DEPARTMENT OF REGULATORY AGENCIES

Division of Insurance

3 CCR 702-4

LIFE ACCIDENT AND HEALTH

DRAFT Proposed Amended Regulation 4-2-49

CONCERNING THE DEVELOPMENT AND IMPLEMENTATION OF A UNIFORM DRUG BENEFIT PRIOR AUTHORIZATION PROCESS, AND THE REQUIRED DRUG APPEALS PROCESS~~, AND THE COVERAGE OF CERTAIN OPIOID DEPENDENCE AND OTHER SUBSTANCE USE DISORDER TREATMENT DRUGS~~

Section 1 Authority

This regulation is promulgated and adopted by the Commissioner of Insurance under the authority of §§ 10-1-109,10-16-109, 10-16-112.5, 10-16-124.5(3)(a), and 10-16-124.5(3)(c), C.R.S.

Section 2 Scope and Purpose

The purpose of this regulation is to establish the requirements, ~~process,~~ and form to be utilized by carriers, ~~and~~ contracted pharmacy benefit management firms, and private utilization organizations for the prior authorization process for prescription drug benefits. The regulation includes requirements regarding the special exception process for non-formulary prescription drug authorization requests~~, and to adopt the changes mandated by House Bill 19-1269.~~ The regulations implementing the reporting and posting on prior authorizations required by § 10-16-124.5(3.5)(a), C.R.S. are contained in Colorado Insurance Regulation 4-2-101.

Section 3 Applicability

Except as noted, the provisions of this regulation shall apply to all carriers that offer ~~carriers that market individual and group~~ health benefit plans in the state of Colorado which provide prescription drug benefits.

Except as required by Sections ~~5.A. and~~ 5.~~B~~., the provisions of this regulation do not apply to non-profit health maintenance organizations with respect to managed care plans that provide a majority of covered professional services through a single contracted medical group. Carriers, regardless of whether the carrier utilizes a pharmacy benefit management firm or a private utilization review organization are subject to the requirements of this Regulation.

Section 4 Definitions

A. "Adverse determination" shall have the same meaning as found at § 10-16-113(1)(b), C.R.S.

B. "Carrier" shall have the same meaning as found at § 10-16-102(8), C.R.S.~~., and shall, for the purposes of this regulation, include a pharmacy benefit management firm contracted by a carrier.~~.

C. "Chronic maintenance drug" shall have the same meaning as found at § 12-280-103(9.5), C.R.S.

D. "Covered person" or "patient" ~~means,~~ for the purposes of this regulation, ~~the person entitled to receive benefits or services under a health benefit plan~~shall have the same meaning as found at § 10-16-102(15).~~.~~

E. "Designated representative" or "designee" means, for the purposes of this regulation:

1. A person, including the treating health care professional or a person authorized by subsection 4.E.2., to whom a covered person has given express written consent to represent the covered person;

2. A person authorized by law to provide substituted consent for a covered person, including but not limited to a guardian, agent under a power of attorney, a proxy, or a designee of the Colorado Department of Health Care Policy and Financing; and/or

3. In the case of an urgent care request, a health care professional with knowledge of the covered person's medical condition.

~~D~~F. "Drug benefit" means, for the purposes of this regulation, the provision of a drug used to treat a covered medical condition of a covered person.

~~E~~G. "FDA" ~~means,~~ for the purposes of this regulation, ~~the Food and Drug Administration in the United States Department of Health and Human Services~~shall have the same meaning as found at § 10-16-102(27.5), C.R.S.

~~F~~H. "Health benefit plan" shall have the same meaning as found at § 10-16-102(32), C.R.S.

~~G~~I. "Health maintenance organization" shall have the same meaning as found at § 10-16-102(35), C.R.S.

J. "Medication-Assisted Treatment" or "MAT" means, for the purposes of this regulation, the use of an FDA-approved medication 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.

~~H~~K. "Non-grandfathered" means, for the purposes of this regulation, a health benefit plan that does not qualify as a grandfathered health benefit plan as defined in § 10-16-102(31), C.R.S.

~~I~~L. "Pharmacy benefit management firm" shall have the same meaning as found at § 10-16-102(49), C.R.S.

~~J~~M. "Prescribing provider" shall have the same meaning as found at § 10-16-124.5(8)(a), C.R.S.

N. "Prior authorization" shall have the same meaning as found at § 10-16-122.5(7)(d), C.R.S.

O. "Private utilization review organization" shall have the same meaning as found at § 10-16-112.5(7)(e), C.R.S.

~~K~~P. "Small group health benefit plan" means, for the purposes of this regulation, a health benefit plan sold to a small employer as defined in § 10-16-102(61)(b) C.R.S.

Q. "Substance use disorder" 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)(I)(A)-(C), C.R.S.

~~L~~R. "Urgent prior authorization request" shall have the same meaning as found at § 10-16-124.5(8)(b), C.R.S.

Section 5 ~~Rules~~ Special Exception Processes for Non-formulary Drug Authorization Requests for Non-Grandfathered Individual and Small Group Health Benefit Plans

~~A. All carriers issuing individual and group health benefit plans shall make available and provide coverage for, without prior authorization, a five (5) day supply of at least one (1) of the FDA-approved drugs prescribed for the treatment of opioid dependence. This requirement is limited to a first request within a twelve (12) month period.~~

~~B. Special Exception Processes for Non-formulary Drug Authorization Requests for Non-Grandfathered Individual and Small Group Health Benefit Plans~~

A~~1~~. Carriers shall have standard and expedited exception processes that allow a covered person, the covered person's designee, or the covered person's prescribing provider (or other prescriber) to request and gain access to clinically-appropriate drugs not otherwise covered by his or her health benefit plan pursuant to 45 C.F.R. § 156.122(c) and this Section 5~~.B~~.

~~2~~B. Standard Exception Requests

~~a~~1. A carrier shall make its determination on a standard exception request and shall notify the covered person or the covered person's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than seventy-two (72) hours following receipt of the request.

~~b~~2. A carrier that grants a standard exception request shall provide coverage of the non-formulary drug for the duration of the prescription, including refills, as long as the covered person remains covered under the individual or small group health benefit plan.

~~3~~C. Expedited Exception Requests

1~~a~~. A carrier shall have a process for a covered person, the covered person's designee, or the covered person's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances. Exigent circumstances exist when a covered person is suffering from a health condition that may seriously jeopardize the covered person's life, health, or ability to regain maximum function or when a covered person is undergoing a current course of treatment using a non-formulary drug.

2b. A carrier shall make its coverage determination on an expedited exception request and shall notify the covered person or the covered person's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than twenty-four (24) hours following receipt of the request.

3c. A carrier that grants an exception based on exigent circumstances shall provide coverage of the non-formulary drug for the duration of the exigency, as long as the covered person remains covered under the individual or small group health benefit plan.

D4. External Exception Request Reviews

1a. If the carrier denies a request for a standard exception under Section 5.B.2. or for an expedited exception under Section 5.CB.3., it shall have a process for the covered person, the covered person's designee, or the covered person's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.

2b. A carrier shall ensure that the independent review organization makes its determination on the external exception request and notifies the covered person or the covered person's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than seventy-two (72) hours following its receipt of the request, if the original request was a standard exception request under Section 5.B.2. or no later than twenty-four (24) hours following its receipt of the request, if the original request was an expedited exception request under Section 5.CB.3.

3c. If the independent review organization overturns the carrier's denial of a standard exception request, the carrier shall provide coverage of the non-formulary drug for the duration of the prescription as long as the covered person remains covered under the individual or small group health benefit plan.

4d. If the independent review organization overturns the carrier's denial of an expedited exception request, the carrier shall provide coverage of the non-formulary drug for the duration of the exigency as long as the covered person remains covered under the individual or small group health benefit plan.

~~C. A prior authorization process for a drug benefit, as developed by a carrier, shall:~~

~~1. Be made available electronically to the prescribing provider;~~

~~2. Make the following information available and accessible in a centralized location on the carrier's or its designated pharmacy benefit management firm's website:~~

~~a. The prior authorization requirements and restrictions, including, but not limited to:~~

~~(1) The prescribing provider's obligation to respond to requests for additional information; and~~

~~(2) When requests will be deemed "approved" or "denied";~~

~~b. An alphabetical list of drugs, including both brand name and scientific name, that require prior authorization, including the clinical criteria and supporting references that will be used in making a prior authorization determination;~~

~~c. Written clinical criteria that include the criteria for reauthorization of a previously approved drug, if applicable, after the previous approval period has expired; and~~

~~d. The standard form for prior authorization for a drug benefit, provided in Appendix A of this regulation.~~

~~3. Include evidence-based guidelines to be used by the carrier when making prior authorization determinations;~~

~~4. Allow for, but not require, the electronic submission of prior authorization requests for a drug benefit to the carrier.~~

Section 6 Prescription Drug Prior Authorization Request Process

A. A prior authorization process for a drug benefit shall:

1. Utilize the standard form for submitting prior authorization requests for a drug benefit, provided in Appendix A of this regulation. This form applies to written and electronic submissions. Carriers may continue to use their current electronic prior authorization processes so long as such processes and forms comply with the substantive requirements of the standard form found in Appendix A.

2. Be made available electronically to the prescribing provider and allow for, but not require, the electronic submission of prior authorization requests for a drug benefit to the carrier.

~~D~~B. Urgent prior authorization requests.

1. For requests not subject to Section 5~~.B.~~, a carrier shall process and provide notification of approval or denial to the patient, prescribing provider, and dispensing pharmacy, if applicable, within one (1) business day of receiving an urgent prior authorization request. Carriers shall include appropriate information on the expedited appeals process related to urgent care situations as required by § 10-16-113(3)(a)(III), C.R.S., and Colorado Insurance Regulation 4-2-17 ~~its associated regulation~~ with any denial of an urgent prior authorization request.

   a. If additional information is required to process an urgent prior authorization request, the carrier must advise the prescribing provider of any and all information needed within one (1) business day of receiving the request.

   b. If additional information is required to process an urgent prior authorization request, the prescribing provider shall submit the information requested by the carrier within two (2) business days of receiving such a request from the carrier.

   c. If the additional information requested from the prescribing provider is not received within two (2) business days of the prescribing provider receiving such a request, the request shall be deemed denied. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy, if applicable, with a confirmation of the denial within one (1) business day of the date the request was deemed denied.

   d. Once the requested additional information is received, the carrier shall make a determination in accordance with Section ~~5~~6.~~D~~B.1., of this regulation.

2. If a carrier does not request additional information or provide notification of approval or denial, as required by Section ~~5~~6.~~D~~B.1., the request shall be deemed approved. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy, if applicable, with a confirmation of the deemed approval within one (1) business day of date the request was deemed approved.

~~E~~C. Non-urgent prior authorization requests.

1. For requests not subject to Section 5~~.B.~~, a carrier shall process and provide notification of approval or denial to the patient, prescribing provider, and dispensing pharmacy, if applicable, within two (2) business days of receiving a non-urgent prior authorization request that has been submitted through the carrier's electronic pre-authorization system.

    a. If additional information is required, the carrier must advise the prescribing provider of any and all information needed within two (2) business days of receiving the non-urgent prior authorization request.

    b. If additional information is required to process a non-urgent prior authorization request, the prescribing provider shall submit the information requested by the carrier within two (2) business days of receiving such a request from the carrier.

    c. If the additional information requested from the prescribing provider is not received within two (2) business days of the prescribing provider receiving such a request, the request shall be deemed denied. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy, if applicable, with a confirmation of the denial within two (2) business days of the date the request was deemed denied.

    d. Once the requested additional information is received, the carrier shall make a determination in accordance with Section ~~5~~6.~~E~~C.1. or Section ~~5~~6.~~E~~C.2., of this regulation, as applicable.

2. A carrier shall process and provide notification of approval or denial to the patient, prescribing provider, and dispensing pharmacy, if applicable, within three (3) business days of receiving a non-urgent prior authorization request that has been submitted via facsimile, electronic mail, or verbally with associated written confirmation.

3. If a carrier does not request additional information or provide notification of approval or denial within:

    a. Two (2) business days of the receipt of an electronically filed non-urgent prior authorization request, as required by Section ~~5~~6.~~E~~C.1., the request shall be deemed approved. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy, if applicable, with a confirmation of the deemed approval within two (2) business days of the date the request was deemed approved; or

    b. Three (3) business days of the receipt of a non-urgent prior authorization request that has been submitted via facsimile, electronic mail, or verbally with associated written confirmation, as required by Section ~~5~~6.~~E~~C.2., the request shall be deemed approved. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy, if applicable, with a confirmation of the deemed approval within two (2) business days of the date the request was deemed approved.

Section 7 Notification Requirements for Prescription Drug Prior Authorizations

~~F~~A. When notifying a prescribing provider of a prior authorization approval, a carrier shall include:

1. A unique prior authorization number attributable only to that drug benefit approval request;

2. Specifications for the particular approved drug benefit, and the source and date of the clinical criteria used to make the determination for each particular drug;

3. The next date for review of the approved drug benefit; and

4. A link to the current criteria that will need to be submitted in order to reapprove the current prior authorization.

~~G~~B. When notifying a prescribing provider or covered person of a prior authorization denial, a carrier shall include:

1. A ~~a~~ notice to the prescribing provider, covered person and dispensing pharmacy, if provided, that the covered person has the right to appeal the adverse determination pursuant to §§ 10-16-113 ~~and 10-16-113.5, C.R.S.~~, ~~and their associated regulations~~and Colorado Insurance Regulation 4-2-17, and the ability to request an independent external review pursuant to § 10-16-113.5, C.R.S., and Colorado Insurance Regulation 4-2-21.

2. Information regarding which prescription drugs and dosages in the same class as the denied prescription drug are covered under the health benefit plan.

C. Beginning January 1, 2027, for any provider prior authorization requests received through a secure electronic transmission system, the carrier shall accept and respond to the request through the secure electronic transmission system.

Section 8 Duration of Prior Authorization Approval

For approval of requests not subject to Section 5, and except as provided in Section 9, the prior authorization approval is valid for at least one (1) year from the date of approval.

~~H. For approval of requests not subject to Section 5.B., the prior authorization approval is valid for at least one hundred eighty (180) days after the date of approval.~~

~~I. If a prior authorization request is submitted electronically, verbally, via facsimile, or electronic mail, the response to that request shall be made through the same medium, or in a manner specifically requested by the provider.~~

Section 9 Additional Requirements for Specific Prescription Drugs

~~J~~A. No carrier shall impose any prior authorization requirements for any FDA-approved Medication-Assisted Treatment used in the treatment of a substance use disorder.~~Beginning January 1, 2020, any carrier that provides prescription drug benefits for the medication-assisted treatment of substance use disorders shall not impose any prior authorization requirements for any FDA-approved medication on the carrier's formulary.~~

B. Any carrier that provides prescription drug benefits for chronic maintenance drugs shall not impose prior authorization requirements for any FDA-approved medication for three (3) years if the carrier has previously approved a prior authorization for the covered person for use of the chronic maintenance drug. For approved prior authorization requests for chronic maintenance drugs, the provider may adjust the dose and frequency consistent with § 10-16-124.5(6.2), C.R.S.

This section does not apply if any of the requirements in § 10-16-124.5(5)(b)(II), C.R.S. are met including but not limited to if the wholesale acquisition cost of the chronic maintenance drug exceeds a dollar amount as no less than thirty thousand dollars for a twelve-month supply or for a course of treatment that is less than twelve months in duration.

~~**Section 6 Form**~~

~~All carriers shall utilize the uniform prior authorization form found in Appendix A of this regulation.~~

Section ~~7~~10 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 ~~8~~11 Incorporated Materials

45 C.F.R. § 156.122(c), published by Government Printing Office shall mean ~~shall mean~~ 45 C.F.R. § 156.122(c) as published on the effective date of this regulation and does not include later amendments to or editions of 45 C.F.R. § 156.122(c). A copy of 45 C.F.R. § 156.122(c) 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. § 156.122(c) may be requested from the Colorado Division of Insurance for a fee. A copy may also be obtained online at www.ecfr.gov.

Section ~~9~~12 Enforcement

Noncompliance with this regulation may result 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 civil penalties, issuance of cease and desist orders, and/or suspensions or revocation of license, subject to the requirements of due process.

Section ~~10~~13 Effective Date

This regulation shall become effective on ~~October 1, 2019~~January 1, 2026~~.~~.

Section ~~11~~14 History

New regulation effective July 15, 2014.
Amended regulation effective January 1, 2019.
Amended regulation effective October 1, 2019.
Amended regulation effective January 1, 2026.

APPENDIX A

[CARRIER LOGO]
[CARRIER NAME]

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to:
[CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM CONTACT INFORMATION]

As of January 1, 2020, no prior authorization requirements may be imposed by a carrier for any FDA-approved prescription medication on its formulary which is approved to treat substance use disorders.

☐ Urgent [1]	☐ Non-Urgent		
Requested Drug Name:			
Is this drug intended to treat opioid dependence?		Yes ☐	No ☐
If Yes, is this a first request within a 12-month period for prior authorization for this drug? * If Yes, prior authorization is not required for a 5-day supply of any FDA-approved drug for the treatment of opioid dependence and there is no need to complete this form. * If No, as of January 1, 2020, a prior authorization is not required for prescription medications on the carrier's formulary and there is no need to complete this form.		Yes * ☐	No * ☐

Patient Information:	Prescribing Provider Information:
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:	☐ New Request ☐ Reauthorization		
Patient Diagnosis and ICD Diagnostic Code(s):			
Drug(s) Requested (with J-Code, if applicable):			
Strength/Route/Frequency:			
Unit/Volume of Named Drug(s):			
Start Date and Length of Therapy:			
Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:			
Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response: [ADD ADDITIONAL LINES AS NEEDED SO AS TO CONTAIN ALL APPROVAL CRITERIA]			
For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to:	☐ Patient's Home ☐ Physician Office	☐ Other:	
Prescriber or Authorized Signature:		Date:	

	Dispensing Pharmacy Name and Phone Number:
	☐ **Approved** ☐ **Denied**
	If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function or could subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

APPENDIX A

[CARRIER LOGO]
[CARRIER NAME]

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to:
[CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM CONTACT INFORMATION]

No carrier shall impose any prior authorization requirements for any FDA-approved Medication-Assisted Treatment used in the treatment of a substance use disorder

☐ **Urgent** [1]	☐ **Non-Urgent**		
Requested Drug Name:			
Is this drug being prescribed to treat substance use disorder ?	**Yes** ☐	**No** ☐	

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:	☐ New Request	☐ Reauthorization	
Patient Diagnosis and ICD Diagnostic Code(s):			
Drug(s) Requested (with J-Code, if applicable):			
Strength/Route/Frequency:			
Unit/Volume of Named Drug(s):			
Start Date and Length of Therapy:			
Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:			
Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response: [ADD ADDITIONAL LINES AS NEEDED SO AS TO CONTAIN ALL APPROVAL CRITERIA]			
For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to:	☐ Patient's Home	☐ Physician Office	☐ Other:
Prescriber or Authorized Signature:		Date:	
Dispensing Pharmacy Name and Phone Number:			

☐ **Approved**	☐ **Denied**
If denied, provide reason for denial, and specify which drugs and dosages in the same class as the drug for which the prior authorization request was denied are covered under the covered persons plan	

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function or could subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.