

#### DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

**SUBJECT:** SPA 2021-0003 Medication Assisted Treatment

<u>DESCRIPTION</u>: This proposed rule amends the Arkansas Medicaid State Plan to add a new section for Medication Assisted Treatment (MAT). The addition implements guidance from the Centers for Medicare and Medicaid Services based on Section 1006(b) of the SUPPORT Act. The rule includes reimbursements based on the rate methodology used for individual MAT services provided within other sections of the Medicaid State Plan.

<u>PUBLIC COMMENT</u>: No public hearing was held on this proposed rule. The public comment period expired May 8, 2021. The agency indicated that it received no public comments.

The proposed effective date is July 1, 2021. Per the agency, CMS approval will be retroactive to October 1, 2020.

**<u>FINANCIAL IMPACT</u>**: The agency indicated that this proposed rule has a financial impact.

Per the agency, this rule implements a federal rule or regulation. The estimated cost to implement the federal rule or regulation is \$800,718.75 for the current fiscal year (\$230,366.78 in general revenue and \$570,351.97 in federal funds) and \$1,067,625 for the next fiscal year (\$304,032.91 in general revenue and \$763,592.09 in federal funds). The total estimated cost by fiscal year to state, county, and municipal government to implement this rule is \$230,366.78 for the current fiscal year and \$304,032.91 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 amend the State Plan to establish a separate and distinct Medication Assisted Treatment Program.

(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 the Federal Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), § 1902(a)(10)(A) of the Social Security Act, based on guidance from CMS's State Health

Official Letter #20005, dated December 30, 2020.

- (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:

Section 1902(a)(10)(A) of the Social Security Act, (SUPPORT Act) requires states to implement a Medication Assisted Treatment Program for Opioid Use Disorders for reimbursement by Medicaid. The rule seeks to assist clients in recovery from addiction to Opioids.

(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 have been identified.

(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 were 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.

**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); *see also* Ark. Code Ann § 20-10-203(b). 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 rule implements provisions from the federal SUPPORT Act, which altered the definition of medication-assisted treatment and required state Medicaid plans to provide coverage for medication-assisted treatment "for the period beginning October 1, 2020, and ending September 30, 2025[.]" 42 U.S.C. § 1396d(a)(29).

# FINANCIAL IMPACT STATEMENT

# PLEASE ANSWER ALL QUESTIONS COMPLETELY

DE	PARTMENT	Department	of Human Servi	ces		
DI	VISION	Division of	Medical Services	S		
PE	RSON COMPL	ETING THIS	STATEMENT	Jason Callan		
TE	LEPHONE 50	1-320-6540	FAX	EMAIL: jaso	n.callan@dhs.a	arkansas.gov
To Sta	comply with Aratement and file t	k. Code Ann. § wo copies with	§ 25-15-204(e), point the questionnai	please complete the followire and proposed rules.	ving Financial	Impact
SH	ORT TITLE O	F THIS RUL	E _SPA 2021-0	003, Medication Assisted	Treatment	
1.	Does this propo	sed, 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.	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 p	proposing a mo	ore costly rule, pl	lease state the following:		
	(a) How the additional benefits of the more costly rule justify its additional cost;					
	(c) Whether the		of the more costl	the interests of public hea	alth, safety, or	welfare, and if
	(d) Whether the explain.	ne reason is wi	thin the scope of	f the agency's statutory au	athority; and if	so, please
4.				al rule or regulation, please	state the follow	ring:
<u>Cu</u>	rrent Fiscal Yea	<u>ır</u>		Next Fiscal Year		
Fed Cas Spe	neral Revenue leral Funds sh Funds ecial Revenue ner (Identify)	\$230,366.78 \$570,351.97 0 0		General Revenue Federal Funds Cash Funds Special Revenue Other (Identify)	\$304,032.91 \$763,592.09 0 0 0	
Tot	al	\$800,718.75		Total	\$1,067,625.0	00

Revised June 2019

Current Fiscal Y	<u>'ear</u>	Next Fiscal Year	
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Total	\$ 0	Total	\$ 0
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  - No alternatives have been identified
- (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 were 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
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The Agency monitors State and Federal rules and policies for opportunities to reduce and control cost

# 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. 501-563-76	Mac.E.Golden
NAME OF PRESENTER AT	COMMITTEE MEETING Elizabeth Pitman
PRESENTER E-MAIL Eli	zabeth.Pitman@dhs.arkansas.gov
necessary.	on <u>completely</u> using layman terms. You may use additional sheets, if
of this Rule" below.  D. Submit two (2) copies of the	dexing your rules, please give the proposed citation after "Short Title aris questionnaire and financial impact statement attached to the front sposed rule and required documents. Mail or deliver to:
Arkansas Legis Bureau of Legis One Capitol M Little Rock, AR	Rules Review Section lative Council slative Research all, 5th Floor
	rule? SPA 2021-0003 Medication Assisted Treatment
2. What is the subject of the pr	oposed rule? See Attached.
	ly with a federal statute, rule, or regulation? Yes No Section 1006(b); Section 1005(a)(29)
4. Was this rule filed under the	emergency provisions of the Administrative Procedure Act?
If yes, what is the effective of	Yes 🗌 No 🖂
When does the emergency ru	ile expire?
Will this emergency rule be procedure Act?	promulgated under the permanent provisions of the Administrative  Yes No



Division of Medical Services P.O. Box 1437, Slot S295 Little Rock, AR 72203-1437 P: 501.320.6266 F: 501.404.4619 HUMANSERVICES ARKANSAS GOV

April 06, 2021

Ms. Jessica Sutton, Administrator Administrative Rules Review Section Arkansas Legislative Council Bureau of Legislative Research #1 Capitol, 5<sup>th</sup> Floor Little Rock, AR 72201

Dear Ms. Sutton:

Re: SPA 2021-0003 Medication Assisted Treatment

Please arrange for this rule to be reviewed by the ALC-Administrative Rules Subcommittee. If you have any questions or need additional information, please contact Mac Golden, Office of Rules Promulgation at 501-563-7634 or by emailing <a href="Mac.E.Golden@dhs.arkansas.gov">Mac.E.Golden@dhs.arkansas.gov</a>.

Sincerely,

Janet Mani Director

JM:

Attachments

# FINANCIAL IMPACT STATEMENT

# PLEASE ANSWER ALL QUESTIONS COMPLETELY

DE	PAR	TMENT	Department	of Human Servi	ices	statistic "	
DΓ	VISI	ON	Division of	Medical Service	es		
PE	RSO	N COMP	LETING THIS	STATEMENT	Jason Callan		
TE	LEP	HONE 5	01-320-6540	FAX	EMAIL: jason	n.callan@dhs.a	arkansas.gov
To Sta	com ateme	ply with A ent and file	rk. Code Ann. { two copies with	§ 25-15-204(e), the questionna	please complete the follow ire and proposed rules.	ing Financial	Impact
SF	IOR	TITLE (	OF THIS RUL	E SPA 2021-0	0003, Medication Assisted	Treatment	unani.
1.	Doe	s this prop	osed, amended,	or repealed rule	e have a financial impact?	Yes 🖂	No 🗌
2.	ecor	nomic, or o	other evidence a		able scientific, technical, available concerning the the rule?	Yes 🖂	No 🗌
3.				tives to this rule ostly rule consid	, was this rule determined dered?	Yes 🖂	No 🗌
	If ar	n agency is	proposing a mo	ore costly rule, p	please state the following:		
	(a)	How the	additional bene	fits of the more	costly rule justify its addit	ional cost;	
	(b) — (c)	Whether		of the more cost	tly rule;	ılth, safety, or	welfare, and if
	(d)	Whether explain.	the reason is wi	thin the scope o	of the agency's statutory au	thority; and if	so, please
4.	If the	e purpose o	of this rule is to in	mplement a feder	ral rule or regulation, please	state the follow	ving:
	(a)	What is t	he cost to imple	ement the federa	l rule or regulation?		
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Fee Ca Sp	deral sh Fu ecial	Revenue Funds ands Revenue dentify)	\$230,366.78 \$570,351.97 0 0		General Revenue Federal Funds Cash Funds Special Revenue Other (Identify)	\$304,032.91 \$763,592.09 0 0	
То	tal		\$800,718.75		Total	\$1,067,625.0	00

From:

Lisa Teague

To:

register@sos.arkansas.gov

Cc:

Jack Tiner; Mac Golden; Eric Collins

Subject: Date:

Wednesday, April 7, 2021 11:01:00 AM

Attachments:

DHS/DMS-Proposed- Filing- Medication Assisted Treatment SOS Initial Filing Packet - Medication Assisted Treatment.pdf

image001.png image002.png image003.png image004.png image005.png image009.png image012.png image013.png image014.png

image015.png

Attached is the proposed rule change for Medication Assisted Treatment. The public notice will appear in the Arkansas-Democrat Gazette on April 9, 10, and 11. The public comment period ends May 08, 2021.

Please let me know if anything else is needed.

Thank you,



Office of Rules Promulgation

DHS Program Administrator

Phone: 501-396-6428 700 Main St./Slot S295 Little Rock, AR 72203

lisa.teague@dhs.arkansas.gov

humanservices.arkansas.gov





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General Revenue	\$0	General Revenue	\$0
Federal Funds	\$0	Federal Funds	\$0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0
Total	\$ 0	Total	\$ 0
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tills fulc: 15 tills ti	ic cost of the program of	r grant? Please explain how the g	government is affected.
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What is the additional cost of the state rule?

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# STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM

ATTACHMENT 4.19-B Page 17

STATE ARKANSAS

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE

October 1, 2020

#### 29. Alternative Benefit Plan (ABP) (continued)

## A. Human Papillomavirus (HPV) immunization

Effective for dates of service on or after January 1, 2014, the Arkansas Medicaid program will cover HPV immunization for ABP beneficiaries. These immunizations will be covered for age groups as recommended by the Centers for Disease Control (CDC). Reimbursement for ages nineteen (19) and over will be based on eighty percent (80%) of the 2014 Arkansas Blue Cross Blue Shield rate for this immunization. Reimbursement for ages eighteen (18) and under will be based on the Arkansas Medicaid Vaccines for Children (VFC) reimbursement rate for non-ABP beneficiaries as of January 1, 2014.

#### 30. 1905(a)(29) Medication-Assisted Treatment (MAT)

Effective for dates of service on or after October 1, 2020 through September 30, 2025, reimbursement is based on the rate methodology used for individual MAT services provided within other sections of the Medicaid State Plan, Attachment 4.19-B:

- Pages 1aaa through 1aaaa:
  - Rural Health Clinic Services and other ambulatory services that are covered under the plan and furnished by a rural health clinic
- Pages 1b through 1bbbb:
  - <u>Federally Qualified Health Center (FQHC)</u> services and other ambulatory services that are covered under the plan and furnished by an FQHC in accordance with section 4231 of the State Medicaid Manual (HCFA-Pub-45-4) (continued)
- Pages 1c through 1ccc:
  - Laboratory and X-ray Services and Other Tests
- Page 2, 2.1, 2c:
  - O Physician's Services
- Pages 4 through 4aaa:
- Reimbursement for unbundled prescribed drugs and biologicals used to treat opioid use disorder (OUD) will be reimbursed using the same methodology as described for prescribed drugs as referenced in Attachment 4.19-B, Pages 4-4aaa, Section 12.a. for both dispensed and administered prescribed drugs.
- Page 5aa:
  - Outpatient Behavioral Health Services (Other diagnostic, screening, preventative and rehabilitative services)
- Page 14:
  - Advance Practice Nurse and Registered Nurse Practitioner licensed as such by the Arkansas State Board of Nursing

Except as otherwise noted in the plan, state developed fee schedule rates are the same for both governmental and private providers of services for MAT. All rates are published on the agency's website.

# STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM

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STATE ARKANSAS

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Except as otherwise noted in the plan, state developed fee schedule rates are the same for both governmental and private providers of services for MAT. All rates are published on the <a href="majerney"><u>agency's</u></a> <a href="majerney"><u>website</u>.

TN: 2021-0003 Approval Date: Effective Date: 10/01/2020

Supersedes: TN 13-0030

Supplement 5 to Attachment 3.1-A Page 1 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Citation: 3.1(a)(1) Amount, Duration, and Scope of Services: Categorically Needy

(Continued)

1905(a)(29) \_\_\_X\_MAT as described and limited in Supplement \_\_5\_ to Attachment 3.1-A.

ATTACHMENT 3.1-A identifies the medical and remedial services provided to the categorically needy.

TN: 2021-0003 Supersedes: NEW

Approval Date:

Supplement 5 to Attachment 3.1-A Page 2 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

#### i. General Assurance

MAT is covered under the Medicaid state plan for all Medicaid beneficiaries who meet the medical necessity criteria for receipt of the service for the period beginning October 1, 2020, and ending September 30, 2025.

#### ii. Assurances

a. The state assures coverage of Naltrexone, Buprenorphine, and Methadone and all of the forms of these drugs for MAT that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Arkansas assures coverage of any additional drugs or biologicals when they are approved hereafter through the end of this section of state plan on September 30, 2025.

- b. The state assures that Methadone for MAT is provided by Opioid Treatment Programs that meet the requirements in 42 C.F.R. Part 8.
- c. The state assures coverage for all formulations of MAT drugs and biologicals for Opioid Use Disorder (OUD) that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

TN: 2021-0003 Supersedes: NEW Approval Date:

Supplement 5 to Attachment 3.1-A Page 3 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

iii. Service Package

The state covers the following counseling services and behavioral health therapies as part of MAT.

a) Please set forth each service and components of each service (if applicable), along with a description of each service and component service.

MAT is covered under section 1905(a)(29) for the period of 10/01/2020 through 9/30/2025.

#### Services available:

- 1. Individual Behavioral Health Counseling
- 2. Group Behavioral Health Counseling
- 3. Marital/Family Behavioral Health Counseling with Patient Present
- 4. Marital/Family Behavioral Health Counseling without Patient Present
- 5. Psychoeducation
- 6. Multi-Family Behavioral Health Counseling
- 7. Crisis Intervention
- 8. Acute Crisis Units
- 9. Substance Abuse Detoxification

TN: 2021-0003 Supersedes: NEW Approval Date:

Supplement 5 to Attachment 3.1-A Page 4 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

- b) Please include each practitioner and provider entity that furnishes each service and component service.
  - 1. Physicians, Physician Assistants and Nurse Practitioners who possess a valid and current X-DEA identification number. These practitioners may provide counseling and behavioral health therapies within the scope of their licensures.
  - 2. Licensed Behavioral Health Practitioners: Licensed Psychologists (LP), Licensed Psychological Examiners Independent (LPEI), Licensed Professional Counselors (LPC), Licensed Certified Social Workers (LCSW), Licensed Marital and Family Therapists (LMFT),. This group's role is to provide the behavioral and substance use disorder counseling required under the Person-Centered Treatment Plan. They may practice within the same provider entity as the X-DEA practitioner, or individually. If within the same entity, they may also provide other mandatory services within the scope of practice.

TN: 2021-0003 Supersedes: NEW Approval Date:

Supplement 5 to Attachment 3.1-A Page 5 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

c) Please include a brief summary of the qualifications for each practitioner or provider entity that the state requires. Include any licensure, certification, registration, education, experience, training, and supervisory arrangements that the state requires.

Physicians and Nurse Practitioners must be Arkansas Licensed and possess a current and valid X-DEA number from Substance Abuse and Mental Health Services Administration (SAMHSA).

Physician Assistants must have a legal agreement to practice under an Arkansas Licensed Physician per Arkansas statute and possess a current and valid X-DEA number from SAMHSA.

Licensed Psychologists (LP), Licensed Psychological Examiners – Independent (LPEI), Licensed Professional Counselors (LPC), Licensed Certified Social Workers (LCSW), and Licensed Marital and Family Therapists (LMFT) must possess a current and valid Arkansas license.

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Supplement 5 to Attachment 3.1-A Page 6 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

X	The state has drug utilization controls in place. (Check each of
	following that apply)
	Generic first policy
X	Preferred drug lists
	Clinical criteria
X	Quantity limits
	The state does not have drug utilization controls in place.

#### v. Limitations

Describe the state's limitations on amount, duration, and scope of MAT drugs, biologicals, and counseling and behavioral therapies related to MAT.

MAT drugs and biologicals are limited based on the FDA indication and manufacturers' prescribing guidelines. Some oral medications are also subject to status on the Preferred Drug List.

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TN: 2021-0003 Supersedes: NEW

Supplement 5 to Attachment 3.1-A Page 7 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

As of 1/1/2020 the preferred oral agents for MAT therapy no longer require a Prior Authorization.

The Arkansas Medicaid Pharmacy program removed the prior authorization for preferred Buprenorphine products on 1/1/2020, due to Arkansas State Law from Act 964 which prohibits a prior authorization for Medication Assisted Treatment of Opioid Use Disorder. The removal of prior authorization was for MAT treatment according to SAMHSA guidelines. In addition, on 1/22/2021, per section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to be covered, Arkansas instructed the pharmacy vendor to bypass the non-rebate-participation, repackaged indicator, inner indicator, and prioritize coverage of all the pharmacy MAT products.

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing section 1006(b) of the SUPPORT for Patients and Communities Act (P.L. 115-271) enacted on October 24, 2018. Section 1006(b) requires state Medicaid plans to provide coverage of Medication-Assisted Treatment (MAT) for all Medicaid enrollees as a mandatory Medicaid state plan benefit for the period beginning October 1, 2020, and ending September 30, 2025. Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 # 60). Public burden for all of the collection of information requirements under this control number is estimated to take about 80 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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Supplement 1 to Attachment 3.1-B Page 1 October 1, 2020

#### State of Arkansas

1905(a)(29) Medication Assisted Treatment (MAT)

Citation: 3.1(b)(1) Amount, Duration, and Scope of Services: Medically Needy

(Continued)

1915(a)(29) \_\_X\_\_MAT as described and limited in Supplement 1 to Attachment 3.1-B.

ATTACHMENT 3.1-B identifies the medical and remedial services provided to the medically needy.

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Supplement 1 to Attachment 3.1-B Page 2 October 1, 2020

#### State of Arkansas

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Medically Needy (continued)

#### i. General Assurance

MAT is covered under the Medicaid state plan for all Medicaid beneficiaries who meet the medical necessity criteria for receipt of the service for the period beginning October1, 2020, and ending September 30, 2025.

#### ii. Assurances

a. The state assures coverage of Naltrexone, Buprenorphine, and Methadone and all of the forms of these drugs for MAT that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Arkansas assures coverage of any additional drugs or biologicals when they are approved hereafter through the end of this section of state plan on September 30, 2025.

- b. The state assures that Methadone for MAT is provided by Opioid Treatment Programs that meet the requirements in 42 C.F.R. Part 8.
- c. The state assures coverage for all formulations of MAT drugs and biologicals for Opioid Use Disorders (OUD) that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

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Supplement 1 to Attachment 3.1-B Page 3 October 1, 2020

#### State of Arkansas

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Medically Needy (continued)

iii. Service Package

The state covers the following counseling services and behavioral health therapies as part of MAT.

a) Please set forth each service and components of each service (if applicable), along with a description of each service and component service. MAT is covered under section 1905(a)(29) for the period of 10/01/2020 through 9/30/2025.

#### Services available:

- 1. Individual Behavioral Health Counseling
- 2. Group Behavioral Health Counseling
- 3. Marital/Family Behavioral Health Counseling with Patient Present
- 4. Marital/Family Behavioral Health Counseling without Patient Present
- 5. Psychoeducation
- 6. Multi-Family Behavioral Health Counseling
- 7. Crisis Intervention
- 8. Acute Crisis Units
- 9. Substance Abuse Detoxification

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Supplement 1 to Attachment 3.1-B Page 4 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

- b) Please include each practitioner and provider entity that furnishes each service and component service.
  - 1. Physicians, Physician Assistants and Nurse Practitioners who possess a valid and current X-DEA identification number. These practitioners may provide counseling and behavioral health therapies within the scope of their licensures.
  - 2. Licensed Behavioral Health Practitioners: Licensed Psychologists (LP), Licensed Psychological Examiners Independent (LPEI), Licensed Professional Counselors (LPC), Licensed Certified Social Workers (LCSW), Licensed Marital and Family Therapists (LMFT). This group's role is to provide the behavioral and substance use disorder counseling required under the Person-Centered Treatment Plan. They may practice within the same provider entity as the X-DEA practitioner, or individually. If within the same entity, they may also provide other mandatory services within the scope of practice.

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Supplement 1 to Attachment 3.1-B Page 5 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

c) Please include a brief summary of the qualifications for each practitioner or provider entity that the state requires. Include any licensure, certification, registration, education, experience, training and supervisory arrangements that the state requires.

Physicians and Nurse Practitioners must be Arkansas Licensed and possess a current and valid X-DEA number from Substance Abuse and Mental Health Services Administration (SAMHSA).

Physician Assistants must have a legal agreement to practice under an Arkansas Licensed Physician per Arkansas statute and possess a current and valid X-DEA number from SAMHSA.

Licensed Psychologists (LP), Licensed Psychological Examiners – Independent (LPEI), Licensed Professional Counselors (LPC), Licensed Certified Social Workers (LCSW), and Licensed Marital and Family Therapists (LMFT) must possess a current and valid Arkansas license.

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Supplement 1 to Attachment 3.1-B Page 6 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

X	The state has drug utilization controls in place. (Check each of
	following that apply)
	Generic first policy
<u>X</u>	Preferred drug lists
	Clinical criteria
X	Quantity limits
	The state does not have drug utilization controls in place.

#### v. Limitations

Describe the state's limitations on amount, duration, and scope of MAT drugs, biologicals, and counseling and behavioral therapies related to MAT.

MAT drugs and biologicals are limited based on the FDA indication and manufacturers' prescribing guidelines. Some oral medications are also subject to status on the Preferred Drug List.

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Supplement 1 to Attachment 3.1-B Page 7 October 1, 2020

#### State of ARKANSAS

1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

As of 1/1/2020 the preferred oral agents for MAT therapy no longer require a Prior Authorization.

The Arkansas Medicaid Pharmacy program removed the prior authorization for preferred Buprenorphine products on 1/1/2020, due to Arkansas State Law from Act 964 which prohibits a prior authorization for Medication Assisted Treatment of Opioid Use Disorder. The removal of prior authorization was for MAT treatment according to SAMHSA guidelines. In addition, on 1/22/2021, per section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to be covered, Arkansas instructed the pharmacy vendor to bypass the non-rebate-participation, repackaged indicator, inner indicator, and prioritize coverage of all the pharmacy MAT products.

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing section 1006(b) of the SUPPORT for Patients and Communities Act (P.L. 115-271) enacted on October 24, 2018. Section 1006(b) requires state Medicaid plans to provide coverage of Medication-Assisted Treatment (MAT) for all Medicaid enrollees as a mandatory Medicaid state plan benefit for the period beginning October 1, 2020, and ending September 30, 2025. Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 # 60). Public burden for all of the collection of information requirements under this control number is estimated to take about 80 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-26-12 Baltimore, Maryland21244-1850



SHO# 20-005

RE: Mandatory Medicaid State Plan Coverage of Medication-Assisted Treatment

December 30, 2020

Dear State Health Official:

The Centers for Medicare & Medicaid Services (CMS) is issuing the following guidance about section 1006(b) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (herein referred to as the SUPPORT Act) (Pub. L. No. 115-271). To increase access to medication-assisted treatment (MAT) for opioid use disorders (OUD), section 1006(b) of the SUPPORT Act requires states to provide Medicaid coverage of certain drugs and biological products, and related counseling services and behavioral therapy. This State Health Official Letter (SHO Letter) also describes available opportunities for increasing treatment options for substance use disorders (SUD) generally. CMS encourages states to consider these opportunities when implementing the mandatory MAT coverage under section 1006(b) of the SUPPORT Act. The new required benefit is limited to the use of MAT for the treatment of OUD, and thus this SHO Letter is generally focused on that topic, not on treatment services for other SUDs, including alcohol use disorders.

#### Background

Section 1006(b) of the SUPPORT Act, signed into law on October 24, 2018, amends section 1902(a)(10)(A) of the Social Security Act (the Act) to require state Medicaid plans to include coverage of MAT for all eligible to enroll in the state plan or waiver of state plan. Section 2601 of the Continuing Appropriations Act, 2021 and other Extensions Act, Pub. L. No. 116-159, amended the SUPPORT Act to specify that the rebate requirements in section 1927 shall apply to any MAT drug or biological described under the mandatory benefit to the extent that the MAT drug or biological is a covered outpatient drug. (More information on section 2601 is in the section below entitled, "MAT Drug Coverage and Section 1927 Manufacturer Rebates.") Section 1006(b) also adds a new paragraph 1905(a)(29) to the Act to add the new required benefit to the definition of "medical assistance" and to specify that the new required benefit will be in effect for the period beginning October 1, 2020, and ending September 30, 2025.

In addition, section 1006(b) adds section 1905(ee)(1) to the Act to define MAT, for purposes of the new required coverage, as:

... all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section

<sup>&</sup>lt;sup>1</sup> SUPPORT for Patients and Communities Act, Pub. L. No. 115–271 (2018), https://www.congress.gov/115/plaws/publ271/PLAW-115publ271.pdf.

351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and[,] ... with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.

CMS interprets section 1905(ee)(1) of the Act to require that states include as part of the new mandatory benefit all forms of drugs and biologicals that the Food and Drug Administration (FDA) has approved or licensed for MAT to treat OUD. Currently, the FDA has approved the following drugs used for MAT to treat OUD: methadone, buprenorphine, and naltrexone.<sup>2</sup> Only those formulations of drugs or biologicals that are approved or licensed by the FDA for MAT to treat OUD must be covered under the new mandatory Medicaid benefit. There are currently no FDA-licensed biological products to treat OUD.<sup>3</sup>

#### **Medication-Assisted Treatment**

While states are required to cover all drugs and biologicals approved or licensed by the FDA used for MAT to treat OUD under the new mandatory benefit, various considerations affect which medication should be provided to a particular patient.<sup>4</sup>

Methadone is a long-acting synthetic opioid <u>agonist</u> medication with a long history of use in treatment of OUD in adults. Methadone is indicated for the detoxification treatment of opioid addiction as well as maintenance treatment of opioid addiction in conjunction with appropriate social and medical services.<sup>5</sup>

Methadone for treatment of OUD must be administered by an Opioid Treatment Program (OTP). Currently, solid (non-dispersible) and dispersible tablets, as well as the liquid concentrate, are labeled for use in such outpatient OUD therapy. These products cannot be dispensed from a pharmacy for the purpose of treating OUD. OTPs must have a current, valid certification from the Substance Abuse and Mental Health Services Administration (SAMHSA) and be accredited by an independent, SAMHSA-approved accrediting body. Effective January 1, 2020, the Medicare program began covering and reimbursing OUD treatment services furnished by an OTP.

<sup>&</sup>lt;sup>2</sup> U.S. Food and Drug Administration (FDA). Information about Medication-Assisted Treatment (MAT). FDA web site. <a href="https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat">https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat</a>; Substance Abuse and Mental Health Services Administration (SAMHSA). Medication-Assisted Treatment. SAMHSA website. <a href="https://www.samhsa.gov/medication-assisted-treatment">https://www.samhsa.gov/medication-assisted-treatment</a>

<sup>&</sup>lt;sup>3</sup> "Information about Medication-Assisted Treatment (MAT)," U.S. Food and Drug Administration, last modified February 14, 2019, <a href="https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat">https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat</a>.

<sup>&</sup>lt;sup>4</sup> SAMHSA. Office of the Surgeon General. Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington (DC). U.S. Department of Health and Human Services. 2016 Nov. Chapter 4, Early Intervention, Treatment, and Management of Substance Use Disorders. Available from: https://www.ncbi.nlm.nih.gov/books/NBK424859/.

<sup>&</sup>lt;sup>5</sup>FDA. Dolophine Highlights of Prescribing Information.

https://www.accessdata.fda.gov/drugsatfda/docs/label/2018/006134s045lbl.pdf

<sup>&</sup>lt;sup>6</sup> SAMHSA. Certification of Opioid Treatment Programs. SAMHSA website. https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs.

<sup>&</sup>lt;sup>7</sup> SUPPORT Act, Section 2005, Medicare Coverage of Certain Services Furnished by Opioid Treatment Programs. See also CMCS Informational Bulletin, "Guidance to State Medicaid Agencies on Dually Eligible Beneficiaries Receiving Medicare Opioid Treatment Services Effective January 1, 2020" (Dec. 17, 2019), <a href="https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib121719.pdf">https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib121719.pdf</a>

Buprenorphine is a synthetic opioid medication that acts as a <u>partial agonist</u>, <u>blocking and only weakly activating the opioid receptor</u>, thus blunting the euphoric effects of other opioids for the treatment of OUD.<sup>8</sup>

Buprenorphine is currently available in several dosage forms, including an oral dissolvable film, sublingual tablet, and injection. It is available as a single ingredient or in combination with naloxone, an antagonist (or blocker) of opioid receptors to prevent attempted misuse by injection. For more information on the FDA approved medications for treatment of OUDs, see SAMHSA's Treatment Improvement Protocol 63 as well as the FDA web site:

https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm600092.htm.9

Long-acting buprenorphine injections are a route of administration that may help to improve patient adherence, may reduce the risk of accidental exposures, theft, or deliberate misuse, and may reduce risks associated with office visits during the COVID-19 pandemic. Sublocade is a once-monthly injection designed to deliver buprenorphine at sustained levels of medication throughout the month.

• <u>Naltrexone</u> is a synthetic opioid <u>antagonist</u> – it blocks opioids from binding to receptors and is FDA-approved for the prevention of relapse to opioid dependence, following opioid detoxification. Naltrexone is well-tolerated following detoxification. It has no potential for abuse, and it is not addictive.<sup>12</sup> Long-acting injectable naltrexone is FDA-approved with recommended dosing once every four weeks<sup>13</sup> for maintenance of abstinence.<sup>14</sup> Naltrexone can be prescribed by any clinician who is licensed in the state to prescribe medications.<sup>15,16</sup>

https://www.accessdata.fda.gov/drugsatfda\_docs/label/2018/020732s018lbl.pdf

<sup>&</sup>lt;sup>8</sup> FDA. Subutex Highlights of Prescribing Information.

SAMHSA, Treatment Improvement Protocol: Medications for Opioid Use Disorder, May 2020.
 <a href="https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006">https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006</a>
 Volkow ND. Collision of the COVID-19 and Addiction Epidemics. Ann Intern Med. 2020; 173(1):61-62. doi:10.7326/M20-1212

<sup>&</sup>lt;sup>11</sup> Crist, Richard C et al. Pharmacogenetics of Opioid Use Disorder Treatment. CNS drugs. 2018; vol. 32 (4): 305-320. doi:10.1007/s40263-018-0513-9.

<sup>&</sup>lt;sup>12</sup> National Institute on Drug Abuse. (2018, January 17). Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition). <a href="https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/evidence-based-approaches-to-drug-addiction-treatment/pharmacotherapies.">https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/evidence-based-approaches-to-drug-addiction-treatment/pharmacotherapies.</a>

<sup>&</sup>lt;sup>13</sup> FDA. ReVia Highlights of Prescribing

Information.https://www.accessdata.fda.gov/drugsatfda\_docs/label/2013/018932s017lbl.pdf

<sup>&</sup>lt;sup>14</sup> Tanum L, Solli KK, Latif ZE, Benth JŠ, Opheim A, Sharma-Haase K, Krajci P, Kunøe N. Effectiveness of Injectable Extended-Release Naltrexone vs Daily Buprenorphine-Naloxone for Opioid Dependence: A Randomized Clinical Noninferiority Trial. JAMA Psychiatry. 2017 Dec 1;74(12):1197-1205. doi: 10.1001/jamapsychiatry.2017.3206. Erratum in: JAMA Psychiatry. 2018 Mar 14;75(5):530. PMID: 29049469;

PMCID: PMC6583381.

<sup>&</sup>lt;sup>15</sup> SAMHSA. Naltrexone. SAMHSA website.

https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.

<sup>&</sup>lt;sup>16</sup> We note that in addition to the MAT drugs listed here that are required to be covered for management of opioid dependency under the new benefit at section 1905(a)(29) of the Act, states that provide optional coverage of prescribed drugs under section 1905(a)(12) must do so consistent with sections 1902(a)(54) and 1927, which require coverage of all drugs and biologicals that satisfy the definition of a covered outpatient drug at sections 1927(k)(2)-(4), if the manufacturer has a national drug rebate agreement in effect. In that some medications not defined as MAT

To address the full scope of patients' treatment needs, section 1905(ee)(1) defines the required MAT benefit as including counseling services and behavioral therapy related to the drugs and biologicals covered under the new mandatory benefit. While states have flexibility to specify which counseling services and behavioral therapy they will include in the new mandatory benefit, states that already cover MAT successfully often cover a range of effective behavioral health services for beneficiaries with OUD receiving MAT, including the following:

- <u>Individual/Group Therapy</u> generally helps patients identify treatment goals and potential solutions to problems that cause emotional stress; seeks to restore communication and coping skills; strengthens self-esteem; and promotes behavior change and optimal mental health. Cognitive behavioral therapy is a type of therapy that has been shown to be successful in treating individuals with OUD.
- Peer Support Services are typically understood to be services in which a qualified peer support provider (also called a recovery coach or peer recovery support specialist) assists individuals with their recovery from substance use disorders, including OUD. Peer support services can also be offered in relation to co-occurring mental disorders and OUD. Services can include counseling on coping with symptoms and navigating early stages of the recovery process; modeling appropriate behavior, skills, and communication; engagement with a supportive community of recovering peers; and helping the person access community resources. CMS has issued guidance that addresses requirements for peer support providers.<sup>17</sup>
- <u>Crisis Intervention Services</u> are typically provided to immediately reduce or eliminate
  the risk of physical or emotional harm. Services can include evaluation, triage, and
  access to services; and treatment to effect symptom reduction, harm reduction, and/or
  safe transition of individuals in acute crisis to the appropriate level of care for
  stabilization.

#### **MAT Provider Landscape**

Section 3502 of the Drug Addiction Treatment Act of 2000<sup>18</sup> amended the Controlled Substances Act (CSA) to permit qualified physicians to receive a waiver of the CSA's separate registration requirements for prescribing and dispensing certain opioid medications, such as buprenorphine, to treat OUD. Because of concerns about the lack of access to OUD treatment, Congress expanded the types of practitioners who are eligible for a waiver to prescribe and dispense buprenorphine to treat OUD. The Comprehensive Addiction and Recovery Act of 2016 allowed nurse practitioners and physician assistants to qualify for a waiver.<sup>19</sup> Additionally,

may be used to assist in short or long-term treatment success for beneficiaries with OUD, such as medications to treat opioid withdrawal symptoms, CMS would encourage states to focus on optimal patient outcomes in decisions that impact coverage and access.

<sup>17</sup> https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD081507A.pdf.

<sup>&</sup>lt;sup>18</sup> Children's Health Act of 2000, Section 3501, Drug Addiction Treatment Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000). https://www.govinfo.gov/content/pkg/PLAW-106publ310/pdf/PLAW-106publ310.pdf.

<sup>&</sup>lt;sup>19</sup> Comprehensive Addiction and Recovery Act of 2016, Section 303, Medication-assisted Treatment for Recovery from Addiction, Pub. L. No. 114–198, 130 Stat. 69, (2016). <a href="https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf">https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf</a>

section 3201 of the SUPPORT Act<sup>20</sup> extends eligibility for prescribing buprenorphine for the treatment of OUD to clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives until October 1, 2023.

Section 3201 of the SUPPORT Act also expands the eligibility of certain physicians and other qualifying practitioners to treat up to 100 patients in the first year of waiver receipt if they satisfy one of the following two conditions found in regulation:<sup>21</sup>

- 1) The physician holds a board certification in addiction medicine or addiction psychiatry by the American Board of Preventive Medicine or the American Board of Psychiatry and Neurology; or
- 2) The practitioner provides MAT in a "qualified practice setting." A qualified practice setting is one that:
  - a. Provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;
  - b. Provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services:
  - c. Uses health information technology systems such as electronic health records in accordance with practice setting requirements;
  - d. Registers for their state prescription drug monitoring program where operational and in accordance with federal and state law; and
  - e. Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or federal health benefits.

After one year at the 100-patient limit, physicians and qualifying other practitioners who meet the above criteria can apply to increase their patient limit to 275.<sup>22</sup>

#### **Current MAT State Plan Coverage**

Currently, all state Medicaid programs cover some form of buprenorphine and extended-release naltrexone for treatment of OUD. In addition, most states also cover some form of the counseling and behavioral therapies that are necessary to provide evidence-based MAT. Methadone is indicated for use as part of an MAT protocol for treating OUD, but also for pain management. When used for treating OUD, methadone can only be administered by OTPs, which must be certified by SAMHSA and registered with the Drug Enforcement Administration (DEA).<sup>23</sup> OTPs must be licensed in the state in which they operate and accredited by a

<sup>&</sup>lt;sup>20</sup> SUPPORT Act, Section 3201, Allowing for More Flexibility with Respect to Medication-Assisted Treatment for Opioid Use Disorders.

<sup>&</sup>lt;sup>21</sup> 21 U.S.C. 823(g)(2)(B)(II)(bb) – (cc); Medication Assisted Treatment for Opioid Use Disorders, 42 C.F.R. 8.610, 42 C.F.R. 8.615.

<sup>&</sup>lt;sup>22</sup> 21 U.S.C. 823(g)(2)(B)(II)(dd); Medication Assisted Treatment for Opioid Use Disorders, 42 C.F.R. 8.610 – 655.

<sup>&</sup>lt;sup>23</sup> We note that in contrast, when methadone is used for the treatment of pain, it can be dispensed from pharmacies, which are not able to dispense methadone for OUD unless they are also certified as OTPs.

SAMHSA-approved accrediting body.<sup>24</sup> Additionally, federal regulations at 42 C.F.R. part 8 impose standards governing, for example, required services, staff credentials, patient admission criteria, and patient confidentiality criteria.<sup>25</sup> In a report on the use of medications to treat OUD in the 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, SAMHSA found that methadone is covered for MAT to treat OUD by Medicaid in 42 of the 53 states and territories included in the report.<sup>26</sup>

#### **Institution for Mental Diseases (IMD) Exclusion**

Frequently, MAT-related counseling and behavioral therapy are provided on-site at clinics and health centers where buprenorphine and/or naltrexone are dispensed. Primary care providers who prescribe MAT drugs often partner with local substance use disorder treatment or mental health care agencies to connect individuals to counseling. Federal regulation requires patients who receive treatment in an OTP to receive access to<sup>27</sup> medical, counseling, vocational, educational, and other assessment and treatment services, in addition to prescribed medication.<sup>28</sup> Medications for MAT, as well as the counseling and behavioral therapies, can also be furnished in inpatient and residential settings such as psychiatric hospitals, inpatient units, or residential treatment programs, including in IMDs, but Medicaid coverage is generally not available unless the setting is not an IMD or an exception to the IMD exclusion applies, as discussed below.

An IMD is defined in section 1905(i) of the Act as a "hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services." Under section 1905(a) of the Act, there is a general prohibition on Medicaid payment for any services provided to any individual under age 65 who resides in an IMD. This is commonly known as the "IMD exclusion." The IMD exclusion applies to any care or services provided inside or outside of the facility or hospital to a Medicaid beneficiary residing in an IMD, unless an exception to the IMD exclusion applies. As specifically relevant here, MAT and counseling and behavioral therapies provided in an IMD would not be covered by Medicaid unless an exception to the IMD exclusion applies.

Currently, there are several exceptions to the IMD exclusion and other authorities that permit short-term stays in IMDs. First, Medicaid payment is permitted for inpatient hospital services, nursing facility services, and intermediate care facility services provided in IMDs to individuals age 65 and older. Second, Medicaid payment is permitted for inpatient psychiatric hospital services for individuals under age 21, sometimes referred to as the "psych under 21 benefit," furnished by a psychiatric hospital, a general hospital with a psychiatric program that meets the applicable Conditions of Participation, or an accredited psychiatric facility that meets certain requirements, commonly referred to as a "Psychiatric Residential Treatment Facility." 30

<sup>&</sup>lt;sup>24</sup> SAMHSA. Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose. HHS Publication No. SMA-18-5093, page 39.

<sup>&</sup>lt;sup>25</sup> 42 C.F.R. 8.12.

<sup>&</sup>lt;sup>26</sup> SAMHSA. HHS Publication No. SMA-18-5093, page 39. Published November, 2018

<sup>&</sup>lt;sup>27</sup> SAMHSA, Treatment Improvement Protocol: Medications for Opioid Use Disorder, May 2020. https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006

<sup>&</sup>lt;sup>28</sup> 42 C.F.R 8.12(f)

<sup>&</sup>lt;sup>29</sup> 42 C.F.R. 440.140

<sup>30 42</sup> C.F.R. 440.160

Third, section 1012 of the SUPPORT Act, entitled "Help for Moms and Babies," added a new limited exception to the IMD exclusion. For more information, see the CMCS Informational Bulletin, "State Guidance for the New Limited Exception to the IMD Exclusion for Certain Pregnant and Postpartum Women, July 26, 2019." Fourth, section 5052 of the SUPPORT Act, entitled, "State option to provide Medicaid coverage for certain individuals with substance use disorders who are patients in certain institutions for mental diseases," amended the IMD exclusion and established a new section 1915(*l*) of the Act. This provision permits states to cover a state plan option to provide services to Medicaid beneficiaries age 21 through 64 who have at least one SUD diagnosis and reside in an eligible IMD. The period of this state plan option is from October 1, 2019 through September 30, 2023. For more information, see State Medicaid Director Letter (SMDL) # 19-0003, Re: Implementation of Section 5052 of the SUPPORT for Patients and Communities Act – State Plan Option under Section 1915(*l*) of the Social Security Act, November 6, 2019.<sup>32</sup>

Other authorities that permit short-term stays in IMDs include section 1115 demonstrations. CMS announced a section 1115 demonstration initiative where states can receive federal financial participation (FFP) for the continuum of services to treat addictions to opioids or other substances, including services provided to beneficiaries residing in IMDs. For more information, see section 1115 SUD Demonstrations, SMDL # 17-003, Re: Strategies to Address the Opioid Epidemic, November 1, 2017. Finally, states may receive FFP for monthly capitation payments for beneficiaries age 21 through 64 receiving SUD treatment in an IMD for a short-term stay of no more than 15 days during the period of the monthly capitation payment so long as criteria identified in the managed care regulation are met. <sup>34</sup>

# SUPPORT Act Section 1006(b) Coverage

Section 1006(b) of the SUPPORT Act requires states to begin implementing MAT as a mandatory Medicaid state plan benefit for categorically needy populations for the 5-year period beginning October 1, 2020. Under the definition of the new mandatory benefit at section 1905(ee)(1) of the Act, states are required to cover all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat OUDs. CMS interprets the statute to require coverage of all forms of the drugs and biologicals that the FDA has approved or licensed for treatment of OUD. States are also required to cover counseling services and behavioral therapies associated with provision of the required drug and biological coverage.

## **Exception for Provider Shortage**

Section 1905(ee)(2) of the Act provides that states may be excused from the mandatory coverage requirement if, before the requirement takes effect on October 1, 2020, the state "certifies to the satisfaction of the Secretary that implementing such provisions statewide for all individuals eligible to enroll in the State plan (or waiver of the State plan) would not be feasible by reason of

https://www.medicaid.gov/federal-policy-guidance/downloads/cib072619-1012.pdf.

https://www.medicaid.gov/federal-policy-guidance/downloads/smd19003.pdf.

https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.

<sup>&</sup>lt;sup>34</sup> 42 C.F.R. 438.6(e)

a shortage of qualified providers of medication-assisted treatment, or facilities providing such treatment, that will contract with the State or a managed care entity with which the State has a contract under section 1903(m) or under section 1905(t)(3)."

In CMS's view, the purpose of the new requirement is to increase access to MAT to treat OUD for Medicaid beneficiaries, and this can only be accomplished by increasing the enrollment in Medicaid of OTPs and other MAT providers and practitioners. CMS therefore expects states to conduct provider outreach and enrollment as they prepare to meet the new requirements. As discussed above, because methadone for treatment of OUD can only be provided in OTPs, states that do not already enroll OTPs as Medicaid providers will be expected to take action to do so. Additionally, if a state has MAT providers operating in the state that are not currently enrolled in the Medicaid program, states are expected to permit any willing and qualified provider to become a Medicaid provider for the newly required MAT benefit, so that beneficiaries may receive these services from the qualified and willing provider of their choice, consistent with section 1902(a)(23) of the Act and 42 C.F.R. 431.51.

CMS expects a state seeking the exception under section 1905(ee)(2) to document in its exception request that it has made a good faith effort toward enrolling providers of MAT for the Medicaid fee-for-service program, Medicaid managed care organizations (MCOs), and primary care case managers (PCCMs). Such documentation would include information about state review of MCO demonstrations of adequate capacity to furnish services under 42 C.F.R. 438.207; state standards for uniform credentialing policies that MCOs must use in accordance with 42 C.F.R. 438.214(b); and MCO policies and procedures for credentialing and recredentialing network providers, required under 42 C.F.R. 438.214. A state requesting an exception should conduct a detailed accounting of the current MAT providers in the state, both those that are enrolled in the Medicaid program and those that are not, and should detail in its exception request the process that the state has undertaken to contract with MAT providers (and/or to encourage that MAT providers contract with the state's Medicaid MCOs and/or PCCMs) and the reasons why the providers are not willing to enroll.

We recognize that there may be state-specific administrative challenges with providing CMS with the information necessary for the Secretary to determine that the state has satisfactorily certified to the existence of a shortage of providers, especially in light of the fact that this guidance is being issued after October 1, 2020, the effective date of the new MAT coverage requirement. Therefore, CMS will not require states seeking this exception to have submitted a request for the exception before October 1, 2020. Instead, CMS will accept state requests for this exception on or before January 14, 2021. The request for the exception should be submitted at the same time as a request for flexibility under section 1135 of the Act with respect to state plan amendment (SPA) submission and notice timelines (as described further below). If a state is not granted an exception based on a shortage of providers or facilities, then the state will need to submit a SPA, and requesting flexibility with respect to SPA submission and notice timelines could help the state to safeguard a SPA effective date of October 1, 2020 if the exception request is denied. For further detail, please refer to the "SPA Submission Requirements and Opportunity to Request Section 1135 Flexibility With Respect to SPA Submission and Notice Timelines" section below.

CMS remains committed to providing technical assistance to states and other stakeholders in understanding the mandatory MAT benefit and developing implementation approaches that result in the provision of Medicaid services in a manner compliant with program requirements.

States that seek an exception based on a shortage of providers or facilities should submit their request on or before January 14, 2021 to the Regional SPA/Waiver mailbox that is currently used for Medicaid SPA submissions. If the state is participating in the pilot for the new "One CMS Portal," the request for the exception based on a shortage of providers or facilities should be submitted via the portal. The information detailed below should be included with the request, which should include the state's certification that it cannot come into compliance with the new requirement due to a shortage of providers. States may, but are not required to, use the following format.

[Insert name of state] certifies that implementing the MAT benefit specified in section 1905(a)(29) of the Act is not feasible due to a shortage of qualified providers or facilities that will enroll in the state Medicaid program or contract with a Medicaid managed care organization (MCO) or Primary Care Case Manager to furnish one or more of the required MAT benefit components, and requests an exception from the requirement to provide this benefit for this reason.

The state's request should include all of the following information:

- a. A description of the state's current qualified provider and facility status, including the number, type, and location of qualified providers and facilities that furnish MAT.
- b. A brief description of the process that the state has undertaken to contract with all qualified MAT providers and facilities and reasons why the providers did not contract with the state or a managed care organization or Primary Care Case Manager.
- c. For all Medicaid MCOs in the state, the written policies and procedures for selection and retention of network providers required by 42 C.F.R. 438.214, and copies of the assurances of adequate capacity and supporting documentation required by 42 C.F.R. 438.207(b), along with the state's certification and supporting documentation required by 438.207(d).
- d. A description of the unmet need caused by the shortage of qualified providers or facilities among eligible children and adults whom the state identifies as individuals with OUD who could benefit from MAT.
- e. A description of the state's plan to enroll additional qualified providers or facilities to ensure that all individuals eligible for MAT under the state plan (or a waiver of the state plan) are able to access it, and the date when the state thinks it will resolve the qualified provider or facilities shortage.

All exceptions approved under section 1905(ee)(2) will be for the full five-year period that the new MAT benefit is required. However, if a state decides to come into compliance with the MAT benefit requirement after receiving an exception under section 1905(ee)(2), CMS will be available to provide technical assistance to the state.

## Extension of Compliance Deadline Due to Legislative Delay

Section 1006(b)(4)(B) of the SUPPORT Act (which was not codified in any provision of the Social Security Act) provides for an "exception" to the October 1, 2020 effective date of the new MAT benefit "for state legislation." Essentially, this provision provides for an extension to the required start date of the new coverage requirement if the only reason the state cannot come into compliance by October 1, 2020 is due to lack of state legislation that is needed to meet the requirement. Not all states will be able to seek this extension, because it depends on the timing of the state's first regular legislative session that began after the date of enactment of the SUPPORT Act (October 24, 2018). If the Secretary of Health and Human Services determines that state legislation is needed to bring the state plan into compliance with the new coverage requirement, the Secretary will not consider the state to be out of compliance with the new coverage requirement solely on the basis of a failure to enact the required state legislation before the first day of the first calendar quarter beginning after the close of the first regular session of the state's legislature that begins after October 24, 2018. If a state's first regular legislative session beginning after October 24, 2018 was the calendar year that began on January 1, 2019 and ended on December 31, 2019, the state would not be able to seek this extension because it would have had only until December 31, 2019 to enact any required legislation, and the first day of the first calendar quarter that begins after that date is January 1, 2020 - well before October 1, 2020.

If, however, a state's first regular legislative session beginning after October 24, 2018 does not end until on or after October 1, 2020, and the Secretary determines that legislation was necessary to meet the new coverage requirement, but the necessary legislative authorization was not obtained, the state could seek to delay compliance with the new coverage requirement until the first day of the first calendar quarter after the legislative session ends. Such a state is expected to come into compliance with the new coverage requirement by the first day of the first calendar quarter after the end of the legislative session, unless the exception in section 1905(ee)(2) applies. If a state has a two-year legislative session, each year of the session shall be considered to be a separate regular session of the state legislature for purposes of this extension. This means that a state would not have a longer extension if it has a two-year legislative session; such a state is treated like a state with a one-year legislative session, and any applicable extension ends on the first day of the first calendar quarter following the end of the first year of the two-year session.

CMS will grant an extension based on legislative delay only if a legislative delay is the only reason that a state cannot meet the requirement, and only when the first regular legislative session that began after October 24, 2018 ends on or after October 1, 2020, as discussed above. States should submit requests for the legislative delay extension on or before January 14, 2021 to the Regional SPA/Waiver mailbox that is currently used for Medicaid SPA submissions. If the state is participating in the pilot for the new "One CMS Portal," the request for the legislative delay extension should be submitted via the portal. The request should include documentation to support that the state's first regular legislative session that began after October 24, 2018 did not end until on or after October 1, 2020, that state legislation is needed to come into compliance with the new coverage requirement, and that the legislative delay is the only reason the state cannot come into compliance as of October 1, 2020. States are encouraged to submit a request for flexibility under section 1135 of the Act with respect to SPA submission and notice timelines,

as discussed below under "SPA Submission Requirements and Opportunity to Request Section 1135 Flexibility With Respect to SPA Submission and Notice Timelines," at the same time as the request for the legislative delay extension, in order to help safeguard a SPA effective date of October 1, 2020 if the state's request for a legislative delay extension is not granted. States may, but are not required to, use the following format for their legislative delay extension submission:

[Insert name of state] requests an exception based on the need for legislative authority to cover the benefit described in section 1905(a)(29) of the Social Security Act, and submits documentation to support that the state's first regular legislative session that began after October 24, 2018 will not end until on or after October 1, 2020. [Describe the documentation that is attached or that accompanies the request and include information about the state's legislative calendar so CMS can determine the state's compliance date.]

States that are granted an extension due to legislative delay will still need to follow the SPA submission requirements below and submit a SPA consistent with the extended compliance deadline.

# SPA Submission Requirements and Opportunity to Request Section 1135 Flexibility With Respect to SPA Submission and Notice Timelines

SPA effective date requirements outlined at 42 C.F.R. 430.20 provide for an effective date retroactive to the first day of the quarter in which the SPA was submitted. In addition, the public notice requirements at 42 C.F.R. 447.205 require states to publish notice of proposed changes in methods and standards for setting payment rates for services before the proposed effective date of the change. Accordingly, under these rules, states have only until December 31, 2020 to submit a SPA establishing coverage or payment for the new MAT benefit that would take effect October 1, 2020. Additionally, any SPA setting payment rates for the new benefit could take effect only after the state issues public notice of the proposed payment changes. Thus, states would have had to publish notice of their payment rate changes by September 30, 2020, for changes to take effect October 1, 2020.

CMS is aware that most states have been unable to submit a SPA for the new MAT benefit that meets these submission and notice timing requirements because they have had to focus almost exclusively on responding to the COVID-19 pandemic throughout much of 2020. At the same time, the opioid crisis has only been exacerbated by the COVID-19 pandemic. During the COVID-19 public health emergency (PHE), disruptions in treatment have resulted in a resurgence of relapses and fatal overdoses among individuals with OUD.<sup>35</sup>

Consequently, in order to help ensure that beneficiaries can access coverage for the new MAT benefit effective retroactively to October 1, 2020, CMS is giving states the opportunity to request that CMS exercise its section 1135 authority to modify the regulatory deadlines associated with SPA submission and public notice for coverage and payment SPAs for the new MAT benefit while the COVID-19 PHE is still in effect.<sup>36</sup> CMS strongly recommends that states submit these

<sup>35</sup> https://qz.com/1889798/covid-19-is-making-the-opioid-crisis-much-worse

<sup>&</sup>lt;sup>36</sup> Section 1135 authority permits the Secretary to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements during a PHE, in order to ensure, to the maximum extent feasible, that sufficient health care items and services are available to meet the needs of individuals enrolled in those programs.

requests on or before January 14, 2021. Specifically, if responding to the COVID-19 pandemic has delayed a state's ability to submit a coverage or payment SPA for the new MAT benefit or provide public notice of payment rate changes related to the new MAT benefit under the time frames set forth at 42 C.F.R. 430.20 and 447.205, the state may request flexibility regarding the timing of the SPA public notice and submission process for these SPAs, so that it can submit SPAs adding coverage and payment for the new mandatory MAT benefit at section 1905(a)(29) of the Act in the first quarter of 2021 that would be effective October 1, 2020. If a state does not submit a request for section 1135 flexibility as described herein and submits a SPA after December 31, 2020 to add the new mandatory MAT benefit, then the SPA's effective date would be on (or sometime after) January 1, 2021, beneficiaries might not be able to access all available MAT coverage before that date, and the state would not be in timely compliance with the new coverage requirement.

CMS will provide states with this flexibility only if they meet the following conditions. First, all state requests for modification of the deadlines for MAT SPA submission and public notice under section 1135 must be submitted and approved during the COVID-19 PHE, and all MAT SPAs must be submitted on or before March 31, 2021. Second, states must solicit and should consider public comments and comments received through tribal consultation before finalizing the SPAs that will take effect. States must conduct tribal consultation if required under section 1902(a)(73)(A) before submission of their MAT SPAs, even if CMS approves a modification under section 1135 of the 42 C.F.R. 447.205 notice timelines. Additionally, CMS strongly recommends that states conduct any public notice required under 42 C.F.R. 447.205 before submitting their MAT SPAs, even if CMS approves a modification under section 1135 of the timeline for that notice. If states have had to put in place interim coverage or rate policies for the new MAT benefit while preparing their SPAs for submission and finalizing them for approval, they would be expected to give effect to the rates and coverage policies that are ultimately approved retroactive to the effective date of October 1, 2020. States seeking these section 1135 flexibilities should submit a letter to Jackie Glaze at Jackie Glaze@cms.hhs.gov by January 14, 2021. In addition to a statement explaining that the state's response to the COVID-19 pandemic has delayed its ability to submit coverage and/or payment SPAs for the new MAT benefit according to the regulatory SPA submission and notice timelines, the letter should include the following language (as applicable):

## Request for Modifications under Section 1135

Pursuant to section 1135(b)(5) and/or 1135(b)(1)(C) of the Act, the state Medicaid agency requests modification of SPA submission requirements at 42 C.F.R. 430.20, in order to submit a SPA implementing section 1905(a)(29) of the Act by March 31, 2021 that would take effect on October 1, 2020.

Pursuant to section 1135(b)(5) and/or 1135(b)(1)(C) of the Act, the state Medicaid agency requests modification of the public notice time frames set forth at 42 C.F.R. 447.205, in order to obtain an effective date of October 1, 2020 for its SPA implementing statewide methods and standards for setting payment rates for the benefit described at section 1905(a)(29) of the Act. The state will issue public notice as soon as possible, and in no event later than February 28, 2021.

With respect to SPA submissions related to coverage and payment for the new MAT benefit, states should take the following steps.

States should submit an amendment to their Medicaid state plans (including to Alternative Benefit Plans, if applicable), no later than December 31, 2020 (or March 31, 2021, if CMS has approved section 1135 flexibility as discussed above) after having conducted public notice and tribal consultation, as needed, to cover, under the new mandatory benefit at section 1905(a)(29) of the Act, all FDA-approved or licensed drugs and biologicals used for MAT to treat OUD, as well as all forms of the drugs and biologicals approved or licensed by the FDA for MAT to treat OUD, and associated counseling services and behavioral therapies. States should submit their SPAs to the Regional SPA/Waiver mailbox that is currently used for other Medicaid SPA submissions. If a state is participating in the pilot for the new "One CMS Portal," the SPA should be submitted via the portal.

States that already use existing Medicaid authorities to cover items and services that will now be covered under the new mandatory MAT benefit, including FDA-approved or licensed drugs and biologicals used for MAT to treat OUD, and associated counseling services and behavioral therapies, are expected to submit a SPA to move their coverage of these items and services to a new page in their Medicaid state plans for the new mandatory benefit at section 1905(a)(29) of the Act.

In addition to submitting SPAs to add the mandatory MAT benefit to the state plan, states will need to propose associated changes to the payment section of the state plan. States will need to submit a new Attachment 4.19-B page for the mandatory benefit at section 1905(a)(29) that describes the rate-setting methodology used to pay for the services covered under the mandatory MAT benefit. The rate-setting methodology for the new MAT benefit must be consistent with section 1902(a)(30)(A) of the Act, which requires Medicaid payments to be "consistent with efficiency, economy, and quality of care" and to be "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." States may include all medical service costs associated with furnishing the MAT benefit services to Medicaid beneficiaries (such as salaries, fringe benefits, supplies, and equipment) in their rate-setting methodology for the new MAT benefit, and the methodology must be a comprehensive description within the state plan consistent with 42 C.F.R. 430.10. As states have a variety of options to choose from in how they pay for MAT services, CMS is available to provide assistance to states as they develop SPA proposals. We encourage states to reach out to their state lead in the Medicaid and CHIP Operations Group for technical assistance.

As with any SPA submission, CMS expects states to comply with all SPA requirements that are not waived or modified, including those found in 42 C.F.R. 440.200, et seq., and to provide information on the source of the non-federal share of the service payments and information on the rate-setting methodology. Specific guidance related to SPA submission procedures may be found on the Medicaid.gov web page.

# MAT Drug Coverage and Section 1927 Manufacturer Rebates

CMS interprets section 1905(ee)(1) of the SUPPORT Act to require that states include as part of the new mandatory benefit all forms of drugs and biologicals that the FDA has approved or licensed for MAT to treat OUD. More specifically, under the new mandatory MAT benefit, states are required to cover such FDA approved or licensed drugs and biologicals used for indications for MAT to treat OUD.

Statutory amendments were made to the original language at sections 1905(a)(29) and 1905(ee) by Section 2601 of the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. No. 116-159) to specify that the rebate requirements in section 1927 shall apply to any MAT drugs or biologicals described under the mandatory benefit at section 1905(ee)(1)(A), that are furnished as medical assistance under sections 1905(a)(29) and section 1902(a)(10)(A), and are covered outpatient drugs, as that term is defined at section 1927(k)(2). In determining whether such a MAT drug or biological satisfies the definition of a covered outpatient drug, such MAT drugs or biologicals are deemed prescribed drugs for such purposes. More specifically, these amendments ensure that MAT drugs and biologicals can be included in the Medicaid Drug Rebate Program (MDRP). Additionally, for MAT drugs or biologicals that are also covered outpatient drugs, the amendments also ensure a state's ability to seek section 1927 rebates and apply drug utilization management mechanisms (such as preferred drug lists and prior approval), and establish a manufacturer's obligation to pay appropriate rebates and comply with all applicable drug product and drug pricing reporting and payment of rebates. The change in law is effective as if included in the enactment of the SUPPORT Act, which was October 24, 2018.

CMS expects that most manufacturers of MAT drugs and biologicals currently have in effect a rebate agreement with the Secretary and pay rebates to states for all drugs and biologicals that meet the definition of covered outpatient drug (COD) in section 1927(k) of the Act, and if not, that manufacturers of these drugs and biologicals will likely enter into a rebate agreement with the Secretary and pay rebates to states. Should an FDA-approved MAT drug or biological for OUD not meet the definition of a covered outpatient drug, or if the drug is a covered outpatient drug, but the manufacturer does not have a rebate agreement in effect with the Secretary, the state would still be required to cover the drug or biological under the MAT mandatory benefit, and the drug or biological would be eligible for FFP, but not rebates. States could subject MAT drugs or biologicals that are not covered outpatient drugs to prior approval or other utilization management mechanisms under 42 C.F.R. 440.230 as described below, including in order to prioritize coverage of those drugs that are covered outpatient drugs, but the state still must provide coverage for MAT drugs that are not covered outpatient drugs if they are medically indicated for the beneficiary, consistent with 42 C.F.R. 440.230(b).

#### State Use of Utilization Management Mechanisms

As a reminder, states may use utilization management controls to promote the efficient delivery of care and to control costs.<sup>37</sup> States can use the Section 1927 utilization management mechanisms for MAT drugs used for OUD that are covered outpatient drugs, such as

<sup>&</sup>lt;sup>37</sup> Medicaid and CHIP Payment and Access Commission's (MACPAC) October 2019, Report to Congress: Utilization Management of Medication-Assisted Treatment in Medicaid, <a href="https://www.macpac.gov/wp-content/uploads/2019/10/Report-to-Congress-Utilization-Management-of-Medication-Assisted-Treatment-in-Medicaid.pdf">https://www.macpac.gov/wp-content/uploads/2019/10/Report-to-Congress-Utilization-Management-of-Medication-Assisted-Treatment-in-Medicaid.pdf</a>

encouraging the use of generic products, creating a preferred drug list, or choosing to implement prior authorization to manage drug classes that may require additional monitoring.

For MAT drugs that are covered outside of a rebate agreement, or would be covered outpatient drugs, except that they are subject to the limiting definition at section 1927(k)(3) (e.g. those that are paid as part of a bundle), states may use the utilization management mechanisms authorized under 42 C.F.R. 440.230. In these cases, states may propose limits on the amount, duration, and scope of these drugs under the MAT benefit, including to encourage the use of the most cost-effective MAT drugs and biologicals.

# Support to States for Increasing SUD Treatment Options

Well-supported scientific evidence demonstrates that treatment for substance use disorders – including inpatient, residential, and outpatient treatment – is cost-effective compared with no treatment. <sup>38</sup> Existing Medicaid authorities, as well as new opportunities afforded by the SUPPORT Act, are available to help states expand their SUD service continuum, which can include MAT.

Section 1115 demonstration projects – In November 2017, CMS announced a section 1115 initiative that affords states the opportunity to receive federal financial participation (FFP) for expenditures on the continuum of services to treat SUD, including expenditures on treatment while Medicaid enrollees are residing in residential treatment facilities that are IMDs. Such expenditures can generally not be federally matched under Medicaid due to the IMD exclusion. As part of this initiative, states may develop innovative approaches to inpatient and residential care for individuals with SUDs that are expected to supplement and coordinate with community-based care to provide a robust continuum of care in the state. Participating states are required to ensure residential settings included in these demonstrations are either offering beneficiaries access to MAT on-site or facilitating beneficiaries' access to MAT off-site.<sup>39</sup>

Section 1003 of the SUPPORT Act – Section 1003 requires the Secretary to conduct a demonstration project to increase Medicaid SUD provider capacity. In 2019, CMS awarded planning grants to 15 states to conduct an assessment of SUD treatment and recovery needs of the state. The planning grants may also support activities to recruit, train, and provide technical assistance for providers; to improve reimbursement; and to expand the number or treatment capacity of Medicaid providers. Up to five of the states that received planning grants will be selected to implement demonstrations and receive enhanced federal reimbursement for increases in Medicaid SUD treatment and recovery services expenditures. For more information on this demonstration project, and the 15 states that were awarded planning grants, see the Medicaid.gov web page. 40

<u>Section 1006(a) of the SUPPORT Act</u> – Section 1006(a) of the SUPPORT Act permits CMS to extend, at state request, the period of 90% federal match from eight to 10 fiscal year quarters for

<sup>&</sup>lt;sup>38</sup> Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health.* Washington, DC: HHS, November 2016. Chapter 4, Early Intervention, Treatment, and Management of Substance Use Disorders. <a href="https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf">https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf</a>.

<sup>&</sup>lt;sup>39</sup> SMDL # 17-003, Re: Strategies to Address the Opioid Epidemic, November 1, 2017, https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.

<sup>40</sup> https://www.medicaid.gov/medicaid/benefits/bhs/support-act-provider-capacity-demos/index.html

health home SPA approved on or after October 1, 2018. The Medicaid health home state plan option (authorized under section 1945 of the Act) promotes coordination of primary and acute physical and behavioral health services and long-term services and supports. Specific guidance related to the health home Medicaid state plan option, including guidance on health home services, health home providers, state reporting, and developing payment methodologies, can be found on the Medicaid gov web page. Information on section 1006(a) of the SUPPORT Act is also available in the policy guidance tab on the Medicaid gov web page.

Section 7181 of the SUPPORT Act – Section 7181 of the SUPPORT Act reauthorized and modified the "State and Tribal Response to the Opioid Crisis" grants established under section 1003 of the 21st Century Cures Act. Section 7181 requires the grants to be awarded to Indian tribes in addition to states and territories. This provision also expands the types of activities that grants may support to include the establishment of prescription drug monitoring programs and training for health care practitioners in preventing diversion of controlled substances. It also emphasizes flexibility with use of funds by permitting resources to be directed "in accordance with local needs related to substance use disorders."

Section 7181 authorizes \$500 million for each of Fiscal Years 2019-2021, which would remain available until expended. It authorizes a set-aside of up to 15% for states with the highest age-adjusted rate of drug overdose death based on the ordinal ranking of states according to the Centers for Disease Control and Prevention (CDC)<sup>44</sup>. SAMHSA will provide state agencies and Indian tribes with technical assistance on grant application and submission procedures, award management activities, and enhancing outreach and direct support to rural and underserved communities and providers in addressing the opioid crisis.

<u>Telehealth</u> – HHS developed materials to help clarify how clinicians can use telemedicine as a tool to expand buprenorphine-based MAT for OUD treatment under current DEA regulations. This information includes a clinical practice example that is consistent with applicable DEA and HHS administered authorities. It is hoped that the materials help expand providers' ability to prescribe MAT to patients, including remote patients under certain circumstances. This information can be found on the HHS.gov web page.<sup>45</sup>

Telehealth could be especially helpful in supporting access to buprenorphine in rural areas, where there may be a smaller number of waivered providers able to prescribe buprenorphine for the treatment of OUD in settings other than federally regulated opioid treatment programs.<sup>46</sup>

<sup>41</sup> https://www.medicaid.gov/medicaid/ltss/health-homes/index.html.

<sup>42</sup> CMCS Informational Bulletin, Guidance for States on the Availability of an Extension of the Enhanced Federal Medical Assistance Percentage (FMAP) Period for Certain Medicaid Health Homes for Individuals with Substance Use Disorders (SUD), May 7, 2019, https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib/050719.pdf.

<sup>43</sup> https://www.govinfo.gov/content/pkg/PLAW-115publ271/html/PLAW-115publ271.htm

<sup>44</sup> https://www.cdc.gov/drugoverdose/data/statedeaths.html

<sup>&</sup>lt;sup>45</sup> https://www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-hhs-statement-final-508compliant.pdf. default/files/2018-09/hhs-telemedicine-hhs-statement-final-508compliant.pdf. default/files/2018-09/hhs-telemedicine-hhs-statement-final-fi

CMS also released a State Medicaid Director Letter (SMDL) in June 2018, "Leveraging Medicaid Technology to Address the Opioid Crisis," that includes a section on how states can leverage telehealth technologies to improve access to SUD treatment. This SMDL also discusses the potential availability of enhanced federal funding to support telehealth-enabling technologies. Additionally, consistent with section 1009(b)(1) of the SUPPORT Act, CMS issued guidance on federal Medicaid reimbursement for services to treat SUD furnished via telehealth, including in School-Based Health Centers. Services discussed in this guidance include assessment, MAT, counseling, medication management, and medication adherence with prescribed medication regimes.

#### **Conclusion**

MAT is an effective, comprehensive, and evidence-based treatment that is integral to addressing the nation's opioid crisis. Section 1006(b) of the SUPPORT Act amended the Social Security Act to require states to cover MAT for all eligible to enroll in the state plan or waiver of state plan. The new mandatory MAT benefit includes all FDA-approved drugs and licensed biologicals used for MAT to treat OUD, as well as associated counseling and behavioral therapies. CMS interprets the statute to require coverage of all forms of drugs and biologicals approved or licensed by the FDA for use as MAT to treat OUD. CMS is available to provide technical assistance and looks forward to working with states to ensure Medicaid beneficiaries with OUD receive the services they need. If you have any questions, please contact Kirsten Jensen, Director of the Division of Benefits and Coverage, at Kirsten.Jensen@cms.hhs.gov.

Sincerely,

/s/

Anne Marie Costello Acting Deputy Administrator and Director

cc: State Mental Health Directors

State Substance Use Directors

State Opioid Treatment Authorities

State Budget Officers

State Pharmacy Directors

National Association of Medicaid Directors

National Association of State Mental Health Program Directors

National Association of State Alcohol and Drug Abuse Directors

Association of State and Territorial Health Officials

National Association of State Budget Officers

National Conference of State Legislatures

47 https://www.medicaid.gov/federal-policy-guidance/downloads/smd18006.pdf.

<sup>&</sup>lt;sup>48</sup> CMCS Informational Bulletin, April 2, 2020. Rural Health Care and Medicaid Telehealth Flexibilities, and Guidance Regarding Section 1009 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271), entitled Medicaid Substance Use Disorder Treatment via Telehealth. <a href="https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib040220.pdf">https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib040220.pdf</a>

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