DEPARTMENT OF REGULATORY AGENCIES

Division of Insurance

3 CCR 702-4

LIFE, ACCIDENT AND HEALTH

DRAFT Proposed Amended Regulation 4-2-75

CONCERNING REQUIREMENTS FOR REPORTING MEDICATION-ASSISTED TREATMENT COVERAGE

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Section 1 Authority

This regulation is promulgated and adopted by the Commissioner of Insurance under the authority of §§ 10-1-109, 10-16-109, and 10-16-710, and 10-16-148, C.R.S.

Section 2 Scope and Purpose

The purpose of this regulation is to establish the data reporting requirements for carriers concerning the coverage of medication-assisted treatment as required by § 10-16-710, C.R.S.

Section 3 Applicability

This regulation applies to all carriers marketing and issuing or renewing health benefit plans in the individual, small group and large group markets in Colorado, including non-grandfathered plans, short-term limited duration health insurance policies, and student health insurance coverage, on or after the effective date of this regulation. This regulation does not apply to limited benefit plans, as defined in § 10-16-102(32)(b), C.R.S., and exclusions for coverage of specific mandated benefits as found at § 10-16-104(1.4), C.R.S.

Section 4 Definitions

- A. "Carrier" shall have the same meaning as found at § 10-16-102(8), C.R.S.
- B. "Health benefit plan" shall have the same meaning as found at § 10-16-102(32), C.R.S.
- C. "Medication-assisted treatment" or "MAT" means, for the purposes of this regulation, the use of an FDA-approved medication alone or in combination with evidence-based behavioral therapies to treat a substance use disorder or withdrawal or treat or prevent the relapse of a substance use

- disorder., including, but not limited to, opioid use disorder, tobacco use disorder, and alcohol use disorders. shall have the same meaning as found at § 23-21-803(4), C.R.S
- D. "Medication to treat opioid use disorder" or "MOUD" shall mean medications to treat opioid use disorder as defined in this regulation.
- Opioid use disorder or "OUD" shall mean a substance use disorder relating to the use of an opioid.
- "Opioid Treatment Program" or "OTP" shall mean a program with current, valid certification from the Substance Abuse and Mental Health Services Administration and qualified by the Secretary of Health and Human Services under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. § 823(g)(1)) to dispense opioid drugs in the treatment of opioid use disorder. It must be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the U.S. Attorney General under section 303(g)(1), to be registered by the U.S. Attorney General to dispense opioid agonist treatment medications to individuals for treatment of opioid use disorder.
- GF. ""Prior authorization" shall have the same meaning as found at § 10-16-112.5(7)(d), C.R.S.
- <u>GH.</u> "SERFF" means, for the purposes of this regulation, the NAIC System for Electronic Rate and Form Filing.
- HIG. "Short-term limited duration health insurance policy" and "short-term policy" shall have the same meaning as found at § 10-16-102(60), C.R.S.
- IJ. "Step therapy" shall have the same meaning as found at § 10-16-145(1)(g), C.R.S.
- HJK. "Student health insurance coverage" and "student health policy" shall have the same meaning as found at § 10-16-102(65), C.R.S.
- "Substance use disorder" or "SUD" means, for the purposes of this regulation, all disorders that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use, or an equivalent category, in the mental, behavioral, and neurodevelopmental disorders chapter, or an equivalent chapter, or disorders listed as a substance-related and addictive disorder in the manuals referenced in § 10-16-104(5.5)(d)(II)(A), C.R.S. the recurring use of alcohol and/or drugs that causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities.
- JLM. "Substance use disorder benefits" means, for the purposes of this regulation, the benefits supplied for items or services for substance use disorders, for health benefit plans shall have the same meaning as found at 45 C.F.R. § 146.136(a)(2), except for generally recognized independent standards of current medical practice shall also include the Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood as referenced in § 10-16-104(5.5)(d)(II)(A), C.R.S.

Section 5 Reporting Requirements

- A. Carriers shall annually report the data in Sections 5.BC through 5.GF to the Commissioner of Insurance using the templates in Attachment A and instructions provided by the Division.
- B. Timing and Format of Filings

- 1. No later than September 1, 2021, carriers shall report all required data for medication-assisted treatment (MAT) and medication to treat opioid use disorder (MOUD) coverage provided in the 2020 calendar year.
- 1.2. On February 1, 2022, and annually thereafter, cCarriers shall report all required data for MAT coverage in the previous calendar year by February 1 of each year.
- 32. Annual reports shall include data pertaining to the carrier's coverage of MAT, as well as coverage administered by third-party administrators (TPAs).
- 3. Carriers shall submit the completed templates and documents in SERFF as an "Annual Medication-Assisted Treatment (MAT) Reporting (4-2-75)" filing. This filing shall be submitted separately from any rate, form, annual certification, binder or network adequacy filing.
- 4. Carriers shall use "On Approval" for the "Implementation Date" in SERFF.
- 5. Carriers shall use "File and Use" for the "Requested Filing Mode" in SERFF.
- BC. Carriers shall provide the following information for each network regarding in_network providers that meet federal and state requirements are federally licensed to prescribe MAT for substance use disorders (SUD), and including opioid use disorder (OUD), including buprenorphine.
 - 1. The number of <u>SUD</u> providers by <u>provider</u> type at the beginning of the calendar year;
 - 2. The number of <u>SUD</u> providers by <u>provider</u> type at the end of the calendar year;
 - 3. The number of SUD <u>treatment programs and opioid treatment programs (OTPs)</u> and the types of MAT medications provided at each type of program;
 - 4. The number of Opioid Treatment Programs (OTPs), the MAT medications provided, and the number of providers who are authorized to dispense or administer prescribe methadone for the treatment of OUD; and
 - 5. The number of SUD providers in each county.; and
 - 6. The number of providers with a federal waiver to prescribe buprenorphine for the treatment of OUD.
- Carriers shall provide the Division with the total number of <u>unique</u> plan enrollees <u>that used SUD</u> <u>services throughout the previous calendar year</u>, at the beginning <u>of the previous calendar year</u>, and <u>at the end of the previous calendar plan</u> year.
- DE. <u>Carriers shall report data relating to medications prescribed for the treatment of SUD in the previous calendar year.</u> Such data shall include:
 - Carriers shall provide to the Division tThe total number of prescriptions filled by unique enrollees for MAT medications for SUD and the average number of prescriptions filled per unique enrollee for MAT medications for SUD and OUDin the prior calendar year.
 - The total number of prescriptions filled by unique enrollees for SUD that applied prior authorization, step therapy, quantity limits, or other utilization management protocols, and:
 - a. The name and dosage of the prescription medications and the applicable SUD;

- b. Whether prior authorization or step therapy were required for each medication; and
- The total number of claims that were approved or denied for each medication,
 and the top three reasons that the carrier or pharmacy benefit manager denied claims for the medication.
- 3. The total number of requests for a prescription medication for SUDs that is not otherwise included in the formulary, including the number of claims approved, and denied, and in progress, as well as the top three reasons that the carrier or pharmacy benefit management firm denied the claims.
- EF. Carriers shall provide to the Division a detailed description of its efforts to ensure sufficient capacity for and access to MAT for SUD, including the following:
 - 1. Policies and procedures to ensure enrollee access to OTPs, including any policies and procedures to assist with transportation, telehealth services, take-home dosing, and complementary behavioral health services;
 - 2. The methodology or other formal processes used by the carrier and TPA, if applicable, to determine network sufficiency to ensure access to MAT for SUD and OUD, and process(es) undertaken if the carrier or TPA has found insufficiencies;
 - 3. Policies and procedures regarding prior authorization requirements for MAT for SUD and OUD, including requirements for pregnant and parenting people as well as minors;
 - 4. Coverage and utilization management for MAT prescriptions, including differences in coverage and utilization management provisions for different FDA-approved medications for the treatment of OUD;
 - <u>35.</u> Processes to recruit and retain providers to prescribe MAT for SUD and OUD, including care received in an OTP and office-based buprenerphine, to enrollees; and
 - 64. The evidentiary or other standards and practices used to determine eligibility of providers who prescribe MAT for SUD and OUD to join the network.
- G. Carriers shall provide to the Division all documentation and supporting data regarding coverage of MAT for SUD in compliance with Colorado law, including the following information:
 - The carrier's public-facing Colorado prescription drug formularies (e.g., "standard formulary") for each applicable market, which must show if the formulary contains FDA-approved medications for all SUDs;
 - A description and list of the tier placements for each FDA-approved prescription
 medication used in the treatment of SUDs to determine compliance with the requirements
 to place at least one FDA-approved medication for SUDs on the lowest-cost tier of the
 formulary;
 - 3. For carriers that apply prior authorization requirements, Tthe written policies and procedures regarding prior authorization requirements for MAT for SUD, including requirements for pregnant and parenting people as well as minors. If prior authorization is required for MAT for SUD, carriers must provide an overview of the carrier's or TPA's policies and procedures regarding requiring prior authorization, including the appeals process when a medication is denied, and an explanation for how the applied prior authorization meets the requirements laid out in § 10-16-148, C.R.S., and this regulation.

This should include, at a minimum, the education and professional qualifications of the reviewer who is responsible for making the determinations at each level of the appeals process. If a carrier does not apply prior authorization requirements, a carrier must attest in a template provided by the Division that it does not apply such requirements; and

4. For carriers that apply utilization management requirements, Aa list of all utilization management requirements that a carrier applies for prescription drugs used for SUDs, including differences in coverage and utilization management provisions for different FDA-approved medications for the treatment of SUDs, supported by the carrier's written policies and procedures for these requirements. If a carrier does not apply any utilization management requirements, a carrier must attest in a template provided by the Division that it does not apply such requirements.

Section 6 Incorporation by Reference

45 C.F.R. § 146.136(a)(2) shall mean 45 C.F.R. § 146.136(a)(2) as published by the Government Printing Office on the effective date of this regulation and does not include later amendments to or editions of 45 C.F.R. § 146.136(a)(2). A copy of 45 C.F.R. § 146.136(a)(2) may be examined during regular business hours at the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, Colorado, 80202. A certified copy of 45 C.F.R. § 146.136(a)(2) may be requested from the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, CO 80202. A charge for certification or copies may apply. A copy may also be obtained online at www.ecfr.gov.

Section 76 Severability

If any provision of this regulation or the application of it to any person or circumstance is for any reason held to be invalid, the remainder of this regulation shall not be affected.

Section 87 Enforcement

Noncompliance with this regulation may result, after proper notice and hearing, in the imposition of any of the sanctions made available in the Colorado statutes pertaining to the business of insurance or other laws which include the imposition of fines, issuance of cease and desist orders, and/or suspensions or revocation of license. Among others, the penalties provided for in §10-3-1108, C.R.S., may be applied.

Section 98 Effective Date

This regulation shall be effective on January 30, 2026. June 15, 2021.

Section 109 History

New regulation effective June 15, 2021. Amended regulation effective January 30, 2026.

Attachment A: Medication-Assisted Treatment (MAT) Reporting Requirements

Carriers shall use this template to submit annual reporting requirements to the Division pursuant to Colorado Insurance Regulation 4-2-75 and § 10-16-710 CRS as it applies to the carrier and third-party administrator (TPA), if applicable. When providing information regarding medication assisted treatment (MAT) for substance use disorder (SUD) and opioid use disorder (OUD), please differentiate data between the two treatment types. Do not include OUD-specific data in SUD-specific data.

Carrier	-
TPA (if applicable)	-
Network	-
Contact Name	-
Contact Email	-
Date of Submission	-

1. Indicate the number of in-network providers that are federally-licensed to provide MAT for SUD and OUD at the beginning of the calendar year and at the end of the calendar year, including the type of medications available to treat opioid use disorder (MOUD).

Beginning of Calendar Year

Provider Type	SUD	OUD	MOUD
Physician, MD or DO			
Nurse Practitioner			
Physician Assistant			
Clinical Nurse Specialist			
Certified Registered Nurse Anesthetist			
Certified Nurse-Midwife			
Other			

End of Calendar Year

Provider Type	SUD	OUD	MOUD
Physician, MD or DO			
Nurse Practitioner			
Physician Assistant			
Clinical Nurse Specialist			
Certified Registered Nurse Anesthetist			

Certified Nurse-Midwife		
Other		

 Provide the number of SUD and opioid treatment programs in the network, as well as the type of MOUD.

Type of Program	Number	Type(s) of MOUD
SUD treatment program		
Opioid treatment program		

3. Provide the number of providers treating SUD & OUD in each county at the end of the calendar year.

County	SUD	OUD	County	SUD	OUD
Adams	_	_	Kit Carson	-	-
Alamosa	_	-	La Plata	_	_
Arapahoe	_	-	Lake	1	_
Archuleta	_	-	Larimer	1	_
Baca	-	_	Las Animas	1	_
Bent	_	1	Lincoln	1	_
Boulder	-	-	Logan	1	_
Broomfield	-	_	Mesa)	_
Chaffee	-	_	Mineral	ı	_
Cheyenne		-	Moffat	ı	_
Clear Creek	,	-	Montezuma	ı	_
Conejos	-	-	Montrose	-	_
Costilla	-	-	Morgan	_	_
Crowley	-	-	Otero	_	_
Custer	_	_	Ouray	ı	_
Delta	-	_	Park	ı	_
Denver	-	_	Phillips	1	_
Dolores	-	_	Pitkin	1	_
Douglas	-	_	Prowers	1	_
Eagle	_	_	Pueblo	1	_
El Paso	_	_	Rio Blanco	ı	_
Elbert	_	_	Rio Grande	-	_
Fremont	-	_	Routt	-	_
Garfield	_	_	Saguache	1	_
Gilpin	_	_	San Juan	-	_
Grand	=	_	San Miguel	ı	_

Gunnison	_	_	Sedgwick	_	_
Hinsdale	_	_	Summit	_	_
Huerfano	-	_	Teller	_	_
Jackson	-	_	Washington	_	_
Jefferson	-	_	Weld	_	_
Kiowa	_	_	Yuma	_	_

4. Provide the number of providers who are authorized to prescribe methadone for the treatment of OUD at the beginning and end of the calendar year in the network.

Time Period	Providers
Beginning of Calendar Year	
End of Calendar Year	

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any I	policies an	d procec	lures to	assist w	rith transp	ortation,	telehealth	services, to	ake-home	dosing,	and
	olementary									J,	

6. Provide the number of unique enrollees at the beginning of the calendar year and end of the calendar year using SUD and OUD services.

Time Period	Enrollees
Beginning of Calendar Year	
End of Calendar Year	

7. Provide the number of unique patients being seen for MAT for SUD, OUD, and MOUD.

Provider Type	Number of Patients - SUD	Number of Patients - OUD	Number of Patients Receiving MOUD
Physician, MD or DO			
Nurse Practitioner			
Physician Assistant			
Clinical Nurse Specialist			

Certified Registered Nurse Anesthetist		
Certified Nurse- Midwife		
Other		

8. Provide the total number of prescriptions that were filled by unique enrollees for MAT for SUD and OUD in the calendar year.

Condition Type	Total Prescriptions filled by Unique Enrollees
SUD	
OUD	

9. Provide a 'yes' or 'no' response following questions regarding MAT for SUD.

→ Yes → No	Is prior authorization, step therapy, or other utilization management policies required for any FDA-approved medications used as part of the treatment of SUD?
→ Yes → No	Is prior authorization, step therapy, or other utilization management policies required for any FDA-approved medications used as part of MAT for OUD?
← Yes ← No	Does the formulary use place any of the medications used for OUD, SUD, alcohol use disorder, or nicotine dependence on the lowest-cost tier of the formulary?
C Yes C No	Does the formulary contain all FDA-approved medications for the treatment of OUD, SUD, alcohol use disorder, and nicotine dependence?
○ Yes ○ No	Is Naloxone covered? Please list all formulations that are covered below.
	Is Buprenorphine covered? Please list all formulations that are covered below.
○ Yes ○ No	Is Methadone covered?
→ Yes → No	Is Naltrexone covered?
→ Yes → No	Is Disulfiram covered?

○ Yes ○ No	Is Acamprosate covered?
○ Yes ○ No	Is Clonidine covered?

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- 10. If prior authorization is required for MAT for SUD or OUD, provide an overview of the carrier's or TPA's policies and procedures regarding requiring prior authorization, including the appeals process when a medication is denied. This should include, at a minimum, the education and professional qualifications of the reviewer who is responsible for making the determinations at each level of the appeals process.
- 11. Provide an overview of any other utilization management protocols in place for each covered medication, including differences in utilization management provisions for different FDA-approved medications for the treatment of OUD.
- 12. Provide a detailed description of the carrier's and TPA's, if applicable, processes to recruit and retain providers that prescribe MAT for SUD and OUD, including both care received in an OTP and office-based buprenorphine and methadone, to enrollees.
- 13. Provide a detailed description of the methodology or other formal processes used by the carrier and TPA, if applicable, to determine network sufficiency to ensure access to MAT for SUD and OUD and process(es) undertaken if the carrier or TPA has found insufficiencies;
- 14. Provide a detailed description of the evidentiary or other standards and practices used to determine eligibility of providers that are federally licensed to prescribe MAT for SUD and OUD to join the network.