules for MAT and minimum requirement compliance standards; Section 263.000 is revised to clarify where to locate information regarding procedures for physician-administered drugs; Section 263.100 is added to explain coverage for MAT prescription products; Section 272.600 is added to explain special reimbursement rules for MAT may be available; Section 292.920 is added to outline special billing procedures for MAT.

Outpatient Behavioral Health Services: Section 211.200 has a grammatical change; Section 214.200 is added to explain coverage rules for MAT and minimum requirement compliance standards.

Pharmacy: Section 211.105 is added to explain coverage and limitations for MAT products in the pharmacy program; Section 213.100 is revised to add prescriptions for Opioid Use Disorder and tobacco cessation products to the list of monthly prescription limits.

Federally Qualified Health Center: Section 212.220 is revised to add MAT for Opioid Use Disorders when furnished in collaboration with a physician; Section 220.000 is revised to exempt MAT for Opioid Use Disorder from the twelve (12) FQHC core service encounter per state fiscal year limit; Section 220.200 is revised to add Opioid Use Disorder when treated with MAT to the list of diagnoses for extension of benefits; Section 262.430 is added to provide guidelines for MAT billing.

Hospital: Section 272.501 is revised to incorporate coverage of MAT and Opioid Use Disorder treatment drugs when provided according to rules promulgated into the Arkansas Medicaid Physician's provider manual.

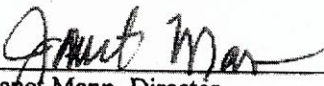
Nurse Practitioner: Section 252.448 is revised to incorporate coverage of MAT and Opioid Use Disorder treatment drugs when provided according to rules promulgated into the Arkansas Medicaid Physician's provider manual.

Rural Health Clinic: Section 211.100 is revised to include MAT for Opioid Use Disorders as a core service; Section 218.100 is revised to explain that the established benefit limit does not apply to individuals receiving MAT for Opioid Use Disorders when it is the primary diagnosis; Section 252.400 has been added as a place holder for Special Billing Procedures; Section 252.401 has been added to provide guidance for claims submitted for the Upper Respiratory Infection Acute Pharyngitis episode; Section 252.402 has been added to provide guidance for MAT billing procedures.

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 June 13, 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

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 501-537-2064 **FAX** 501-682-8155 **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 Medication Assisted Treatment including the following provider manuals: Federally Qualified Health Center1-19, Hospital-5-19, Nurse Practitioner-3-19, Outpatient Behavioral Health Services-1-19, Physician-4-19 and Rural Health Clinic-1-19; Pharmacy-2-19; Section I-4-19; State Plan Amendment #2020-0013

- 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

General Revenue _____
Federal Funds _____
Cash Funds _____

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____

Special Revenue _____
 Other (Identify) _____
 Total _____

Special Revenue _____
 Other (Identify) _____
 Total _____

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

Current Fiscal Year

Next Fiscal Year

General Revenue 265,017
 Federal Funds 659,767
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total 924,784

General Revenue 316,355
 Federal Funds 793,274
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total 1,109,629

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

\$ 265,017

\$ 316,355

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: **To combat opioid use disorders.**

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute: **To comply with ACT 964 which mandates that Arkansas Medicaid not require prior authorization other than a valid prescription and compliance with MAT guidelines by the Substance Abuse and Mental Health Services Administration.**

- (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; **To combat opioid use disorders. To comply with ACT 964 which mandates that Arkansas Medicaid not require prior authorization other than a valid prescription and compliance with Medication Assisted Treatment guidelines by the Substance Abuse and Mental Health Services Administration.**
- (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; **No alternatives are proposed at this time.**
- (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; **No comments have been received.**
- (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 **Not applicable**
- (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. **The Agency Monitors State and Federal Rules and Policies for opportunities to reduce and control cost.**

Statement of Necessity and Rule Summary

Medication Assisted Treatment

Statement of Necessity

Summary:

The Division of Medical Services (DMS) provider manuals and Arkansas Medicaid state plan are revised to comply with Act 964 of 2019. The purpose of the Act is to increase services and medications available to Arkansas Medicaid eligible beneficiaries diagnosed with Opioid Use Disorders. Act 964 mandates that Arkansas Medicaid may not require prior authorization (PA) nor impose other requirements other than a valid prescription and compliance with Medication-Assisted Treatment (MAT) guidelines by the Substance Abuse and Mental Health Services Administration (SAMHSA). The intent of the Act is to remove barriers to patients obtaining coverage for buprenorphine, naloxone, naltrexone, methadone, and their various formulations and combinations approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid addiction. This mandate to remove PA requirements pertains to prescription drugs for treatment of opioid addiction designated as preferred on the evidence-based preferred drug list (PDL) provided there is at least one (1) of each of the drugs which has the preferred designation on the PDL, or available without PA. In addition, under Act 964, prescriptions for these drugs for this purpose may not count against any prescription limits imposed. An additional change was made to clarify that tobacco cessation products do not count toward the three- prescription limit.

SAMHSA defines MAT as the use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders. A combination of medication and behavioral therapies is effective in the treatment of substance use disorders and can help some people to sustain recovery. This definition and other MAT guidelines can be found at:

<https://www.integration.samhsa.gov/clinical-practice/mat/mat-overview>. Only providers who have an X-DEA identification number on file with Arkansas Medicaid may prescribe medication required for the treatment of Opioid Use Disorder as part of a MAT program for Arkansas Medicaid beneficiaries. These MAT providers are responsible for coordinating all follow-up and referrals for counseling and other services in conjunction with prescribing medications. In support of building capacity for SAMHSA-compliant practices, Arkansas Medicaid is promulgating additional policy to recognize the importance of physician visits, counseling, and behavioral therapies in conjunction with prescribed medication by removing barriers to access. Visits to enrolled MAT practitioners will be excluded from the programmatic visit limits when the claim is coded with a specific Opioid Use Disorder (OUD) diagnosis. These services will also be excluded from the \$500 lab and x-ray limit.

Rule Summary

The proposed effective date for the rule revisions is September 1, 2020. The rule revisions are as follows:

- **Physician:** **Sections 201.500 through 201.520** are revised to reflect Arkansas Medicaid participation requirements for providers of MAT for Opioid Use Disorder; **Section 203.270** is revised to replace the word “Mental” with “Behavioral”; **Section 203.271** is added to explain the MAT Provider role for administering Opioid Use Disorder services; **Section 225.000** is revised to automatically extend the outpatient hospital visit benefit limit when Opioid Use Disorder is rendered once monthly by MAT providers; **Section 225.100** is revised to automatically override benefit limitations when one (1) Opioid Use Disorder test per month is ordered by a MAT provider; **Section 226.000** is revised to automatically extend the physician visit benefit limit when services are rendered for Opioid Use Disorder once monthly by MAT providers; **Sections 230.000 through 230.100** are added to explain coverage rules for MAT and minimum requirement compliance standards; **Section 263.000** is revised to clarify where to locate information regarding procedures for physician-administered drugs; **Section 263.100** is added to explain coverage for MAT prescription products; **Section 272.600** is added to explain special reimbursement rules for MAT may be available; **Section 292.920** is added to outline special billing procedures for MAT.
- **Outpatient Behavioral Health Services:** **Section 211.200** has a grammatical change; **Section 214.200** is added to explain coverage rules for MAT and minimum requirement compliance standards.
- **Pharmacy:** **Section 211.105** is added to explain coverage and limitations for MAT products in the pharmacy program; **Section 213.100** is revised to add prescriptions for Opioid Use Disorder and tobacco cessation products to the list of monthly prescription limits.
- **Federally Qualified Health Center:** **Section 212.220** is revised to add MAT for Opioid Use Disorders when furnished in collaboration with a physician; **Section 220.000** is revised to exempt MAT for Opioid Use Disorder from the twelve (12) FQHC core service encounter per state fiscal year limit; **Section 220.200** is revised to add Opioid Use Disorder when treated with MAT to the list of diagnoses for extension of benefits; **Section 262.430** is added to provide guidelines for MAT billing.
- **Hospital:** **Section 272.501** is revised to incorporate coverage of MAT and Opioid Use Disorder treatment drugs when provided according to rules promulgated into the Arkansas Medicaid Physician’s provider manual.
- **Nurse Practitioner:** **Section 252.448** is revised to incorporate coverage of MAT and Opioid Use Disorder treatment drugs when provided according to rules promulgated into the Arkansas Medicaid Physician’s provider manual.
- **Rural Health Clinic:** **Section 211.100** is revised to include MAT for Opioid Use Disorders as a core service; **Section 218.100** is revised to explain that the established benefit limit does not apply to individuals receiving MAT for Opioid Use Disorders when it is the primary diagnosis; **Section 252.400** has been added as a place holder for Special Billing Procedures; **Section 252.401** has been added to provide guidance for claims submitted for the Upper Respiratory Infection Acute Pharyngitis episode; **Section 252.402** has been added to provide guidance for MAT billing procedures.
- **The Arkansas Medicaid State Plan:** has been updated throughout to add MAT program guidelines.

1 State of Arkansas As Engrossed: H3/25/19 S4/3/19

2 92nd General Assembly

A Bill

3 Regular Session, 2019

HOUSE BILL 1656

4
5 By: Representative D. Ferguson

6 By: Senator Bledsoe

For An Act To Be Entitled

9 AN ACT TO AMEND THE PRIOR AUTHORIZATION TRANSPARENCY
10 ACT; TO PROHIBIT PRIOR AUTHORIZATION FOR MEDICATION-
11 ASSISTED TREATMENT; TO DECLARE AN EMERGENCY; AND FOR
12 OTHER PURPOSES.

Subtitle

15 TO AMEND THE PRIOR AUTHORIZATION
16 TRANSPARENCY ACT; TO PROHIBIT PRIOR
17 AUTHORIZATION FOR MEDICATION-ASSISTED
18 TREATMENT; AND TO DECLARE AN EMERGENCY.

22 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

24 SECTION 1. Arkansas Code § 23-99-1103(8), concerning the definition of
25 "healthcare insurer" under the Prior Authorization Transparency Act, is
26 amended to read as follows:

27 (8)(A)(i) "Healthcare insurer" means an entity that is subject
28 to state insurance regulation, including an insurance company, a health
29 maintenance organization, self-insured health plan for employees of a
30 governmental entity, and a hospital and medical service corporation, a risk-
31 based provider organization, and a sponsor of a nonfederal self-funded
32 governmental plan.

33 (ii) "Healthcare insurer" includes Medicaid where
34 specifically referenced in § 23-99-1119.

35 (B) "Healthcare insurer" does not include:

36 (i) workers' compensation plans or A workers'



1 (c) If a new formulation or medication approved by the United States
2 Food and Drug Administration for use as a prescription for medication-
3 assisted treatment becomes available after the effective date of this section
4 and is either more expensive or has not been shown to be more effective than
5 the formulations and medications in subsection (a) of this section, then the
6 healthcare insurer may require prior authorization of the new formulation or
7 medication.

8 (d) A healthcare insurer utilizing a tiered drug formulary shall place
9 on the lowest-cost benefit tier at least one (1) product for each of the
10 following medications that is approved by the United States Food and Drug
11 Administration:

12 (1) Buprenorphine;

13 (2) Naloxone;

14 (3) Naltrexone;

15 (4) Methadone; and

16 (5) A product containing both buprenorphine and naloxone.

17 (e) For purposes of any limit a healthcare insurer imposes on the
18 number of prescriptions for a patient, a prescription for medication-assisted
19 treatment shall not be counted.

20 (f) This section does not affect the responsibility of a healthcare
21 provider to comply with the standard of care for medication-assisted
22 treatment, including without limitation the use of therapy in combination
23 with medication.

24 (g) The Arkansas Medicaid Program shall have until January 1, 2020, to
25 comply with this section.

26
27 SECTION 4. EMERGENCY CLAUSE. It is found and determined by the
28 General Assembly of the State of Arkansas that medication-assisted treatment
29 is effective at treating opioid addiction and results in substantial cost
30 savings; that some healthcare insurers, including Medicaid, are placing
31 numerous prior authorization requirements on healthcare providers and their
32 patients who are in need of medication-assisted treatment; that these
33 requirements are counterproductive; and that this act is immediately
34 necessary because, as a result of these requirements, patients resort to
35 continued illegal drug use to stop withdrawals and physicians may be deterred
36 from treating patients due to the difficult prior authorization requirements.

1 State of Arkansas As Engrossed: H3/25/19 S4/3/19

2 92nd General Assembly **A Bill**

3 Regular Session, 2019 HOUSE BILL 1656

4

5 By: Representative D. Ferguson

6 By: Senator Bledsoe

7

8 **For An Act To Be Entitled**

9 AN ACT TO AMEND THE PRIOR AUTHORIZATION TRANSPARENCY
10 ACT; TO PROHIBIT PRIOR AUTHORIZATION FOR MEDICATION-
11 ASSISTED TREATMENT; TO DECLARE AN EMERGENCY; AND FOR
12 OTHER PURPOSES.

13

14

15 **Subtitle**

16 TO AMEND THE PRIOR AUTHORIZATION
17 TRANSPARENCY ACT; TO PROHIBIT PRIOR
18 AUTHORIZATION FOR MEDICATION-ASSISTED
19 TREATMENT; AND TO DECLARE AN EMERGENCY.

20

21

22 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

23

24 SECTION 1. Arkansas Code § 23-99-1103(8), concerning the definition of
25 "healthcare insurer" under the Prior Authorization Transparency Act, is
26 amended to read as follows:

27 (8)(A)(i) "Healthcare insurer" means an entity that is subject
28 to state insurance regulation, including an insurance company, a health
29 maintenance organization, self-insured health plan for employees of a
30 governmental entity, and a hospital and medical service corporation, a risk-
31 based provider organization, and a sponsor of a nonfederal self-funded
32 governmental plan.

33 (ii) "Healthcare insurer" includes Medicaid where
34 specifically referenced in § 23-99-1119.

35 (B) "Healthcare insurer" does not include:

36 (i) ~~workers' compensation plans or~~ A workers'



1 compensation plan; or

2 (ii) Medicaid, except as provided under § 23-99-
3 1119 or when Medicaid services are managed or reimbursed by a healthcare
4 insurer; or

5 ~~(C) "Healthcare insurer" does not include an (iii)~~
6 An entity that provides only dental benefits or eye and vision care benefits;
7

8 SECTION 2. Arkansas Code § 23-99-1103, concerning the definitions
9 under the Prior Authorization Transparency Act, is amended to add an
10 additional subdivision to read as follows:

11 (21) "Prescription for medication-assisted treatment" means any
12 prescription for medication used as treatment for opioid addiction approved
13 by the United States Food and Drug Administration.
14

15 SECTION 3. Arkansas Code Title 23, Chapter 99, Subchapter 11, is
16 amended to add an additional section to read as follows:

17 23-99-1119. Medication-assisted treatment for opioid addiction.

18 (a) Except in the case of injectables, a healthcare insurer, including
19 Medicaid, shall not:

20 (1) Require prior authorization in order for a patient to obtain
21 coverage of buprenorphine, naloxone, naltrexone, methadone, and their various
22 formulations and combinations approved by the United States Food and Drug
23 Administration for the treatment of opioid addiction; or

24 (2) Impose any other requirement other than a valid prescription
25 and compliance with the medication-assisted treatment guidelines issued by
26 the Substance Abuse and Mental Health Services Administration under the
27 United States Department of Health and Human Services in order for a patient
28 to obtain coverage for buprenorphine, naloxone, naltrexone, methadone, and
29 their various formulations and combinations approved by the United States
30 Food and Drug Administration for the treatment of opioid addiction.

31 (b) Subdivision (a)(1) of this section shall only apply to the
32 Arkansas Medicaid Program as it pertains to prescription drugs for treatment
33 of opioid addiction designated as preferred on the evidence-based preferred
34 drug list provided there is at least one (1) of each of the drugs listed in
35 subdivision (a)(1) of this section with the preferred designation on the
36 preferred drug list or available without prior authorization.

1 (c) If a new formulation or medication approved by the United States
2 Food and Drug Administration for use as a prescription for medication-
3 assisted treatment becomes available after the effective date of this section
4 and is either more expensive or has not been shown to be more effective than
5 the formulations and medications in subsection (a) of this section, then the
6 healthcare insurer may require prior authorization of the new formulation or
7 medication.

8 (d) A healthcare insurer utilizing a tiered drug formulary shall place
9 on the lowest-cost benefit tier at least one (1) product for each of the
10 following medications that is approved by the United States Food and Drug
11 Administration:

12 (1) Buprenorphine;

13 (2) Naloxone;

14 (3) Naltrexone;

15 (4) Methadone; and

16 (5) A product containing both buprenorphine and naloxone.

17 (e) For purposes of any limit a healthcare insurer imposes on the
18 number of prescriptions for a patient, a prescription for medication-assisted
19 treatment shall not be counted.

20 (f) This section does not affect the responsibility of a healthcare
21 provider to comply with the standard of care for medication-assisted
22 treatment, including without limitation the use of therapy in combination
23 with medication.

24 (g) The Arkansas Medicaid Program shall have until January 1, 2020, to
25 comply with this section.

26
27 SECTION 4. EMERGENCY CLAUSE. It is found and determined by the
28 General Assembly of the State of Arkansas that medication-assisted treatment
29 is effective at treating opioid addiction and results in substantial cost
30 savings; that some healthcare insurers, including Medicaid, are placing
31 numerous prior authorization requirements on healthcare providers and their
32 patients who are in need of medication-assisted treatment; that these
33 requirements are counterproductive; and that this act is immediately
34 necessary because, as a result of these requirements, patients resort to
35 continued illegal drug use to stop withdrawals and physicians may be deterred
36 from treating patients due to the difficult prior authorization requirements.

1 Therefore, an emergency is declared to exist, and this act being immediately
2 necessary for the preservation of the public peace, health, and safety shall
3 become effective on:

4 (1) The date of its approval by the Governor;

5 (2) If the bill is neither approved nor vetoed by the Governor,
6 the expiration of the period of time during which the Governor may veto the
7 bill; or

8 (3) If the bill is vetoed by the Governor and the veto is
9 overridden, the date the last house overrides the veto.

10
11
12 /s/D. Ferguson

13
14
15 APPROVED: 4/12/19