COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2025 Sunset Review

The Colorado Licensing of Controlled Substances Act

October 15, 2025

COLORADO
Department of Regulatory Agencies
Executive Director's Office

October 15, 2025

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Pursuant to section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) at the Department of Regulatory Agencies (DORA) undertakes a robust review process culminating in the release of multiple reports each year on October 15.

A national leader in regulatory reform, COPRRR takes the vision of their office, DORA and more broadly of our state government seriously. Specifically, COPRRR contributes to the strong economic landscape in Colorado by ensuring that we have thoughtful, efficient, and inclusive regulations that reduce barriers to entry into various professions and that open doors of opportunity for all Coloradans.

As part of this year's review, COPRRR has completed an evaluation of the Colorado Licensing of Controlled Substances Act. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2026 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Part 2 of Article 80 of Title 27, C.R.S. The report also discusses the effectiveness of the Behavioral Health Administration in the Department of Human Services in carrying out the intent of the statutes and makes recommendations for statutory changes for the review and discussion of the General Assembly.

To learn more about the sunset review process, among COPRRR's other functions, visit coprrr.colorado.gov.

Sincerely,

Patty Salazar
Executive Director

The Colorado Licensing of Controlled Substances Act

Background

What is regulated?

The Colorado Licensing of Controlled Substances Act (Act) establishes a framework to license facilities that treat substance use disorders with controlled substances.

Why is it regulated?

The purpose of the Act is to prevent misuse and diversion of controlled substances and to align with regulations established by the federal Substance Abuse and Mental Health Services Administration, in the U.S. Department of Health and Human Services, which establishes national standards for facilities that treat substance use disorders with controlled substances and coordinates with states and the Drug Enforcement Administration to regulate them.

Who is regulated?

In fiscal year 23-24, the Behavioral Health Administration (BHA) licensed, under the Act, a total of 109 controlled substance treatment facilities.

How is it regulated?

The BHA, located in the Department of Human Services, is responsible for licensing, inspecting and investigating facilities under the authority of the Act and enforcing the Act.

What does it cost?

In fiscal year 23-24, 4.55 full-time equivalent employees were allocated to the program, and the total program expenditure was estimated to be about $670,000.

What disciplinary activity is there?

Over a five-year period, BHA revoked 1 license, denied 1 license and took 10 other disciplinary actions, including probation or practice limitation.

Key Recommendations

- **Continue the Colorado Licensing of Controlled Substances Act for 15 years, until 2041.**
- **Modernize the definition of "substance use disorder" in the Act to more accurately reflect the type of conditions being treated by BHA-licensed facilities.**
- **Create a new definition of "withdrawal management" that considers the full spectrum of treatment concepts.**
- **Repeal the definitions of "detoxification treatment," "maintenance treatment" and "withdrawal treatment" in the Act, and replace them with the term, "withdrawal management."**

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Background

Sunset Criteria

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria[1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are guided by statutory criteria and sunset reports are organized so that a reader may consider these criteria while reading. While not all criteria are applicable to all sunset reviews, the various sections of a sunset report generally call attention to the relevant criteria. For example,

- In order to address the first criterion and determine whether the program under review is necessary to protect the public, it is necessary to understand the details of the profession or industry at issue. The Profile section of a sunset report typically describes the profession or industry at issue and addresses the current environment, which may include economic data, to aid in this analysis.
- To address the second sunset criterion--whether conditions that led to the initial creation of the program have changed--the History of Regulation section of a sunset report explores any relevant changes that have occurred over time in the regulatory environment. The remainder of the Legal Framework section addresses the fifth sunset criterion by summarizing the organic statute and rules of the program, as well as relevant federal, state and local laws to aid in the exploration of whether the program's operations are impeded or enhanced by existing statutes or rules.
- The Program Description section of a sunset report addresses several of the sunset criteria, including those inquiring whether the agency operates in the public interest and whether its operations are impeded or enhanced by existing statutes, rules, procedures and practices; whether the agency or the agency's board performs efficiently and effectively and whether the board, if applicable, represents the public interest.
- The Analysis and Recommendations section of a sunset report, while generally applying multiple criteria, is specifically designed in response to the fourteenth criterion, which asks whether administrative or statutory changes are necessary to improve agency operations to enhance the public interest.

[1] Criteria may be found at § 24-34-104, C.R.S.

These are but a few examples of how the various sections of a sunset report provide the information and, where appropriate, analysis required by the sunset criteria. Just as not all criteria are applicable to every sunset review, not all criteria are specifically highlighted as they are applied throughout a sunset review. While not necessarily exhaustive, the table below indicates where these criteria are applied in this sunset report.

Table 1
Application of Sunset Criteria

Sunset Criteria	Where Applied
(I) Whether regulation or program administration by the agency is necessary to protect the public health, safety, and welfare.	• Profile of the Industry • Recommendation 1
(II) Whether the conditions that led to the initial creation of the program have changed and whether other conditions have arisen that would warrant more, less, or the same degree of governmental oversight.	• History of Regulation • Recommendations 2, 3 and 4
(III) If the program is necessary, whether the existing statutes and regulations establish the least restrictive form of governmental oversight consistent with the public interest, considering other available regulatory mechanisms.	• Legal Framework • Recommendation 2
(IV) If the program is necessary, whether agency rules enhance the public interest and are within the scope of legislative intent.	• Legal Framework • Program Description and Administration
(V) Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters.	• Legal Framework • Program Description and Administration • Recommendation 3
(VI) Whether an analysis of agency operations indicates that the agency or the agency's board or commission performs its statutory duties efficiently and effectively.	• Program Description and Administration
(VII) Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates.	• Program Description and Administration
(VIII) Whether regulatory oversight can be achieved through a director model.	• Program Description and Administration
(IX) The economic impact of the program and, if national economic information is not available, whether the agency stimulates or restricts competition.	• Profile of the Profession

Sunset Criteria	Where Applied
(X) If reviewing a regulatory program, whether complaint, investigation, and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession or regulated entity.	• Grievances • Critical Incidents • Disciplinary Activity • Recommendation 1
(XI) If reviewing a regulatory program, whether the scope of practice of the regulated occupation contributes to the optimum use of personnel.	• Licensing • Recommendation 2
(XII) Whether entry requirements encourage equity, diversity, and inclusivity.	• Legal Framework • Program Description and Administration
(XIII) If reviewing a regulatory program, whether the agency, through its licensing, certification, or registration process, imposes any sanctions or disqualifications on applicants based on past criminal history and, if so, whether the sanctions or disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subsection (5)(a) of this section must include data on the number of licenses, certifications, or registrations that the agency denied based on the applicant's criminal history, the number of conditional licenses, certifications, or registrations issued based upon the applicant's criminal history, and the number of licenses, certifications, or registrations revoked or suspended based on an individual's criminal conduct. For each set of data, the analysis must include the criminal offenses that led to the sanction or disqualification.	• Collateral Consequences
(XIV) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.	• Recommendations 1, 2, 3 and 4

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review on COPRRR's website at coprrr.colorado.gov.

The Colorado Licensing of Controlled Substances Act (Act) and the functions of the Behavioral Health Administration (BHA), located in the Department of Human Services, as enumerated in Article Part 2 of Article 80 of Title 27, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2026, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of the Act pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed regulation should be continued and to evaluate the Act and the performance of BHA. During this review, BHA must demonstrate that the program serves the public interest. COPRRR's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, COPRRR staff interviewed BHA staff, practitioners and officials with state and national professional associations and reviewed Colorado statutes and rules, and the laws of other states.

The major contacts made during this review include, but are not limited to:

- Behavioral Health Administration,
- Colorado Association of Addiction Professionals,
- Colorado Behavioral Healthcare Council,
- Colorado Organization for the Treatment of Opioid Dependence,
- Colorado Pharmacists Society,
- Colorado Society of Addiction Medicine,
- Department of Health Care Policy & Financing,
- National Association of State Alcohol and Drug Abuse Directors,
- Office of the Attorney General,
- State Board of Pharmacy,
- U.S. Drug Enforcement Administration Services Administration, and
- U.S. Substance Abuse and Mental Health.

Profile of Substance Use Disorder Treatment

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), C.R.S. The first criterion asks whether regulation or program administration by the agency is necessary to protect the public health, safety, and welfare.

To understand the need for regulation, it is first necessary to understand substance use disorders and the use of controlled substances to treat these disorders.

In 1784, Benjamin Rush, a founding father and physician who advocated for the humane treatment of people with mental disorders,[2] argued that addiction, now referred to as substance use disorder, was a disease that should be treated.[3]

Today, a substance use disorder is understood to be a complex disease in which the brain is altered so that it becomes especially difficult to stop using alcohol and other drugs despite a patient's motivation to do so. As a substance use disorder is a chronic disease, even after long periods of sobriety, a patient may relapse. While it cannot be cured, substance use disorder can be managed.[4]

A substance use disorder may be defined as the use of alcohol or other substances that negatively affect an individual's health or causes problems at home, school or in the workplace.[5] Some substances that may lead to dependence include:[6]

- Opiates and other narcotics, such as heroin, fentanyl and prescription pain medication;
- Stimulants, such as cocaine and amphetamines; and
- Depressants, such as alcohol, barbiturates and benzodiazepine.

Treatment by qualified professionals may address the disorder by slowly weaning the individual off the substance or ending the use of the substance all at once. Additionally, treatment involves monitoring and addressing any physical and emotional withdrawal symptoms, teaching individuals in recovery to understand their behavior and providing them with techniques to prevent relapse.[7]

[2] Encyclopaedia Britannica. *Benjamin Rush*. Retrieved September 24, 2025, from www.britannica.com/biography/Benjamin-Rush
[3] Recovery. *Timeline: History of Addiction Treatment*. Retrieved September 26, 2025, from recovery.org/drug-treatment/history/
[4] Substance Abuse and Mental Health Services Administration. *What Is Substance Use Disorder?* Retrieved September 26, 2025, from www.samhsa.gov/substance-use/what-is-sud
[5] MedlinePlus. *Substance Use Disorder*. Retrieved September 26, 2025, from medlineplus.gov/ency/article/001522.htm
[6] MedlinePlus. *Substance Use Disorder*. Retrieved September 26, 2025, from medlineplus.gov/ency/article/001522.htm
[7] MedlinePlus. *Substance Use Disorder*. Retrieved September 26, 2025, from medlineplus.gov/ency/article/001522.htm

Medications used to treat substance use disorders are beneficial to patients because they have been proven to:[8]

- Save lives,
- Improve treatment retention,
- Improve recovery rates,
- Reduce the rates of illegal drug use and other illegal activity,
- Improve employment rates, and
- Improve birth outcomes.

Medications used to treat alcohol use disorders are effective because, depending on the type prescribed, they can have the following effects on patients:[9]

- Decrease cravings for alcohol,[10]
- Cause unpleasant symptoms when combined with alcohol,[11] or
- Block the effects of alcohol.[12]

Because the medications which are used to treat opioid use disorder, such as buprenorphine and methadone, are controlled substances, treatment facilities that administer and dispense them are highly regulated. Many of these requirements are driven by federal law.

Medications used to treat opioid use disorder, depending on the type prescribed, help to:[13]

- Reduce the effects of physical dependence,[14]
- Block the effects of opioids,[15] and
- Reduce opioid cravings and withdrawal.[16]

[8] Substance Abuse and Mental Health Services Administration. *Substance Use Disorder Treatment Options.* Retrieved September 24, 2025, from www.samhsa.gov/substance-use/treatment/options
[9] Substance Abuse and Mental Health Services Administration. *Substance Use Disorder Treatment Options.* Retrieved September 24, 2025, from www.samhsa.gov/substance-use/treatment/options
[10] Substance Abuse and Mental Health Services Administration. *Acamprosate*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/acamprosate
[11] Substance Abuse and Mental Health Services Administration. *Disulfiram*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/disulfiram
[12] Substance Abuse and Mental Health Services Administration. *Naltrexone*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/naltrexone
[13] Substance Abuse and Mental Health Services Administration. *Substance Use Disorder Treatment Options.* Retrieved September 24, 2025, from https://www.samhsa.gov/substance-use/treatment/options
[14] Substance Abuse and Mental Health Services Administration. *Buprenorphine*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/buprenorphine
[15] Substance Abuse and Mental Health Services Administration. *Naltrexone*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/naltrexone
[16] Substance Abuse and Mental Health Services Administration. *Methadone*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/methadone

Methadone is a Schedule II controlled substance, which means it has a high potential for misuse and may cause psychological or physical dependence. Buprenorphine is a Schedule III controlled substance, which means it has potential for misuse and may cause low to moderate physical dependence and high psychological dependence.[17]

Methadone is approved by the Food and Drug Administration to treat opioid use disorder. As long as it is taken as prescribed, methadone is a safe and effective medication. Along with a comprehensive treatment plan, it can support patients who are in recovery.[18]

Like methadone, when taken as prescribed, buprenorphine is a safe and effective medication used to treat opioid use disorder. It can reduce withdrawal symptoms and cravings associated with opioid dependence. Buprenorphine is not as strong as methadone, and it is less likely to be misused.[19] Unfortunately, not all individuals with an opioid use disorder can benefit from buprenorphine.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is a federal agency within the U.S. Department of Health and Human Services. Among its responsibilities, SAMHSA coordinates with states and other federal agencies to regulate treatment facilities that administer and dispense medications to treat opioid use disorder, and it also provides funding to community-based mental health and substance use disorder treatment and prevention services.[20]

Under federal law, methadone can only be administered and dispensed by an opioid treatment program that is:[21]

- Accredited by a SAMHSA-approved accrediting body,
- Certified by SAMHSA,
- Licensed in the state where it operates, and
- Registered with the U.S. Drug Enforcement Administration (DEA).

Additionally, federal regulations require methadone to be dispensed to patients under the supervision of a practitioner. Once the attending practitioner and treatment team determines that it is safe and best for the patient, they may be allowed to take medication at home, without direct supervision, in between visits to the opioid treatment program. Federal regulations also require opioid treatment programs to

[17] Drug Enforcement Administration. *Control Substance Schedules.* Retrieved September 26, 2025, from www.deadiversion.usdoj.gov/schedules/schedules.html
[18] Substance Abuse and Mental Health Services Administration. *Methadone*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/methadone
[19] Substance Abuse and Mental Health Services Administration. *Buprenorphine*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/buprenorphine
[20] *Substance Abuse and Mental Health Services Administration (SAMHSA): Overview of the Agency and Major Programs,* Congressional Research Service (2020), Summary.
[21] Substance Abuse and Mental Health Services Administration. *Become an Opioid Treatment Program (OTP).* Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/opioid-treatment-program/become-otp

provide patients receiving methadone with counseling along with medical, vocational and other services.[22]

Similar to methadone, opioid treatment programs may only dispense buprenorphine if they are certified with SAMHSA and registered with the DEA. Federal regulations also require opioid treatment programs to provide patients receiving buprenorphine with specific services, such as medical services, counseling and drug testing.[23] To increase access to medications for the treatment of opioid use disorder, buprenorphine is authorized to be prescribed and dispensed from a physician's office.[24]

SAMHSA distributes a block grant for substance use disorder prevention and treatment services. Each state must designate a "Single State Agency" to administer the grant.[25] In Colorado, the Behavioral Health Administration (BHA) in the Department of Human Services is the designated Single State Agency.

Additionally, in most states, a State Opioid Treatment Authority (SOTA) acts as the point of contact between the state and SAMHSA, and the SOTA is also responsible for overseeing opioid treatment programs. In Colorado, the Associate Director of Controlled Substance Licensing in BHA acts as the SOTA and is responsible for licensing facilities under the authority of the Colorado Licensing of Controlled Substances Act.

The ninth sunset criterion questions the economic impact of the program and, if national economic information is not available, whether the agency stimulates or restricts competition.

Historically, SAMHSA has awarded millions of dollars in federal funding to support substance use prevention and treatment initiatives in Colorado. In 2021, SAMHSA awarded $27.1 million for the Substance Abuse Prevention and Treatment block grant to be spent by March 14, 2023, and an additional $23.4 million to be spent by September 30, 2025.[26]

[22] Substance Abuse and Mental Health Services Administration. *Methadone*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/methadone
[23] Substance Abuse and Mental Health Services Administration. *Buprenorphine Dispensing by Opioid Treatment Programs (OTPs)*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/opioid-treatment-program/become-otp/buprenorphine-dispensing
[24] Substance Abuse and Mental Health Services Administration. *Buprenorphine*. Retrieved September 26, 2025, from www.samhsa.gov/substance-use/treatment/options/buprenorphine
[25] *Substance Abuse and Mental Health Services Administration (SAMHSA): Overview of the Agency and Major Programs*, Congressional Research Service (2020), Summary.
[26] Colorado Department of Human Services. *Press Release: Colorado receives $94 million federal funding boost for behavioral health services*. Retrieved on September 26, 2025, from cdhs.colorado.gov/press-release/colorado-receives-94-million-federal-funding-boost-for-behavioral-health-services

Legal Framework

History of Regulation

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The first and second sunset criteria question:

> Whether regulation or program administration by the agency is necessary to protect the public health, safety, and welfare; and
>
> Whether the conditions that led to the initial creation of the program have changed and whether other conditions have arisen that would warrant more, less or the same degree of governmental oversight.

One way that COPRRR addresses this is by examining why the program was established and how it has evolved over time.

Colorado first enacted laws regarding controlled substances in 1963, in the form of the State Narcotic Act. Then, in 1968, Colorado enacted the Colorado Dangerous Drug Act. In 1981, the General Assembly combined these two laws into the Colorado Licensing of Controlled Substances Act (Act).

The Act originally addressed licensure requirements for a wide range of professionals, including researchers, analytical laboratories, addiction programs, humane societies that euthanize animals, wholesalers that distribute controlled substances and manufacturers that manufacture or distribute controlled substances. The Act included disciplinary actions in the form of denial, revocation or suspension of a license; listing of unlawful acts; definitions and penalties for procurement of controlled substances by fraud and deceit; and an inventory of Schedule I to V controlled substances.

Recordkeeping requirements for licensees were delineated, along with authorization for inspections, investigations and reporting requirements.

In 1984, responsibility for controlled substance licensing of addiction programs, researchers, and analytical laboratories was placed in the Colorado Department of Human Services (Human Services) in what was then the Alcohol and Drug Abuse Division.

During the 2012 legislative session, following a sunset review of the State Board of Pharmacy, Senate Bill 1311 relocated the Act from the Pharmacy Practice Act where it had been since 1981. It was moved to the statutes administered by Human Services and behavioral health since the Act was implemented by Human Services and not the Pharmacy Board.

In 2017, the language was modernized to refer to substance use disorder rather than addiction, and in 2019, the General Assembly required Human Services to adopt a policy regarding how substance use treatment programs must verify the identity of patients starting treatment, including those without identification and those experiencing homelessness.

Following the 2018 sunset review, the General Assembly created a central registry to register patients who are receiving treatment at an opioid treatment program so that an opioid treatment program can easily verify whether a patient is already receiving medication, such as methadone, from another facility.

In 2022, the General Assembly adopted House Bill 22-1278, which established the Behavioral Health Administration (BHA) within Human Services, and included among its many duties, the administration of the Act.

Legal Summary

The third, fourth and fifth sunset criteria question:

> Whether the existing statutes and regulations establish the least restrictive form of governmental oversight consistent with the public interest, considering other available regulatory mechanisms;
>
> Whether agency rules enhance the public interest and are within the scope of legislative intent; and
>
> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters.

A summary of the current statutes and rules is necessary to understand whether regulation is set at the appropriate level and whether the current laws are impeding or enhancing the agency's ability to operate in the public interest.

The Act creates a state program that aligns with regulations mandated under federal law. Its purpose is to license substance use disorder treatment programs that administer, compound or dispense controlled substances.

Federal Law

Substance Abuse and Mental Health Services Administration

The federal Substance Abuse and Mental Health Services Administration (SAMHSA), in the U.S. Department of Health and Human Services, establishes the qualifications

required for treatment programs to dispense the opioid drugs that are used in the treatment of opioid use disorders. An opioid treatment program must obtain both accreditation from an accreditation body approved by SAMHSA and certification from SAMHSA.[27]

Among other things, an accreditation body's application must contain:

- Standards for accreditation and a detailed discussion of how standards will ensure that each opioid treatment program inspected by the applicant will meet federal standards;[28]
- Description of the applicant's decision-making process;[29]
- Policies and procedures to avoid conflicts of interest by individuals associated with the applicant;[30]
- Experience and training requirements for the applicant's staff, including a description of training policies;[31]
- Fee schedules that include the supporting cost data;[32]
- Assurances that the applicant will implement its responsibilities and a plan for investigating complaints;[33] and
- Policies and procedures to protect confidential information.[34]

The following accreditation bodies are approved in Colorado:

- The Commission on Accreditation of Rehabilitation Facilities International;
- The Joint Commission; and
- The National Commission on Correctional Health Care or NCCHC.

An accreditation body's approval cannot last for more than five years.[35] It must apply for renewal if it chooses to serve beyond its current term.[36]

Once approved, an accreditation body must implement SAMHSA rules and policies concerning inspections, complaints, records and reporting, conflicts of interest, and accreditation practices.[37] SAMHSA will periodically evaluate each accreditation body.[38] If it deems that it is out of compliance, SAMHSA may order corrective action or withdraw approval.[39]

[27] 42 C.F.R. § 8.1.
[28] 42 C.F.R. § 8.3(b)(3).
[29] 42 C.F.R. § 8.3(b)(4).
[30] 42 C.F.R. § 8.3(b)(5).
[31] 42 C.F.R. § 8.3(b)(6) and (b)(7).
[32] 42 C.F.R. § 8.3(b)(8).
[33] 42 C.F.R. § 8.3(b)(9).
[34] 42 C.F.R. § 8.3(b)(10).
[35] 42 C.F.R. § 8.3(g).
[36] 42 C.F.R. § 8.3(c).
[37] 42 C.F.R. § 8.4.
[38] 42 C.F.R. § 8.5.
[39] 42 C.F.R. § 8.6.

SAMHSA also has rules that regulate certification requirements for opioid treatment providers,[40] and establishes federal opioid use disorder treatment standards.[41]

The Federal Controlled Substances Act

The U.S. Drug Enforcement Administration (DEA) is the federal agency responsible for drug control activities, which includes preventing the diversion of pharmaceutical controlled substances.[42] The federal Controlled Substances Act, which governs federal drug enforcement, requires a separate DEA registration to administer or dispense controlled substances to treat substance use disorders, and each place of business is required to have a separate DEA registration.[43]

State Law

Colorado Licensing of Controlled Substances Act

Under the Act, a license is required for each place of business or professional practice that administers, compounds or dispenses controlled substances for the treatment of substance use disorders or withdrawal from addictive substances.[44] A licensee may only administer, compound or dispense controlled substances within the scope of its license and in accordance with the Act and federal law.[45]

However, according to rule, a controlled substance license is not required for an office-based opioid treatment provider that does not dispense, compound or administer a controlled substance from medication that is stocked on site.[46]

If an applicant is registered with the DEA, they are presumed to be qualified.[47]

An applicant is required to maintain adequate and proper facilities to handle and store controlled substances. The applicant must also ensure that controlled substances are not dispensed or distributed illegally.[48]

BHA must issue a license to every substance use disorder treatment program that meets the requirements of the Act unless it is inconsistent with the public interest. To determine the public interest, the Act directs BHA to consider:[49]

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[40] 42 C.F.R. § 8.11.
[41] 42 C.F.R. § 8.12.
[42] *Drug Enforcement Administration, U.S. Department of Justice,* Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations (2022), p. 2.
[43] *Drug Enforcement Administration, U.S. Department of Justice,* Narcotic Treatment Program Manual: A Guide to DEA Narcotic Treatment Program Regulations (2022), p. 3.
[44] § 27-80-204(1), C.R.S.
[45] § 27-80-204(1), C.R.S.
[46] 2 CCR 502-1 § 13.3(B), Behavioral Health Rules.
[47] § 27-80-207(4), C.R.S.
[48] § 27-80-207(1), C.R.S.
[49] § 27-80-205(1), C.R.S.

- Maintenance of effective controls against diversion;
- Compliance with applicable laws;
- Convictions relating to controlled substances;
- Experience manufacturing or distributing controlled substances;
- False or fraudulent information in an application;
- Suspension or revocation of DEA registration; and
- Other factors relevant to and consistent with the peace, health and safety of the public.

In addition to a controlled substance license, an opioid treatment program must obtain:[50]

- DEA registration,
- SAMHSA certification, and
- Federal accreditation.

A license issued under the Act does not permit a licensee to distribute or professionally use controlled substances beyond the scope of the licensee's federal registration.[51]

Anyone who has been convicted within the last two years of a willful violation of the Act or any other state or federal law regulating controlled substances is ineligible for licensure.[52]

BHA may deny, suspend or revoke a license on the following grounds:[53]

- Providing false or fraudulent information in an application;
- Being convicted of, or pleading guilty or *nolo contendere* to, a felony related to a controlled substance;
- Having a DEA registration suspended or revoked; or
- Violating the Act or BHA rules.

BHA may also place a license on probation or place conditions on a license, and BHA is also authorized to fine a licensee up to $500 for violating the Act.[54]

If BHA suspends or revokes a license, it may place a licensee's controlled substances under seal. Unless a court orders otherwise, BHA may not dispose of the substances until either the time to appeal has passed or all appeals have been resolved.[55]

[50] 2 CCR 502-1 § 13.6(B), Behavioral Health Rules.
[51] § 27-80-205(2), C.R.S.
[52] § 27-80-207(3), C.R.S.
[53] § 27-80-208(1), C.R.S.
[54] § 27-80-208(2.5), C.R.S.
[55] § 27-80-208(3), C.R.S.

The Act directs BHA to promptly notify the DEA and any applicable professional licensing agency of all charges, forfeitures and the final disposition of charges.[56]

Colorado peace officers and district attorneys are required to enforce the Act. In doing so, they must also cooperate with all other state and federal law enforcement agencies on issues involving controlled substances.[57]

Similarly, the Act requires BHA to cooperate with local, state and federal law enforcement agencies enforcing controlled substances laws.[58]

Anyone authorized under the Act or the laws of other states to manufacture, purchase, distribute, dispense, administer, store or otherwise handle controlled substances is required to keep extensive records and maintain them for two years after each transaction.[59]

Licensees must keep separate, detailed and accurate records,[60] and they are required to keep a record of any controlled substance that is lost, destroyed or stolen.[61]

Inspections of prescriptions, orders and records may only be conducted by officers who have a duty to enforce controlled substances laws or regulate practitioners. Any officer with knowledge of a prescription, order or record may only disclose this information when it is in connection with a prosecution or proceeding before a court or a licensing authority.[62]

As required under the Act,[63] BHA has established a secure online registry to register patients who are enrolled for treatment in a substance use disorder treatment program.[64] All opioid treatment programs are required to have an account with the registry.[65] The purpose of the online registry is to prevent the misuse and diversion of medications, such as methadone, by providing opioid treatment programs with a system to easily verify whether a patient is already receiving medication from another opioid treatment program.

The Act requires BHA to adopt any rules necessary to implement the Act, including rules for detoxification, maintenance and withdrawal treatment programs,[66] which BHA has done.[67]

[56] § 27-80-208(4), C.R.S.
[57] § 27-80-211(1), C.R.S.
[58] § 27-80-211(2), C.R.S.
[59] § 27-80-210(1), C.R.S.
[60] § 27-80-210(2), C.R.S.
[61] § 27-80-210(4), C.R.S.
[62] § 27-80-212, C.R.S.
[63] § 27-80-215(1)(a), C.R.S.
[64] 2 CCR 502-1 § 13.6.6, Behavioral Health Rules.
[65] § 27-80-215(1)(c), C.R.S.
[66] §§ 27-80-213(1) and (2), C.R.S.
[67] 2 CCR 502-1 § 1.2, Behavioral Health Rules.

BHA has also adopted rules concerning personnel in substance use disorder treatment programs.

According to rule, before hiring or contracting with an individual or accepting an individual for volunteer service, a licensee must conduct a name-based criminal history record check through the Colorado Bureau of Investigation. If the individual has resided in Colorado for three years or less, the licensee must obtain either:[68]

- A name-based criminal history record check from the state, or states, where the individual lived; or
- A national criminal history record check through the Federal Bureau of Investigation.

[68] 2 CCR 502-1 § 2.5(D)(2), Behavioral Health Rules.

Program Description and Administration

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The fifth and sixth sunset criteria question:

> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters; and
>
> Whether an analysis of agency operations indicates that the agency or the agency's board or commission performs its statutory duties efficiently and effectively.

In part, COPRRR utilizes this section of the report to evaluate the agency according to these criteria.

The Behavioral Health Administration (BHA), in the Department of Human Services, is vested with the regulation of substance use disorder treatment programs (treatment programs) under the Colorado Licensing of Controlled Substances Act (Act). Specifically, BHA is responsible for issuing licenses, investigating complaints, conducting inspections, adopting rules and enforcing the Act.

The licensing program in BHA operates in conjunction and in accordance with guidelines established by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the U.S. Department of Health and Human Services.

The purpose of the Act is to provide a regulatory framework that helps to prevent misuse and diversion of controlled substances, such as methadone and buprenorphine, which are used to treat substance use disorders. Federal law requires treatment programs that administer and dispense these substances to obtain a license from the state where they are operating.

In addition to a state license, state and federal law also require opioid treatment programs to be:

- Registered with the U.S. Drug Enforcement Agency (DEA),
- Certified by SAMHSA,
- Accredited by an accrediting body approved by SAMHSA, and
- Compliant with federal and state regulations.

The program is partially cash funded by license fees. However, as the license fees do not support all program activities, the remaining operating expenses are covered by grants and General Fund dollars.

Table 2 illustrates, over a five-year period, the total program expenditures and the full-time equivalent (FTE) employees allocated to the program.

Table 2
Total Program Expenditures and Staffing

Fiscal Year	Expenditures	FTE
19-20	$166,492	2.35
20-21	$171,641	2.35
21-22	$1,681,262	2.25
22-23	$1,849,726	2.55
23-24	$666,187	4.55

The total program expenditures reported in Table 2 are estimates provided by BHA staff.

Prior to July 1, 2022, the controlled substance licensing program was overseen by the Office of Behavioral Health (OBH). The increases in expenditures in 21-22 and 22-23 are attributed to the transition from the OBH to BHA. Additionally, during the five-year period, the total number of treatment programs and patients receiving services increased significantly, which required BHA to hire additional staff in fiscal year 22-23 and 23-24.

As of the writing of this report, 5.1 FTE were allocated to the program.

- **Associate Director** (Program Management II, 1.0 FTE) — Manages operations and personnel for controlled substance licensing and operates as the state's regulatory liaison for SAMHSA, oversees the state Opioid Treatment Program regulation, which includes the Central Registry.

- **Controlled Substance Licensing Manager** (Program Management I, 2.0 FTE) — Conducts site visits, oversees regulatory compliance and licensing, monitors complaints and critical incidents, and provides technical assistance to licensees.

- **Controlled Substance Licensing Coordinator** (Program Coordinator, 1.0 FTE) — Manages the Central Registry on a day-to-day basis, supports site visits along with licensing managers, supports the team with technical and administrative duties, and co-manages critical incident review along with members of the BHA enforcement team.

- **Director of Licensing & Designation** (Compliance Specialist VI, .15 FTE) — Oversees licensing and designation for BHA and daily operations of the Quality and Standards Division.

- **Division Director of Quality & Standards** (Program Management II, 0.5 FTE) — Leads the Quality and Standards Division, oversees regulatory development and implementation and is a member of BHA core leadership team.

- **Data Systems Director** (Program Management II, 0.05 FTE) — Leads a team and makes decisions to ensure all data systems are properly designed, built and prioritized to meet the goals of BHA.

- **Data System Specialist** (Data Management III, 0.1 FTE) — Acts as product and licensing lead and provides vendor escalation support.

- **System Specialist** (Data Management III, 0.1 FTE) — Acts as a provider support lead, responds to Central Registry user questions and requests, creates and deactivates Central Registry accounts and provides escalation support.

- **Contract Digital Advisor** (BHA Contractor, 0.1 FTE) — Supports sprint planning and enhancements for the Central Registry; informs and drives strategy for products across BHA technology and data tools.

- **Electronic Platform Contractor** (BHA Contractor, 0.1 FTE) — Supports BHA's technological needs for the Central Registry.

Licensing

The eleventh and twelfth sunset criteria question whether the scope of practice of the regulated occupation contributes to the optimum use of personnel and whether entry requirements encourage equity, diversity and inclusivity.

In part, COPRRR utilizes this section of the report to evaluate the program according to these criteria.

A controlled substance license is required for all treatment programs that administer, dispense or compound a controlled substance to treat a substance use disorder.[69] However, office-based treatment providers are not required to obtain controlled substance licenses as long as they do not administer, dispense or compound a controlled substance to treat substance use disorders.[70]

A separate license is required for each facility site that is engaged in activities requiring a license.[71]

[69] 2 CCR 502-1 § 13.3(A), Behavioral Health Rules.
[70] 2 CCR 502-1 § 13.3(B), Behavioral Health Rules.
[71] 2 CCR 502-1 § 13.3.1(C), Behavioral Health Rules.

To obtain a controlled substance license, an applicant must submit a completed application, including any necessary documentation and pay the license fee.[72]

The application must be affirmed and signed by a qualified practitioner. It must also include a copy of the applicant's policies and procedures addressing the use of controlled substances in the treatment of substance use disorder.[73] The policies must conform to federal, state and local law pertaining to controlled substances, and they must also address how patients are assessed to determine whether it is appropriate to use controlled substances in treatment.[74]

BHA also conducts a state and national fingerprint-based criminal background check of all owners prior to granting a license.

Additionally, a controlled substance license will not be issued to an applicant if the medical director has been convicted of a willful violation of a controlled substance law.[75] A license may be denied if a practitioner at the treatment program has a felony conviction related to a controlled substance.[76]

Any facility that provides clinical treatment related to substance use disorders must be licensed as a behavioral health entity. The controlled substance license is a secondary license required for those licensed behavioral health entities that administer, dispense and compound controlled substances, such as methadone and buprenorphine, in the treatment of substance use disorders.

A controlled substance license expires annually.[77]

Table 3 provides, over a five-year period, the license fees for controlled substance licenses.

Table 3
Controlled Substance License Fees

Fiscal Year	Initial	Renewal
19-20	$275	$275
20-21	$275	$275
21-22	$500	$500
22-23	$500	$500
23-24	$500	$500

[72] 2 CCR 502-1 § 13.3.2(A), Behavioral Health Rules.
[73] 2 CCR 502-1 § 13.3.2(A), Behavioral Health Rules.
[74] 2 CCR 502-1 § 13.4.1(A), Behavioral Health Rules.
[75] 2 CCR 502-1 § 13.3.1(H), Behavioral Health Rules.
[76] 2 CCR 502-1 § 13.3.5(A)(7), Behavioral Health Rules.
[77] 2 CCR 502-1 § 13.3.1(B), Behavioral Health Rules.

The controlled substance license fees increased in fiscal year 21-22 when the program transferred from OBH to BHA. While the licensing program is intended to be cash funded, the license fees do not currently cover, and historically have not covered, the full cost of the program. The license fees were increased to transition the program into a cash-funded program as intended.

Table 4 provides the total number of treatment programs licensed to administer and dispense controlled substances for substance use disorder treatment.

Table 4
Total Controlled Substance Licenses

Fiscal Year	Initial	Renewal	Total
19-20	9	41	50
20-21	13	50	63
21-22	17	65	82
22-23	14	73	87
23-24	14	95	109

Over the five-year period, the total number of controlled substance licenses issued by BHA has more than doubled. On average, about 13 new facilities were granted licenses each year. The increase in the total number of licensees is attributed to a shift in federal and state regulations, which decreased barriers to care.

For instance, the DEA previously prohibited mobile methadone clinics. With the removal of this barrier, Colorado now has two vans that serve as methadone clinics. Currently, the two vans are serving urban areas: one serves patients outside of primary care clinics and the other serves patients outside of shelters for those experiencing homelessness.

Another barrier to care required patients to go to clinics seven days a week to pick up their medication. Today, patients who are stable can take home medication for longer periods of time.

These changes were initially adopted temporarily during the COVID-19 pandemic, but they are now permanent. Each state is not required to adopt these changes, but Colorado chose to reduce these barriers to increase access to care.

Inspections

BHA audits and inspects applicants upon initial licensure, to renew a license and when staff have concerns about a licensee. BHA may have concerns with a licensee based on a grievance, a critical incident or for other reasons. On-site inspections may be scheduled or unscheduled.

When granting an initial license, BHA conducts a desk audit to verify the applicant has all the credentials required by state and federal law, including:

- DEA registration,
- SAMHSA certification, and
- SAMHSA-approved accreditation.

BHA also looks at the treatment program's policies and financials, and it conducts a preliminary inspection of the building.

If an applicant meets the initial requirements, BHA will grant a six-month provisional license. Prior to granting a full license, BHA conducts an on-site inspection. If the treatment program is substantially compliant, a full license is granted.

Licenses must be renewed annually. Before a license expires, BHA will conduct an onsite inspection.

Table 5 details, over a five-year period, the number of inspections conducted by BHA staff for the controlled substance licensing program.

Table 5
Inspections

Type	FY 19-20	FY 20-21	FY 21-22	FY 22-23	FY 23-24
Initial Licensing Inspections	9	13	17	14	14
License Renewal Inspections	41	50	65	73	97
For-Cause Inspections	0	0	1	2	5
Total	**50**	**63**	**83**	**89**	**116**

The total number of inspections increased over the five-year period, which aligns with the increased number of licensed facilities. While BHA did not report any for-cause inspections in fiscal years 19-20 or 20-21, in the following years, a total of eight of these inspections were conducted. This increase was likely due to an increase in grievances and critical incidents reported to BHA.

Grievances

The tenth sunset criterion requires COPRRR to examine whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession or regulated entity.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

Anyone may file a grievance with BHA, including patients, family members, practitioners and employees. BHA reports that it takes each grievance seriously regardless of the source.

Table 6 demonstrates, over a five-year period, the total number of grievances filed with BHA by fiscal year and type.

Table 6
Grievances

Nature of Grievance	FY 19-20	FY 20-21	FY 21-22	FY 22-23	FY 23-24
Quality of Care and Services	6	11	13	27	40
Unethical Practices	3	4	1	5	2
Safety Concerns	7	10	6	0	2
Access to Care	7	5	7	1	3
Abuse and Neglect	1	0	3	2	5
Denial of Services	2	2	1	13	1
Discrimination	0	1	2	1	3
Fraud	2	6	2	3	3
Access to Records	2	4	0	1	3
Total	**30**	**43**	**35**	**53**	**62**

While the total number of complaints doubled over the five-year period, this increase is consistent with the increase in controlled substance licenses issued by BHA. As the total number of treatment programs providing care doubled, it is reasonable to expect that the number of complaints would also increase.

On average, BHA received about 45 grievances a year. Approximately 43 percent of all complaints related to quality of care and services. However, the rate of quality-of-care grievances increased steadily over the five-year period. In fiscal year 19-20, 20 percent of all complaints related to quality of care, and in fiscal year 23-24, these complaints

represented about 65 percent of all complaints. As the total number of new facilities with controlled substance licenses increased substantially over this period, it is not surprising to see an increase in the rate of quality-of-care complaints.

BHA took over the licensing program in 22-23, and the new agency has adopted new processes and procedures to track and handle grievances, which may have affected the numbers reported in recent years.

When an investigation uncovers a licensed practitioner, such as a doctor or a nurse, who is engaging in unprofessional conduct, BHA requires the licensee to file a report with the appropriate regulatory authority at the Department of Regulatory Agencies. For example, if an investigation uncovers a licensed registered nurse who is diverting medication or who is using drugs or alcohol at work, the licensee must file a report with the Colorado Board of Nursing. BHA then verifies that a report has been filed.

Critical Incidents

All treatment programs are required to report critical incidents such as medical emergencies and deaths to BHA. These incidents may concern specific patients, or they may concern medication errors or diversion. BHA requires these incidents to be reported within 24 hours.

When a licensee submits a critical incident, it must submit a preliminary report. BHA tracks each critical incident, and then it contacts the licensee to follow up on the incident. Depending on the type of incident, BHA may conduct an investigation or follow up with an inspection. If BHA subsequently identifies concerns related to an incident, it requires the licensee to submit a plan to address them.

Table 7 shows, over a five-year period, the total number of critical incidents reported to BHA by fiscal year and type.

Table 7
Critical Incidents

Nature of Critical Incidents	FY 19-20	FY 20-21	FY 21-22	FY 22-23	FY 23-24
Medical Emergency	160	150	262	517	910
Death	69	82	113	132	202
Assault	44	61	93	169	256
Medication Diversion or Error	277	337	361	312	565
Elopement	22	31	54	63	66
Breach of Confidentiality	18	21	11	59	91
Other	91	9	8	28	39
Total	**681**	**691**	**902**	**1,280**	**2,129**

In fiscal year 22-23, BHA changed its approach to enforcing compliance with its incident reporting rules and began educating licensees and their staff about the rules, which likely resulted in more critical incidents being reported. Considering this, a close examination of the trends over the five-year period may be misleading. Nonetheless, as Table 7 clearly demonstrates, the number of critical incidents reported to BHA has increased significantly over the five-year period.

In addition to changes in the approach to incident reporting by BHA, the total number of patients receiving care has also increased significantly, so it is reasonable to expect the number of critical incidents to also increase. For instance, among patients receiving treatment with methadone, between 2020 and 2025, the patient population increased by 40 percent.

A number of conditions has led to the increase in methadone patients. For one, the number of opioid treatment programs has increased, which makes it easier for patients to get into treatment. Also, reduced barriers to medication have resulted in increased medication compliance, which means patients are remaining in treatment for longer periods of time.

Also, during the COVID-19 pandemic, substance use increased and access to mental health services decreased. The availability of fentanyl in Colorado has also resulted in more people having an opioid use disorder.

As regulatory allowance for take home methadone medication for opioid use disorder has increased, stronger medication diversion prevention efforts are necessary. As a result, BHA has increased its enforcement of diversion reporting and adherence to reporting, which likely resulted in an increase in the reports of diversion.

As indicated in Table 7, the total number of medication errors reported to BHA increased significantly in 23-24. This increase is likely due to more medication

encounters following a significant increase in the treatment population, along with regulatory changes that allow prescribers to dispense more take-home methadone to patients, and in doing so alleviating the need for daily visits to methadone clinics. Previously, take-home methadone allowances were considerably more fixed and limited across the patient population. With changes to state and federal opioid treatment program regulations, prescribers may be more flexible and individualized in their approach to dispensing methadone. However, as dispensing is now more complicated, the opportunity for medication errors has also increased.

A medication error may also take place when a nurse dispenses the wrong amount of medication. For instance, the doctor's order may be for 27 milligrams, but a nurse may dispense 270 milligrams instead. An error may also occur when a nurse dispenses medication from the previous doctor's order rather than the new doctor's order.

An elopement refers to a patient who is subject to involuntary treatment, and they have left a treatment facility without permission. It is unclear whether all the elopements reported here are relevant to controlled substance licenses. The data was gathered by collecting all the elopements from facilities that have controlled substance licenses. However, many of these facilities, such as Denver Health, provide a variety of health-care services in addition to administering and dispensing medication for substance use disorders. Methadone clinics, which represent approximately half of all controlled substance licenses, are outpatient clinics rather than secure facilities, so an elopement would not be relevant to this type of licensee.

Similarly, the data related to breaches of confidentiality may be skewed since some of these breaches may have been reported by facilities that provide methadone care along with other types of health-care services.

Table 7 demonstrates that total number of reported deaths increased significantly each year between fiscal year 21-22 and 23-24. In addition to the significant increase in the patient population, BHA now requires licensees to endeavor to determine what happened to an individual when they stop showing up for treatment, such as calling law enforcement and the medical examiner's office. Previously, licensees may have simply discharged a patient when they stopped showing up for treatment rather than attempting to determine why the individual ceased treatment. As a result, deaths may have previously been underreported.

BHA and the treatment facilities do not always know the cause of death of a patient. The licensee may be informed by a family member that a patient has died, but the family does not always know the cause of death. BHA asks for the medical examiner's report and investigates each death to determine whether treatment was a contributing factor.

It should be noted that overdoses related to methadone remain low since patients are less likely to die from an opioid overdose while they are in treatment.

The "other" category in Table 7 refers to incidents that were accidentally reported as critical incidents. Additionally, sometimes a treatment program may select "other" accidentally when it should have selected another category. It is unknown why the number of incidents reported as "other" was much higher in fiscal year 19-20 than in the following years, but it is likely due to differences in data tracking and enforcement.

Disciplinary Activity

The tenth sunset criterion requires COPRRR to examine whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession or regulated entity.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

BHA may deny, suspend or revoke a license. It also has the authority to place a license on probation or place conditions on a license.

Table 8 demonstrates, over a five-year period, the total number of disciplinary actions taken against controlled substance licenses by BHA.

Table 8
Disciplinary Activity

Type of Action	FY 19-20	FY 20-21	FY 21-22	FY 22-23	FY 23-24
Revocation/Surrender/ Voluntary Relinquishment	1	0	0	0	0
Suspension	0	0	0	0	0
Probation/Practice Limitation	0	1	4	3	2
License Denied	0	0	1	0	0
Total Disciplinary Actions	1	1	5	3	2

Over the five-year period, one license was revoked, surrendered or voluntarily relinquished and one license was denied. No licenses were suspended. The majority of disciplinary actions included conditions, such as probation or practice limitations, being placed on a license. BHA took ten such disciplinary actions.

In fiscal year 19-20, an opioid treatment program had its license revoked after an investigation found that the owner was mistreating patients. In fiscal year 21-22, a license renewal was denied to a clinic when it was found to be grossly negligent and

operating without meeting numerous regulatory requirements, such as providing counseling to patients.

When BHA finds that a licensee is not substantially compliant with federal and state regulatory requirements, it may place a treatment program on probation and provide it with an opportunity to come into compliance. Some examples of noncompliance include:

- Failing to have a doctor determine the appropriate level of care before billing for medication,
- Billing for medical care without providing treatment, and
- Having a patient sign a blank sheet of paper and completing the release of information later.

When a licensee is placed on probation, BHA will conduct another on-site inspection after 90 days. If it is still substantially out of compliance, BHA may require the treatment program to relinquish its license. If the treatment program wants to continue operating as a substance use disorder treatment program, it must apply for a new license.

While BHA is authorized to fine a licensee up to $500 for violating the Act, it does not currently exercise its fining authority and reported no fining activity from fiscal year 19-20 to fiscal year 23-24.

Collateral Consequences – Criminal Convictions

The thirteenth sunset criterion requires COPRRR to examine whether the agency, through its licensing, certification or registration process, imposes any sanctions or disqualifications on applicants based on past criminal history and, if so, whether the sanctions or disqualifications serve public safety or commercial or consumer protection interests.

COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The Act has multiple sections that allow BHA to deny, suspend or revoke a license on the basis of a conviction.[78] However, BHA reported no such denials, suspensions or revocations.

[78] §§ 27-80-205(1) and 208(1), C.R.S.

Analysis and Recommendations

The final sunset criterion questions whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest. The recommendations that follow are offered in consideration of this criterion, in general, and any criteria specifically referenced in those recommendations.

Recommendation 1 — Continue the Colorado Licensing of Controlled Substances Act for 15 years, until 2041.

The Colorado Licensing of Controlled Substances Act (Act) is located in Part 2 of Article 80 of Title 27 of the Colorado Revised Statutes (C.R.S.).

The Behavioral Health Administration (BHA), in the Department of Human Services, is vested with the regulation of substance use disorder treatment facilities under the Act. Specifically, BHA is responsible for issuing licenses, investigating complaints, conducting inspections, adopting rules and enforcing the Act.

The licensing program in BHA operates in conjunction and in accordance with guidelines established by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the U.S. Department of Health and Human Services.

Sunset reviews are guided by statutory criteria found in section 24-34-104, C.R.S., and the first criterion asks whether regulation is necessary to protect the health, safety and welfare of the public.

The Act protects the public by establishing a framework to regulate facilities that treat substance use disorders with Schedule II and III controlled substances, such as methadone and buprenorphine. The primary purpose of the Act is to prevent misuse and diversion of controlled substances. It also serves to protect the patients that are being treated in these facilities.

Substance use disorder is a complex disease in which the brain is altered so that it becomes especially difficult to stop using alcohol or other drugs despite a patient's motivation to do so. As substance use disorder is a chronic disease, even after long periods of sobriety, a patient may relapse. While it cannot be cured, substance use disorder can be managed.[79]

Treatment by qualified professionals may address the disorder by slowly weaning the individual off the substance or ending the use of the substance all at once. Treatment also involves monitoring and addressing any physical and emotional withdrawal symptoms, teaching individuals in recovery to understand their behavior and providing

[79] Substance Abuse and Mental Health Services Administration. *What Is Substance Use Disorder?* Retrieved September 26, 2025, from www.samhsa.gov/substance-use/what-is-sud

patients with techniques to prevent relapse.[80] Along with therapy, medication may also be used to treat substance use disorders.

Opioid use disorder is especially difficult to treat. Because the medications that are effective in the treatment of opioid use disorder, such as methadone and buprenorphine, are controlled substances, treatment facilities that administer and dispense them are highly regulated. Many of these requirements are driven by federal law.

Opioid use disorder is a serious public health concern. In 2024, 981 individuals died from opioid overdose in Colorado.

While an important medication for the treatment of opioid use disorder, methadone also has the potential for misuse and, if diverted, may be sold as a street drug. As the following table illustrates, methadone is deadly if taken incorrectly.

Table 9 illustrates, over a five-year period, the total number of deaths in Colorado from opioid overdoses.[81]

Table 9
Colorado Deaths from Opioid Overdoses

Calendar Year	Heroin	Methadone	Fentanyl	Prescription (No Fentanyl)	All Opioids*
2020	220	68	540	258	956
2021	189	54	912	242	1,258
2022	62	61	920	211	1,160
2023	36	42	1,097	176	1,292
2024	30	76	761	201	981
Total	**537**	**301**	**4,230**	**1,088**	**5,647**

* The data in these columns were retrieved from statistics published on the Colorado Department of Public Health and Environment's website. The columns in the table do not necessarily add up to equal the column titled, "All Opioids." Not all of the opioid-related statistics on the website are included in this table, and some of the data in the columns may overlap.

Over the five-year period, 5,647 people died from an opioid overdose in Colorado. Among all opioids, fentanyl was the deadliest, representing approximately 75 percent of all opioid overdose deaths. Prescription opioids represented about 19 percent of all opioid deaths, and heroin and methadone represented 10 percent and 5 percent, respectively.

[80] MedlinePlus. *Substance Use Disorder*. Retrieved September 26, 2025, from medlineplus.gov/ency/article/001522.htm
[81] Colorado Department of Public Health and Environment. *Colorado Drug Overdose Statistics (Search 2000-2024, without race; Select Drug Overdose Category for 1) Heroin, 2) Methadone, 3) Fentanyl, 4) Prescription Opioids without mention of fentanyl and 5) Total Opioids*. Retrieved October 1, 2025, from cdphe.colorado.gov/colorado-drug-overdose-statistics

BHA plays an important role in Colorado residents having access to safe and effective treatment for substance use disorders, which can help mitigate the harm from opioids and other harmful drugs, and the Act provides an important framework to prevent the drugs used to treat opioid use disorder from finding their way to the streets and being misused by patients in treatment.

Over a five-year period, BHA revoked one license, denied one license and took 10 other disciplinary actions, including probation or practice limitations, against facilities that were not substantially compliant with state and federal regulations.

As demonstrated in Table 10, deaths from opioids decreased in 2024. In part, this may be due to reductions in barriers to treatment for opioid use disorder. Also, over the past few years, the patient population receiving treatment with methadone has increased substantially.

Clearly, regulation of facilities that administer and dispense controlled substances to treat substance use disorders is critical to protect the public health, safety and welfare. It is also required by federal law. Without the Act, no facilities in Colorado would be allowed to treat opioid use disorders with controlled substances.

For those with substance use disorders, medication has been demonstrated to:[82]

- Save lives,
- Improve treatment retention,
- Improve recovery rates,
- Reduce rates of illegal drug use and other illegal activity,
- Improve employment rates, and
- Improve birth outcomes.

As the most effective medications for the treatment of opioid use disorder are methadone and buprenorphine, which are Schedule II and Schedule III controlled substances, maintaining these treatment facilities in Colorado is critical. Therefore, the Act should be continued.

The licensing program is largely driven by federal regulations, and during the sunset review, the issues that were raised were largely related to modernizing the Act. Considering this, a 15-year continuation is reasonable.

As the Act is critical for the protection of the public health, safety and welfare, the General Assembly should continue the Act for 15 years, until 2041.

[82] Substance Abuse and Mental Health Services Administration. *Substance Use Disorder Treatment Options.* Retrieved September 24, 2025, from www.samhsa.gov/substance-use/treatment/options

Recommendation 2 — Modernize the definition of "substance use disorder" in the Act to more accurately reflect the type of conditions being treated by BHA-licensed facilities and the practitioners who may diagnose these conditions.

Currently, the Act defines "substance use disorder" as

> a physical or psychological dependence on a controlled substance that develops following the use of the controlled substance on a periodic or continuing basis and is demonstrated by appropriate observation and tests by a person licensed to practice medicine pursuant to Article 240 of Title 12.

This definition is outdated and may not reflect the types of substance use disorders that may be treated by facilities licensed under the Act. For instance, the definition limits substance use disorder to conditions related to controlled substances. While many of the patients being treated in these facilities have substance use disorders related to controlled substances, it is not necessary to limit treatment to those patients. The controlled substance license is required because a facility treats a substance use disorder with a controlled substance, not because the condition being treated relates to a controlled substance.

Additionally, the definition limits diagnosis to a physician. However, multiple types of practitioners, practicing within their scopes of practice, are qualified to diagnose substance use disorders.

Sunset criteria question:

- Whether conditions have changed and whether other conditions have arisen that would warrant more, less, or the same degree of governmental oversight;
- Whether the existing rules and regulations establish the least restrictive form of governmental oversight consistent with the public interest, considering other available regulatory mechanisms; and
- Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel.

To modernize the Act, the definition should be revised to more accurately reflect the conditions being treated and types of practitioners whose various scopes of practice include diagnosis of these conditions. This would also help to eliminate an unnecessary barrier to health care.

Therefore, the General Assembly should modernize the definition of "substance use disorder" in the Act to more accurately reflect the type of conditions being treated by licensed facilities and the practitioners who may diagnose these conditions, such as:

> a chronic relapsing brain disease, which is diagnosed by a licensed practitioner qualified to diagnose substance use disorders, characterized by recurrent use of alcohol, drugs or both, causing clinically significant impairment, including health problems, disability and failure to meet major responsibilities at work, school or home.

Recommendation 3 — Repeal the definitions of and references to "detoxification treatment," "maintenance treatment" and "withdrawal treatment" in the Act, replace them with the term, "withdrawal management," and adopt a new definition of "withdrawal management" that considers the full spectrum of treatment concepts.

Currently, the Act includes three definitions for "detoxification treatment," "withdrawal treatment" and "maintenance treatment."

BHA has already eliminated these terms in its rules. Instead, BHA rules refer to different levels of "withdrawal management." This is consistent with the latest standards adopted by the American Society of Addiction Medication (ASAM).

These terms may be considered by some as outdated. For instance, "detox" or "detoxification treatment" is viewed by some as pejorative and outdated in the field of addiction medicine, and ASAM has eliminated this term from its current standards.

Sunset criteria question whether conditions that led to the creation of the program have changed and whether the agency operates in the public interest and whether its operations are impeded or enhanced by existing statutes, rules, procedures or practices.

In order to modernize the Act, these terms should be repealed and the term, "withdrawal management," which considers the full spectrum of treatment concepts and aligns with current national standards, should replace them.

Therefore, the General Assembly should repeal the definitions of and references to "detoxification treatment," "withdrawal treatment" and "maintenance treatment," and replace them with the term, "withdrawal management," which may be defined as

> a program of treatment that is designed to support the medical and psychiatric stability of a person with a substance use disorder by mitigating physiological signs and symptoms of their substance withdrawal, with the option of administering or dispensing a controlled substance in the course of treatment, approved for such use by federal law or regulation. The course of treatment can range from short-term intoxication management with the goal of reducing more immediately a person's dependence on all substances to long-term medication

management with the goal of decreasing the person's substance dependency over time. The full range of the withdrawal management treatment continuum is intended to be in combination with additional behavioral health interventions designed to attenuate the underlying conditions leading to a substance use disorder.

Recommendation 4 — Amend the Act by adopting technical amendments.

The Act has been in place since 1981. As with any law, it contains instances of outdated, duplicative and confusing language, and the Act should be revised to eliminate obsolete references and to reflect current terminology and administrative practices. These changes are technical in nature, so they will have no substantive impact on the regulation of facilities that treat substance use disorders with controlled substances.

Therefore, the General Assembly should adopt the following technical amendments:

- Amend the Act to make it gender neutral by replacing terms, such as "him," "her," "he" and "she" with gender-neutral terms;
- Clarify that the reference to "controlled substances" in section 27-80-213(2), C.R.S., pertains to the method of treatment and not the affliction;
- Repeal the terms "substance use disorder treatment program" and "substance use disorder" in section 27-80-216, C.R.S., and replace them with "opioid treatment program" and "opioid use disorder" since this provision only pertains to the registry for patients being treated for opioid use disorder in opioid treatment programs; and
- Repeal defined terms, such as "marijuana," that are no longer referenced in the Act.