COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2018 Sunset Review:

Colorado Licensing of Controlled Substances Act

October 15, 2018

COLORADO
Department of Regulatory Agencies
Executive Director's Office

October 15, 2018

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. Since that time, Colorado's sunset process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

Section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), directs the Department of Regulatory Agencies to:

- Conduct an analysis of the performance of each division, board or agency or each function scheduled for termination; and

- Submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination.

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. Accordingly, COPRRR has completed the 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 2019 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Part 2, Article 80 of Title 27, C.R.S. The report also discusses the effectiveness of the Department of Human Services - Office of Behavioral Health in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Marguerite Salazar
Executive Director

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Department of Regulatory Agencies
Colorado Office of Policy, Research & Regulatory Reform

2018 Sunset Review
Colorado Licensing of Controlled Substances Act

SUMMARY

What is regulated?
The Colorado Licensing of Controlled Substances Act (Act) establishes a regime to license programs that treat substance use disorders with controlled substances in order to prevent diversion of controlled substances. The program falls under the umbrella of the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration.

Why is it regulated?
Controlled substances can be used therapeutically and still pose a threat to a person's health. Regulation of facilities helps to minimize risks by noting where, when, and how the drugs are dispensed. Comprehensive recordkeeping minimizes the possibility of diversion and therefore protects the public.

Who is regulated?
During fiscal year 16-17, the Department of Human Services' (DHS) Office of Behavioral Health (OBH) licensed 42 facilities. This number is 247 percent larger than the 17 facilities that were licensed in fiscal year 12-13. This number illustrates the recent explosion in the demand for such services in Colorado.

How is it regulated?
Multiple licenses are required for each location where controlled substances are used to treat substance use disorders or the withdrawal symptoms of substance use disorders under the Act. Facilities are required to be registered with the U.S. Drug Enforcement Administration (DEA), obtain a Substance Use Disorder license (SUD) also issued by OBH, submit a completed application, copies of required documentation, and pay license fees. OBH is charged with ensuring that all state and federal protocols for handling, dispensing, and recording the use of controlled substance are followed in the licensed facilities.

What does it cost?
Funding comes from multiple sources; the Federal Substance Abuse Block Grant, the General Fund allocation for OBH, and the cash fund established by license fees. Approximately five percent of the program is funded by a cash fund. The total program expenditures for fiscal year 16-17 were $69,329 and 0.77 full-time equivalent (FTE) employees were allotted to program implementation. This is because the program was without an administrator for part of the year. In fiscal year 15-16, the program expended $96,439 and allotted 1.1 FTE to program implementation.

What disciplinary activity is there?
Because OBH has no formal, simple, accurate, or objective system to keep track of and categorize incoming complaints and disciplinary actions taken against licenses, there are none to report.

KEY RECOMMENDATIONS

Continue the Act for seven years until 2026.
The Act is the law which authorizes the licensing and regulation of the facilities that treat addiction with controlled substances. Opioid medication-assisted treatment (OMAT) programs typically use methadone, buprenorphine, and naltrexone, all of which are controlled substances, in treatment. The main regulatory focus of the Act is making certain that diversion of the controlled substances used in treatment does not occur. The existence of OMAT programs is an important tool for public protection as is the regulation of such facilities to prevent drug diversion. However, because conditions around such issues are dynamic and constantly changing, the General Assembly should continue the Act for only seven years, until 2026.

Direct OBH to develop a secure online central registry.
To prevent drug diversion, OBH has instituted a central registry on which all patients treated in licensed OMAT programs are registered. Prior to admitting a prospective patient to treatment, the facility is required to submit information to OBH in "prescribed formats" to verify eligibility. There have been multiple problems with the antiquated system employed by OBH. The criteria that direct sunset analysis asks analysis to consider if an agency's operations are impeded by current procedures and practices, and whether duties are performed efficiently and effectively. In the case of the central registry, neither of these questions can be answered affirmatively.

METHODOLOGY

As part of this review, the Colorado Office of Policy, Research and Regulatory Reform staff interviewed OBH staff and facility operators; reviewed program records; interviewed federal government officials and officials with national organizations; observed OBH staff in the performance of thier duties; and reviewed federal laws, Colorado statutes and rules, and the laws of other states.

MAJOR CONTACTS MADE DURING THIS REVIEW

U.S. Drug Enforcement Administration
U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration
Denver Health
University of Colorado Health
Colorado State Board of Pharmacy
Colorado Department of Human Services, Office of Behavioral Health
National Association of State Alcohol and Drug Abuse Directors

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are prepared by:
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Background

Introduction

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 based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- 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;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- 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;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- 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;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

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

- Whether the agency through its licensing or certification process imposes any disqualifications on applicants based on past criminal history and, if so, whether the disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subparagraph (i) of paragraph (a) of subsection (8) of this section shall include data on the number of licenses or certifications that were denied, revoked, or suspended based on a disqualification and the basis for the disqualification; and
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals

who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

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: www.dora.colorado.gov/opr.

The functions of the Department of Human Services - Office of Behavioral Health (OBH) as enumerated in Part 2, Article 80 of Title 27, C.R.S., shall terminate on September 1, 2019, 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 Colorado Licensing of Controlled Substances Act (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 performance of OBH. During this review, OBH 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, the Colorado Office of Policy, Research and Regulatory Reform staff, interviewed OBH staff and facility operators; reviewed program records; interviewed federal government officials and officials with national organizations; observed OBH staff in performance of duties; and reviewed federal laws, Colorado statutes and rules, and the laws of other states.

Profile

The Substance Abuse and Mental Health Services Administration (SAMHSA) was created in 1992 and is the federal government agency that attempts to decrease incidences of substance abuse in the U.S. SAMHSA is located in the U.S. Department of Health and Human Services.[2]

SAMHSA dedicates resources, including programs, policies, information and data, contracts and grants, which are committed to illustrating that:[3]

- Behavioral health is essential to health,
- Prevention works,
- Treatment is effective, and
- People recover from mental and substance use disorders.

Prevention, treatment, and recovery support services are important pieces of a community's health service system.

In 2015, nearly 20 million people in need of substance abuse treatment did not receive it. People who suffer from substance use and/or mental disorders are often excluded from the health care system and must rely on public programs. This hole in services endangers people which, in turn, affects the communities in which they live.[4]

In September 2017, the *New York Times* wrote that, "Opioid addiction has developed such a powerful grip on Americans that some scientists have blamed it for lowering our life expectancy."[5]

[2] SAMHSA. *About Us*. Retrieved November 2, 2017 from https://www.samhsa.gov/about-us
[3] Ibid.
[4] SAMHSA. *Who We Are*. Retrieved November 2, 2017 from https://www.samhsa.gov/about -us/who-we-are
[5] The New York Times. *America's 8-Step Program for Opioid Addiction*. Retrieved January 30, 2018 from https://www.nytimes.com/2017/09/30/opinion/opioid-addiction-treatment-program.html

Opioids occur naturally in the body and include endorphins and endomorphins. There are also a number of broad classes of opioids: natural, semi-synthetic, synthetic and opioid-like agents:[6]

- Natural opiates are alkaloids contained in the resin of the opium poppy. These include morphine and codeine.
- Semi-synthetic opioids are created from the natural opiates and include buprenorphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, and diacetylmorphine, i.e., heroin.
- Synthetic opioids include fentanyl, tramadol, dextropropoxyphene, and methadone.
- Opioid-like agents are chemically different but garner attention from the body's μ-opioid receptor.

This is not a complete listing but many of these drugs are found in medicine cabinets of any American homes.

The Colorado Department of Public Health and Environment (CDPHE) reported that the number of opioid deaths in 2015 in Colorado, was 26.3 percent higher than the number of homicides. CDPHE also reported that one Coloradan died every 36 hours from an opioid overdose.[7]

According to SAMHSA:[8]

> Symptoms of opioid use disorders include strong desire for opioids, inability to control or reduce use, continued use despite interference with major obligations or social functioning, use of larger amounts over time, development of tolerance, spending a great deal of time to obtain and use opioids, and withdrawal symptoms that occur after stopping or reducing use, such as negative mood, nausea or vomiting, muscle aches, diarrhea, fever, and insomnia.

Programs that treat substance use disorders reduce the physical, social, and emotional dangers associated with the disorder.

Detoxification programs provide support during withdrawal from alcohol and/or other drugs. Services may be provided in a unit of a medical facility, in a freestanding residential or community-based setting, or in the home of the person served. There are three basic types of detoxification:[9]

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[6] Medical News. *Opioid Types*. Retrieved January 30, 2018, from http://www.news-medical.net/health/Opioid-Types.aspx
[7] CDHPHE. *Opioid Use In Colorado*. Retrieved January 30, 2018, from https://www.colorado.gov/pacific/sites/default/files/Opioid%20Use%20in%20Colorado%20-%20March%202017.pdf
[8] SAMHSA. *Substance Use Disorders*. Retrieved January 30, 2018, from https://www.samhsa.gov/disorders/substance-use
[9] CARF International. *2018 Behavioral Health Program Descriptions.* p.10. Retrieved January 30, 2018, from http://www.carf.org/programdescriptions/bh/

- Inpatient: This setting is distinguished by services provided in a safe, secure, facility-based setting with 24-hour nursing coverage and ready access to medical care. This is for persons who need round-the-clock supervision in order to successfully manage withdrawal symptoms or when there are additional complications or risk factors that warrant medical supervision, such as co-occurring psychiatric or other medical conditions.
- Residential: This setting is distinguished by services provided in a safe facility with 24-hour coverage by qualified personnel. Persons served need the supervision and structure provided by a 24-hour program but do not have risk factors present that warrant an inpatient setting. It may also be appropriate for persons who lack motivation or whose living situation is not conducive to remaining sober.
- Ambulatory: This setting is distinguished by services provided in an outpatient environment with the persons served residing in their own homes, a sober living environment or other supportive community settings. Persons served in ambulatory settings typically have adequate social supports to remain sober, family involvement in care planning, the ability to maintain regular appointments for ongoing assessment and observation, and the ability to successfully self-manage prescription medications. Persons served in ambulatory settings are concurrently enrolled in or actively linked to a treatment program.

For some individuals, medication-assisted treatment (MAT) is an option. The medications used in MAT for individuals with an opioid use disorder include naltrexone, methadone, and buprenorphine, which are controlled substances [10] approved by the Food and Drug Administration (FDA) for use in the treatment of opioid dependence. The aim of MAT is reducing and eliminating the use of drugs, criminal activity, and the spread of infectious disease while simultaneously improving the life and functioning of the individual.[11]

As stated above, opioids occur naturally in the body. Knowing and understanding that is key in comprehending how substance use disorder is treated pharmacologically. The underlying science for medication-assisted treatment considers that whenever a person uses an opioid drug, it alters the chemistry of the brain. After use, or abuse, the brain may not be able to produce naturally-occurring opioids like endorphins on its own. Because the brain and body require the release of the substances and the damaged brain can no longer produce them, opioid substance use disorder can become a chronic relapsing condition. This can be true of opioids taken with a doctor's direction if there is not close supervision.

At times the brain chemistry is changed to the extent that the inability to produce certain chemicals becomes a permanent condition that an individual must live with

[10] § 18-18-102(5), C.R.S. – "Controlled substance" means a drug, substance, or immediate precursor included in schedules I through V of part 2 of this article, including cocaine, marijuana, marijuana concentrate, cathinones, any synthetic cannabinoid, and salvia divinorum.
[11] CARF International. *Opioid Treatment Program*. Retrieved January 31, 2018, from http://www.carf.org/Programs/OTP/

for the remainder of his or her life. This situation is not unlike a person who lives with heart, lung, or kidney disease every day. The difference is that the diseased organ in this case is the brain. The treatment is similar to the individual on heart medication or on kidney dialysis – the patient treats the less effective organ with opioid replacement medication to compensate for the lack of organ function.

When the individual consumes the replacement medication — naltrexone, methadone, or buprenorphine — he or she is able to function without being "high" or going through withdrawal, and can stabilize enough to live a somewhat normal life. However, to be most effective, treatment takes a three pronged approach: biological, sociological, and psychological. A patient must control both his or her environment and receive mental health therapy in conjunction with the medication.

MAT is not substituting one drug for another. Rather, the medication aids a patient in dealing with withdrawal symptoms and psychological cravings that cause the chemical imbalances. Research verifies that when provided at the proper dose, the medications do not have adverse effects on the patient's mental or physical health, or ability to be gainfully employed.[12] *The Denver Post* has reported that according to Denver Public Health's director, MAT expansion is a top concern for those battling the opioid crisis.[13]

Because treating substance use disorder with medication involves using controlled substances, the facilities that distribute the medication are highly regulated. SAMHSA uses a national accreditation model in the approval and oversight of opioid treatment facilities. In Colorado there are two accreditation organizations: CARF International and the Joint Commission.

A State Opioid Treatment Authority (SOTA) acts as the point of contact between a state and SAMHSA. In Colorado, the Colorado Controlled Substances Administrator, who licenses facilities under the authority of the Act, also acts as the SOTA.

The Office of Behavioral Health is also the recipient of a grant from SAMSHA through the Medication-Assisted Treatment Prescription Drug and Opioid Addiction Grant Program. The grant, awarded in 2016, is $950,000 per year for three years. The grant is established to, among other objectives, make medication-assisted treatment networks more accessible.[14] This program is one small part of a much larger effort in Colorado that deals with substance use disorder in multiple ways, through multiple state agencies.

[12] SAMHSA. *Medication and Counseling Treatment*. Retrieved January 31, 2018, from https://www.samhsa.gov/medication-assisted-treatment/treatment

[13] *Denver Post*, "Methadone clinics in Colorado have doubled in three years, but the state is still short on treatment options." Retrieved February 5, 2018, from https://www.denverpost.com/2018/02/04/colorado-methadone-clinics-drug-treatment-options/

[14] Colorado Department of Human Services. *Medication-Assisted Treatment Prescription Drug and Opiod Addiction (MAT-PDOA) Programs.* Retrieved February 27, 2018, from https://www.colorado.gov/pacific/cdhs/medicated-assisted-treatment-prescription-drug-and-opioid-addiction-mat-pdoa-programs

Legal Framework

History of Regulation

Colorado first enacted laws regarding controlled substances in 1963, in the form of the State Narcotic Act. In 1968, Colorado enacted the Colorado Dangerous Drug Act. In 1981, the Colorado Dangerous Drug Act and the State Narcotic Act were combined 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, manufacturers that manufacture or distribute controlled substances, and wholesalers that 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 drugs. Recordkeeping requirements for licensees were delineated, along with authorization for inspections, investigations, and reports necessary to determine compliance.

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

During the 2012 legislative session, Senate Bill 1311 relocated the Act from the Pharmacy Practice Act where it had been since 1981. It was inserted into the statutes that govern the DHS and behavioral health.

Senate Bill 17-242 changed verbiage throughout the Act. The term "substance use disorder" replaced "addiction."

Legal Summary

The Act creates a state program that exists under the umbrella of federal regulation. Its purpose is to license substance use disorder treatment programs that compound, administer, or dispense controlled substances.[15] A license provides an exemption to the Uniform Controlled Substances Act of 2013 as long as the licensee acts within the scope of the license.[16]

Substance Abuse and Mental Health Services Administration

The U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA) oversees an accreditation program for the

[15] § 27-80-202, C.R.S.
[16] §§ 27-80-204(1)(a) and (2), C.R.S.

nation's opioid treatment programs. SAMHSA provides the federal umbrella under which treatment programs operate. The ultimate purpose of the multi-step federal program is to confirm that practitioners are qualified to dispense the opioid drugs that are used in the treatment of opioid use disorders. Individual program and practitioner certification is made through a SAMHSA approved accreditation body.[17]

Only a state governmental entity, a state political subdivision, or a private nonprofit organization may become an accreditation body.[18] Among other things, an accreditation body's application to be approved must contain:

- Standards for accreditation and a detailed discussion of how standards will ensure that each program inspected by the accreditation body will meet federal standards;[19]
- Description of the applicant's decision-making process;[20]
- Policies and procedures to avoid conflicts of interest by individuals associated with the accreditation body;[21]
- Experience and training requirements for the accreditation body's staff including a description of training policies;[22]
- Fee schedules with supporting data;[23]
- Assurances that the accreditation body will implement its responsibilities and a protocol for investigating complaints;[24]
- Policies and procedures to protect confidential information;[25] and
- Any other information SAMHSA may require.[26]

In Colorado there are two approved accreditation bodies: CARF International and the Joint Commission.

An accreditation body's approval cannot last more than five years.[27] It must apply for renewal if it chooses to serve beyond its current term or notify SAMHSA that it intends not to renew.[28]

Once approved, an accreditation body is accountable for implementing SAMHSA rules and policies concerning inspections, complaints, records and reporting, conflicts of interest, and accreditation practices.[29] SAMHSA will periodically evaluate each

[17] 42 C.F.R. § 8.1
[18] 42 C.F.R. § 8.3(a)
[19] 42 C.F.R. § 8.3(b)(3)
[20] 42 C.F.R. § 8.3(b)(4)
[21] 42 C.F.R. § 8.3(b)(5)
[22] 42 C.F.R. § 8.3(b)(6) and (b)(7)
[23] 42 C.F.R. § 8.3(b)(8)
[24] 42 C.F.R. § 8.3(b)(9)
[25] 42 C.F.R. § 8.3(b)(10)
[26] 42 C.F.R. § 8.3(b)(11)
[27] 42 C.F.R. § 8.3(g)
[28] 42 C.F.R. § 8.3(c)
[29] 42 C.F.R. § 8.4

accreditation body.[30] If it deems that it is out of compliance, SAMHSA may order corrective action or withdraw approval.[31]

SAMHSA also has rules that regulate program treatment and certification standards,[32] the review of program certification suspension or proposed revocation, and adverse actions regarding withdrawal of approval of an accreditation body.[33]

U.S.Drug Enforcement Administration

The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act of 2000 created protocols for licensing those involved in the treatment of opioid addiction. Anyone administering or dispensing approved Schedule II controlled substances, such as methadone, for addiction treatment must be registered with the U.S. Drug Enforcement Administration (DEA) as a Narcotic Treatment Program. Those who administer Schedule III, IV, or V controlled substances in treatment receive a Unique Identification Number. Every dose administered to a patient must have the Unique Identification Number as well as the DEA registration number.[34]

Colorado Licensing of Controlled Substances Act

The Act allows licensees to possess, distribute, dispense, administer, or to conduct research with controlled substances, subject to any limitations on their license and only pursuant to an order form.[35] The Act authorizes the licensing of any person, i.e., any individual, government, governmental subdivision, agency, business trust, estate, trust, partnership, corporation, association, institution, or other legal entity,[36] who is qualified.

If a person has a valid DEA registration as a researcher, he or she is presumed to be qualified.[37] Otherwise, to meet the license qualifications, an applicant must have adequate, proper facilities for handling and storing controlled substances. The applicant must also maintain proper control over the controlled substances to ensure they are not dispensed or distributed illegally.[38] A person who has been convicted within the last two years of a willful violation of the Act, any other state law, or federal law regulating controlled substances is ineligible for licensure.[39]

[30] 42 C.F.R. § 8.5
[31] 42 C.F.R. § 8.6
[32] 42 C.F.R. Part 8 Subpart C
[33] 42 C.F.R. Part 8 Subpart D
[34] US Department of Justice-Drug Enforcement Division-Diversion Control Division. *Practitioner's Manual – Section VI*, Retrieved June 7, 2018, from https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section6.htm
[35] §§ 27-80-204(2), and 27-80-210(5), C.R.S. Compliance with the provisions of federal law respecting order forms is deemed compliance with Act.
[36] § 27-80-203(18), C.R.S.
[37] §§ 27-80-207(2) and (4), C.R.S.
[38] § 27-80-207(1), C.R.S.
[39] § 27-80-207(3), C.R.S.

DHS's Office of Behavioral Health (OBH) issues a license to every researcher and substance use disorder treatment program that meets the requirements of the Act unless it would be inconsistent with the public interest. In determining the public interest, the OBH must consider:[40]

- Maintenance of effective controls against diversion into illegitimate medical, scientific, or industrial channels;
- Compliance with applicable state and local laws;
- Conviction under any federal or state law relating to a controlled substance;
- Experience manufacturing or distributing controlled substances and the existence of effective controls against diversion;
- False or fraudulent information in an application filed under the Act;
- Suspension or revocation of a federal registration to manufacture, distribute, or dispense a controlled substance authorized by federal law; and
- Other factors relevant to and consistent with the public peace, health, and safety.

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.[41]

OBH may fine up to $500, place on probation, place conditions on operations, or deny, suspend, or revoke a license upon a finding of the following violations:[42]

- Furnishing false or fraudulent information in an application;
- Entering a plea of guilty or nolo contendere to, or being convicted of a felony under any state or federal law relating to a controlled substance;
- Having federal registration to manufacture, conduct research with, distribute, or dispense a controlled substance suspended or revoked; and
- Violating any provision of the Act or the State Board of Human Services rules.

If OBH suspends or revokes a license, it may place all of the licensee's controlled substances under seal. DHS cannot dispose of the substances until the time for making an appeal has elapsed or until all appeals are concluded. However, a court has the option of ordering the sale of any perishable controlled substances and depositing the proceeds with the court. When a revocation order becomes final, all controlled substances may be forfeited to the state.[43] DHS has the option of limiting a revocation or suspension to the specific controlled substance that was the basis for the disciplinary action.[44]

[40] § 27-80-205(1), C.R.S.
[41] § 27-80-205(2), C.R.S.
[42] §§ 27-80-208(1) and 208(2.5), C.R.S.
[43] § 27-80-208(3), C.R.S.
[44] § 27-80-208(2), C.R.S.

The Act directs OBH to "promptly" notify the DEA and any applicable professional licensing agency, of all charges and forfeitures as well as the final disposition of charges.[45]

Colorado peace officers and district attorneys are charged with enforcing the Act. In doing so they must work together with all other state and federal law enforcement agencies on issues involving controlled substances.[46] For its part the OBH must:[47]

- Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances;
- Cooperate with the DEA, local, state, and other federal agencies by maintaining a centralized unit to accept, catalogue, file, and collect statistics;
- Respond to referrals, complaints, or other information received regarding possible Act violations and, when appropriate, inspect and investigate the possible violations;
- Cooperate with state licensing boards regarding violations of the Act and make information available to those boards; and
- Engage in educational and research activities designed to determine and prevent the misuse and abuse of controlled substances.

Persons authorized under the Act to manufacture, purchase, distribute, dispense, administer, store, or otherwise handle controlled substances are required to keep extensive records. If a person maintains a record required by federal law that contains substantially the same information, he or she is in compliance with the Act.[48]

A licensee must maintain separate, detailed, accurate records and inventories and retain them for two years after each transaction.[49] The records must include the date the controlled substance was distributed and the name and address of the person to whom it was distributed as well as the kind and quantity.[50]

Licensees must also retain a record of any controlled substance lost, destroyed, or stolen; the kind and quantity of the controlled substance; and the date of the loss, destruction, or theft.[51]

Records made pursuant to the Act are to be kept confidential. Prescriptions, orders, and records are open for inspection only to federal, state, county, and municipal officers whose duty it is to enforce laws relating to controlled substances or the regulation of practitioners. No officer with knowledge of a prescription, order, or

[45] § 27-80-208(4), C.R.S.
[46] § 27-80-211(1), C.R.S.
[47] § 27-80-211(2), C.R.S.
[48] § 27-80-210(3), C.R.S.
[49] § 27-80-210(1), C.R.S.
[50] § 27-80-210(2), C.R.S.
[51] § 27-80-210(4), C.R.S.

record can divulge what is known except in connection with a prosecution or proceeding in a court or before a licensing board.[52]

The recordkeeping provisions only apply if a licensee dispenses, other than by direct administration, a schedule III, IV, or V controlled substance to his or her patients, and the practitioner charges the patients either separately or together with charges for other professional services; or the licensee regularly engages in dispensing a schedule III, IV, or V controlled substance to his or her patients.[53]

The OBH is directed to promulgate and update rules as necessary to implement the Act including rules for research, detoxification treatment, maintenance treatment, and withdrawal treatment programs. The rules are to be made available on its website.[54]

The license requirement in the Act is scheduled to repeal September 1, 2019, subsequent to this sunset review. The review must consider whether the license requirement should be combined with the licensing of any other substance use disorder treatment programs within DHS.[55]

[52] § 27-80-212, C.R.S.
[53] § 27-80-209(4), C.R.S.
[54] § 27-80-213, C.R.S.
[55] § 27-80-204(1)(b), C.R.S.

Program Description and Administration

The Colorado Department of Human Services' Office of Behavioral Health (OBH) licenses substance use disorder treatment programs under the Colorado Licensing of Controlled Substances Act (Act). The main focus of the Act is to ensure that the safeguards preventing drug diversion are in place and working.

Though there is a designated program cash fund established from license fees, it does not support all program activities. The remaining operating expenses are covered by grants and the annual OBH General Fund allocation. Table 1 indicates the total dollars and full-time equivalent (FTE) employees expended on the program during the period examined for this sunset review. It also segregates the expenditure of dollars and FTE funded through the cash fund.

Table 1
Program Expenditures
Fiscal Years 12-13 through 16-17

Fiscal Year	Total Expenditures	Total FTE	Cash Fund Expenditures	Cash Fund FTE
12-13	$28,635	0.30	$1,784	0.1
13-14	$95,272	1.00	$5,767	0.1
14-15	$108,016	1.00	$5,712	0.1
15-16	$96,439	1.00	$5,780	0.1
16-17	$69,329	0.67	$5,388	0.1

Funding comes from multiple sources: the Federal Substance Abuse Block Grant, the General Fund allocation for OBH, and the cash fund established by license fees. The reason for the expenditure fluctuations in fiscal years 12-13 and 16-17 are that the Controlled Substances Administrator (Administrator) position was vacant for part of the year. Table 1 indicates that approximately five percent of the program is funded by the cash fund. This is because there are so few licensees within the state.

The Administrator, classified as a Program Manager I, is the principal employee of the program. The program operates in conjunction and in accordance with guidelines established by the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA). The Administrator directs the licensing functions, which include conducting inspections and investigating complaints under the Act. The Administrator, who is referred to as the State Opioid Treatment Authority (SOTA) in federal parlance, establishes best practices for the state based on local experiences and issues. The Administrator/SOTA is entrusted to analyze data to determine types of substance use disorder issues, drug traffic patterns, and gather input from patients and providers to develop solutions to those recognized problems.

While the specific statutes under sunset review concern the licensing of facilities, the program as constituted in OBH is charged with far more. Along with the functions designated under the Act, the Administrator is also very involved in treatment. He or she advises programs and authorizes doses, levels of treatment, handles patient complaints and patient transfers, and at times acts as an intermediary among facilities on specific cases when they have a common interest or patient. Recall that the focus of the Act is the prevention of diversion.

Licensing

Multiple licenses are required for each location where controlled substances are used to treat substance use disorders or the withdrawal symptoms of substance use disorders under the Act.[56] Facilities are required to be registered with the U.S. Drug Enforcement Administration (DEA).[57] There is also a separate license required by OBH to operate any treatment program, a Substance Use Disorder license (SUD). Though not the subject of this review, the license is required for any facility providing clinical treatment. The SUD license is issued for two years and the fee is $200.

To obtain the controlled substance license necessary to operate a treatment program that uses controlled substances, which is the subject of this review, an applicant must acquire the above DEA authorizations and submit a completed application, copies of necessary documentation, and license fees. This controlled substance license is issued for one year and carries a $275 fee.[58]

The controlled substance license application must be affirmed and signed by a physician. It must include a copy of facility policies and procedures addressing the use of controlled substances in the treatment of substance use disorder and withdrawal.[59] The policies are directed to include the assessment of patients and why it is appropriate to use controlled substances in treatment. The policies must conform to federal, state, and local law pertaining to controlled substances.

[56] 2 CCR 502-1 § 21.300.21(B), Behavioral Health Rules
[57] 2 CCR 502-1 § 21.300.3(D), Behavioral Health Rules
[58] 2 CCR 502-1 § 21.300.22, Behavioral Health Rules
[59] *ibid.*

Table 2 includes all of the programs licensed to use controlled substances in treatment. These include both the opioid treatment programs, which typically treat patients pharmacologically long-term, and detoxification centers, which typically treat patients pharmacologically short-term. The data are not segregated by type of program.

Table 2
Active Licenses
Fiscal Years 12-13 through 16-17

Fiscal Year	Initial License	Renewal	TOTAL
12-13	0	17	17
13-14	5	7	12
14-15	5	19	24
15-16	9	25	34
16-17	7	35	42

Table 2 indicates that the number of facilities decreased significantly, 29 percent, then more than tripled during the period examined. The increase is due to multiple factors. Among the factors; is the expansion of Colorado's Medicaid benefit in 2014 to include coverage for Opiod Medication Assisted Treatment (OMAT) programs licensed under the Act. Another factor is the availability of federal dollars through SAMHSA's Medication-Assisted Treatment Prescription Drug and Opioid Addiction Grant Program. The grant, awarded September 1, 2016, is $950,000 per year for three years.

If a licensee is an OMAT program, it must have a Medical Director who is licensed to practice medicine or nursing in Colorado. The Medical Director is responsible for ensuring that all medications and treatments are handled according to stipulations in law.[60] As of 2018, 22 of the 42 licensed programs were OMATs.

Site Reviews

Routine monitoring is conducted at licensed facilities during normal business hours.[61] Also, according to rule, OBH must conduct unscheduled visits to monitor activities or to investigate complaints.[62] As a program policy, OBH attempts to conduct at least one site review of each licensed facility per year. Facilities are also inspected by their accreditation body for each accreditation renewal, usually every three years, and occasionally the DEA will conduct a random audit or if there is a problem with a facility it will investigate. When there is a problem, it is also possible that all three entities will become involved, and possibly other outside policing agency(s) as well.

[60] 2 CCR 502-1 § 21.320.32, Behavioral Health Rules
[61] 2 CCR 502-1 § 21.300.21(D), Behavioral Health Rules
[62] 2 CCR 502-1 § 21.300.21(E), Behavioral Health Rules

Because preventing diversion is the focus of licensing these facilities, during an inspection, OBH staff checks to see that various clinical treatment and recordkeeping processes and protocols are followed. Among them:

- Treatment documentation;
- Signatures of clients and counselors on documentation;
- Staff documentation; and
- Safety and notification procedures.

These are examined to ensure that drug diversions are not occurring and that treatments are conducted according to best standards of practice.

Table 3 shows the number of site visits made to licensed programs during the period examined for this sunset review.

Table 3
Facility Site Reviews
Fiscal Years 12-13 through 16-17

Fiscal Year	Site Reviews
12-13	17
13-14	22
14-15	24
15-16	34
16-17	42

A comparison of Tables 2 and 3 shows that, except for fiscal year 13-14, the number of site reviews and the number of licensed facilities are in line. During fiscal year 13-14, there were additional site reviews conducted at MAT detoxification programs.

Complaints and Discipline

Because OBH has no formal, simple, accurate, or objective system to keep track of and categorize incoming complaints and disciplinary actions taken against licenses, there are none to report.

Collateral Consequences – Criminal Convictions

Section 24-34-104(6)(b)(IX), C.R.S., requires the Colorado Office of Policy, Research and Regulatory Reform to determine whether the agency under review, through its licensing processes, imposes any disqualifications on applicants or registrants based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

A person who has been convicted within the last two years of a willful violation of the Act, any other state law, or federal law regulating controlled substances is ineligible for licensure.[63]

The Act has multiple sections that allow for a license to be denied, suspended, or revoked due to a conviction.[64] However, OBH reported no such denials, suspensions, or revocations.

[63] § 27-80-207(3), C.R.S.
[64] §§ 27-80-205(1) and 208(1), C.R.S.

Analysis and Recommendations

Recommendation 1 – Continue the Colorado Licensing of Controlled Substances Act for seven years, until 2026.

Codeine, Vicodin and OxyContin are opioids that are prescribed to help individuals cope with pain. Addiction to them can develop from what patients may assume is a risk-free use. Many people become addicted to prescription painkillers and do not realize they have a problem until they stop using the prescription. Issues associated with opioid addiction are in the news quite often. To be clear, all individuals who are prescribed opioids do not become addicted and all individuals who are addicted to opioids did not start using them with a prescription. Still, opioid addiction is a problem in Colorado. The Colorado Department of Human Services' — Office of Behavioral Health (OBH) has called the problem a crisis.[65] OBH states that medication-assisted treatment (MAT) is considered the best of the treatment options.[66]

MAT is a valid way for individuals dealing with addiction-related issues to cope with those issues and lead a relatively normal life. The Colorado Licensing of Controlled Substances Act (Act) is the law which calls for the licensing and regulation of the facilities that treat addiction with controlled substances. Opioid medication-assisted treatment (OMAT) programs typically use methadone, buprenorphine and naltrexone, all of which are controlled substances, in treatment. While the mission of the program developed to implement the Act is treating individuals, the main regulatory focus of the Act is making certain that diversion of the controlled substances used in treatment does not occur.

Drug diversion can be defined as the rerouting of lawful drugs for unlawful reasons. Diversion takes drugs from medically necessary purposes to purposes that are neither typically legal nor medically necessary.[67]

OBH licenses and inspects the treatment facilities to ensure that accurate records are kept and that safety procedures are followed in each licensed facility. The Act operates under the umbrella of the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA authorizes state MAT programs to treat addiction using controlled substances. Having a local authority allows enforcement based on local needs. The specific local authority is an individual called the State Opioid Treatment Authority (SOTA). The SOTA is authorized by SAMHSA and employed by OBH.

[65] Colorado Department of Human Services. *Opioid Crisis in Colorado: The OBH Role, Research and Resources*. Retrieved May 30, 2018, from https://www.colorado.gov/pacific/cdhs/opioid-crisis-colorado-office-behavioral-healths-role-research-and-resources
[66] *ibid.*
[67] Drugwarfacts.org. *Diversion of Prescription Drugs*. Retrieved May 30, 2018, from http://www.drugwarfacts.org/chapter/diversion

A major benefit to having a SOTA is that he or she has the authority to inspect a facility at any time rather than more sporadically, which would be the case if there were no state program. The organizations that accredit facilities[68] inspect only triennially, and the U.S. Drug Enforcement Administration only becomes involved when there is a problem.

OBH is also involved in trying to remove any stigma attached to addiction and promoting the notion that help is available.[69] This program is one small, but necessary, part of a much larger effort in Colorado that deals with substance use disorder. Records noting where, when, and to whom controlled substances have been prescribed, serve the public interest by limiting diversion.

The first criterion that guides analysis for a sunset review reads:

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

In the case of the Act, an affirmative answer is reasonable. The existence of MAT programs is an important tool for public protection as is the regulation of such facilities to prevent drug diversion. While substance use disorder has increased in Colorado, attitudes have changed for the better. Some of Colorado's citizens are more aware of and more concerned about the effects of opioid addiction in Colorado's communities. However, because conditions around such issues are dynamic and constantly changing, the General Assembly should continue the Act for seven years, until 2026.

Recommendation 2 – Direct OBH to develop a secure online central registry.

To prevent drug diversion, OBH has instituted a central registry on which all patients treated in licensed OMAT programs are registered. Prior to admitting a prospective patient to treatment, the facility is required to submit information to OBH in "prescribed formats."[70] No patient can be admitted to treatment when the registry shows him or her currently enrolled in another treatment program.[71]

A provider must fill out the form, and submit it by email to OBH and it is then processed as OBH staff time and labor permits (see Appendix A for a copy of the Central Registry Reporting Form). Because it is processed by OBH staff rather than

[68] In Colorado either CARF International or the Joint Commission accredits treatment facilities.
[69] *Denver Post*. "Colorado launches a nearly $1.8 million campaign to end stigma around opioid addiction." Retrieved May 30, 2018, from https://www.denverpost.com/2018/05/14/lift-the-label-campaign-colorado/
[70] 2 CCR 502-1 § 21.320.9.D.1, Behavioral Health Rules
[71] 2 CCR 502-1 § 21.320.9.D.3, Behavioral Health Rules

data being entered into a computer one time by someone affiliated with the treatment program, there are several things that can go wrong. Mishandling or postponed entry of information means that treatment may be delayed or denied through no fault of the treatment program or the patient. This is an outdated way of doing business and has caused problems for licensees and, more importantly, the patients/clients served by the licensees.

OBH staff may be unavailable to process the form. When staff is unavailable, a program cannot admit and treat a new patient until it contacts every other licensed OMAT program in Colorado to verify the patient has not previously enrolled in and is not being dosed by another program. As of the writing of this sunset review, there were 23 OMAT treatment programs licensed in Colorado. Another option is to turn the patient away until approval can be confirmed. When that happens, there is risk to the patient and the public. If a patient is turned away, there is no guarantee he or she will return.

The 2013 sunset review of the Act recommended that OBH develop secure online access to the central registry. At that time, OBH maintained that there were no problems, the recommendation was not adopted, and the problem has become much worse. In part, it has become worse because the number of OMAT programs has almost doubled and program staff has not increased.

The central registry is a key mechanism in OMAT. It is used to approve and record new patients, take-home medications for those who are in that phase of recovery, and any special circumstances that may occur, such as a patient needing extra doses to travel for work. To make this issue clear, it must be understood that through the central registry, individual OMAT programs interact with OBH more often than with any other regulatory process. For some programs, there may be several interactions per week. Timely, accurate interaction is extremely important to patient and public health, safety, and welfare.

Licensees reported multiple instances when they did not receive timely responses to central registry inquiries. Some of those resulted in patient treatment being delayed and some resulted in the patient leaving the facility without being dosed. To some extent, this is due to OBH staff not being available until 8:00 in the morning, while facilities typically start seeing patients from 5:00 to 6:00 in the morning. The same reports cited instances when the information provided by OBH was incomplete or incorrect and again patient treatment was delayed or postponed.

One must understand that OMAT must follow a schedule. Similar to a person that is being treated for heart, kidney, or other physical disease, skipping and/or delaying treatment can have dire consequences for the patient.

The solution is to develop a secure online system to register individuals, verify eligibility for enrollment, and to securely store relevant medical information.

The National Association of State Alcohol and Drug Directors provided the Colorado Office of Policy, Research, and Regulatory Reform (COPRRR) with state-level information on central registries. Of the 16 states that had a central registry as of November 2015, Colorado is the only state in which state staff enters and has access to individual patient data. In the remaining 15 states, facility staff enters data. Some states have developed their own system and others have contracted with a vendor to supply services.

Having facility staff enter the data eliminates significant wait times for patient approval; eliminates a step in the process which, in turn, decreases the likelihood of human error in data entry; facilitates movement among facilities for people who may have to relocate for employment or other reasons; enables OBH staff to complete other important tasks; and – one of the major justifications for the secure online database in other states – allows treatment records to be accessible in cases of emergency or disaster. This would be advantageous for patients in Colorado in the event of natural disasters such as wildfires, floods, or major winter storms.

A secure online database is not without precedent in Colorado. The concept is similar to the Prescription Drug Monitoring Program (PDMP) database. The PDMP is operated by a third-party vendor and it lists the controlled medications prescribed to many patients in Colorado so that prescribers may check to see what prescriptions a patient is taking prior to prescribing a new pharmaceutical. In fact, the last sunset review of the Act recommended expanded access to the PDMP for certain MAT program personnel and the General Assembly concurred. Having access to the central registry online will ensure that, regardless of the circumstances, an individual who is eligible for treatment may be treated and is not subjected to administrative inefficiencies.

The third criterion that directs sunset analysis asks if an agency operates in the public interest and if operations are impeded by current procedures and practices. The fourth criterion asks if analysis indicates that agency duties are performed efficiently and effectively. In the case of the central registry, agency procedures and practices work counter to the public interest and the duties are not performed efficiently or effectively. For these reasons, the General Assembly should direct OBH to develop a secure online central registry.

Recommendation 3 - Mandate that OBH develop and implement a formal, simple, accurate, and objective system to keep track of and categorize incoming complaints and disciplinary actions.

All governmental programs are expected to be accountable to the public for their activities and to work in the best interests of the public. One important way to measure accountability is through the gathering of data specific to program operations and actions.

The 2013 sunset review of the Act noted that:

> OBH does not have a formal, simple, accurate, objective system to keep track of and categorize incoming complaints. The complaint numbers reported for this sunset review were compiled by staff examining and interpreting hard copies of files, after the fact and without prior involvement in the individual case. The staff did not record the number of complaints that actually came in to OBH, the number resolved without a formal proceeding, or the number withdrawn, among other categories.

COPRRR did not recommend that a system to track complaints and disciplinary actions be developed at that time because OBH explained it was in the process of developing and implementing such a system. Five years later, there is still no formal, simple, accurate, and objective system to keep track of and categorize incoming complaints and disciplinary actions taken against licenses.

Even if complaint numbers are low, regulators have the responsibility to track data associated with the implementation of governmental programs. Accountability for actions and dollars is expected by the General Assembly as agents and advocates of public wellbeing.

Therefore, the General Assembly should mandate that OBH develop and implement a formal, simple, accurate, and objective system to keep track of and categorize incoming complaints and disciplinary actions.

Recommendation 4 – Repeal references to research as a regulated activity in the Act.

Section 27-80-205(3), Colorado Revised Statutes provides that a $25 fee should be charged for a researcher's license. However, the program does not issue licenses to researchers, and while the facility license allows for individuals to compound controlled substances in research, the licensed clinics do not perform research. The DEA requires researchers to be registered and it affirms that researchers work in different clinical settings.

Regulating research is beyond the scope of expertise of OBH staff. A controlled research setting explores and investigates the effects of different compounded controlled substances. The licensed clinics that operate MAT programs dispense controlled substances to MAT patients; they do not conduct research.

Because program staff is not qualified to regulate research and the clinics licensed by the program under the Act do not perform research, the references to research as a regulated activity and should be repealed from the Act.

Administrative Recommendation 1 – OBH should establish a boundary between implementation of the Act and the administration of substance use disorder treatment.

Occasionally the General Assembly provides specific direction regarding items and/or issues that must be examined during a sunset review. Senate Bill 17-242 amended the Act to require sunset analysis to explore whether the licensing required in the Act should be combined with the licensing of other substance use disorder treatment programs.

A major issue that facilities have brought to the attention of COPRRR is that the lines are blurred in the implementation of the Act and the Substance Use Disorder (SUD) license. The Act exists to establish systems which prevent the diversion of controlled substances. The SUD license is required for all facilities that employ therapy to treat individuals whether they are using MAT or not. One program is about process and the other is about functionality.

When the SOTA comes to inspect a facility under the Act, it should be a very mechanical inspection. The inspection is to make sure that systems and protocols such as record keeping and labeling are in place and being followed to prevent diversion.

The SUD administrator looks at individual treatment files from a behavioral health perspective and consults with clinicians on the efficacy of treatment and how well a treatment fits a person.

When the SOTA is also the person getting involved in analyzing treatment, facilities have multiple issues: that the SOTA is getting too much personal information on the patients that he or she does not need to perform the inspection for the controlled substance license; more staff has to be available to speak with the person doing the inspection about different aspects of treatment; and the SOTA gets stretched too thin. When the SOTA is stretched too thin, it results in the types of excessive delays that were written of in Recommendation 2 of this sunset report.

Having the SOTA as the only person in the field may have been a cost-effective way of operating when there were fewer programs. However, as was noted in this sunset report, the number of programs has increased dramatically. Multitasking in the current environment has hampered the delivery of services by the licensees and should be rectified by OBH. While section 27-80-204(1)(b)(II), C.R.S., asks if the Act should be combined with another program, this sunset report recommends the opposite. OBH should separate the administration of the programs with a bright line.

Appendix A - Central Registry Reporting Form

COLORADO
Office of Behavioral Health

Central Registry Reporting Form

Facility (Called/Emailed Central Registry) Name	Staff Name
____	____

Client Name		Social Security #	Birthdate	Admit Date	Discharge Date	Cleared by:
____ First name	____ Last Name	____	____	____	____	☐ Jacquie ☐ Other-who?

☐ METHADONE

☐ BUPRENORPHINE

☐ SUBOXONE

☐ DEATH
DATE: ____

☐ LOCK IN
DATE: ____

☐ LOCK OUT
DATE: ____

NOTES: (ADD ADDITIONAL INFORMATION)____

☐ TRANSFERING TO: ____

☐ TRANSFERRING FROM: ____

MANDY: 303.866.7493

JACQUIE: 303.866.7483

CENTRAL REGISTRY FAX: 303-866-7520