Department of Regulatory Agencies

Office of Policy, Research and Regulatory Reform

2013 Sunset Review: Colorado Licensing of Controlled Substances Act

October 15, 2013

Consumer Protection

Department of Regulatory Agencies

Executive Director's Office
Barbara J. Kelley
Executive Director

John W. Hickenlooper
Governor

October 15, 2013

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 mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA 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 my office's oral testimony before the 2014 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

> The department of regulatory agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...
>
> The department of regulatory agencies shall 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 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 Department of Human Services and staff 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,

Barbara J. Kelley
Executive Director

1560 Broadway, Suite 1550 Denver, Colorado 80202 Phone 303.894.7855
Fax 303.894.7885 Toll Free 800.866.7675 www.dora.state.co.us V/TDD 711

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Executive Director

2013 Sunset Review:
Colorado Licensing of Controlled Substances Act

Summary

What Is Regulated?
The Colorado Licensing of Controlled Substances Act (Act) creates a state program that exists under the umbrella of the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration. Its purpose is to license addiction programs that compound, administer, or dispense controlled substances to treat substance abuse and addiction.

Why Is It Regulated?
Controlled substances are highly regulated, i.e., controlled, because while they can be therapeutic, they can also pose health and safety risks to the public. Among those risks is the possibility of addiction or death from overdose.

Records noting where, when, and to whom controlled substances have been prescribed, serve the public interest by limiting diversion. Drug diversion is the consumption of licit drugs, for illicit purposes. To protect the public from undue exposure to dangerous conditions, it is necessary to regulate both treatment facilities and the treatments they provide.

Who Is Regulated?
A license is required for each location where controlled substances are used to treat addiction or the withdrawal symptoms of addiction. There were 21 facility licenses issued each year during the period under review, fiscal years 07-08 through 11-12.

How Is It Regulated?
To obtain the license necessary to operate an addiction treatment program, an applicant must submit a completed application, copies of necessary documentation, and license fees. A treatment program must also acquire a separate license as an entity authorized to dispense controlled substances. The license for the treatment program is issued for three years and carries a $200 fee. The controlled substance license is renewed annually and is $75 for addiction programs and $25 for researchers.

What Does It Cost?
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 Office of Behavioral Health General Fund allocation. The Colorado Department of Human Services (DHS) expends approximately $50,000 per fiscal year to operate the program. Additionally there is 0.71 of a full-time equivalent employee allotted for program activities.

What Disciplinary Activity Is There?
The program does not have a formal, simple, accurate, objective system to keep track of and categorize complaints and disciplinary action. The data reported for this sunset review were compiled by staff examining and interpreting hard copies of files without prior involvement in the individual case.

Examination indicates that during the period under review, there was one license suspended and one license denied. Both actions concerned the same case in fiscal year 07-08 and the actions were eventually overturned on appeal.

Key Recommendations

Continue the Act for 11 years, until 2025.
The Colorado Attorney General observed the increase in drug use in Colorado and stated,

> Hundreds of Coloradans are dying each year from drug abuse. However, the drugs behind a growing number of these deaths usually are not being purchased on street corners or from drug dealers — the drugs are most commonly found in household medicine cabinets.

Research has demonstrated that pharmacological treatment is effective in treating drug addiction. It is analogous to employing a controlled burn to fight fires. It works well and is a community asset under the right circumstances but can also be dangerous under some conditions. To protect the public from undue exposure to dangerous conditions such as drug diversion, it is necessary to regulate both treatment facilities and the treatments they provide.

Grant the DHS wider disciplinary discretion in implementing the Act.
Currently, the DHS may only deny, suspend, or revoke a license if the licensee violates the Act, regardless of the seriousness of the violation. Typically, a program that licenses a business or occupation has the ability to treat lesser administrative violations with lesser degrees of discipline than license suspension or revocation. Both of those actions are, and should be, reserved for the most egregious violations.

Expand prescription drug monitoring program (PDMP) access to the staff at facilities that treat addiction with controlled substances.
A PDMP is an electronic database that collects data concerning controlled substances dispensed or prescribed to individuals. Currently, only licensed pharmacists and prescribers have access. The PDMP and the Act have similar purposes. The General Assembly created the PDMP to give prescribers a way to monitor an individual patient's use of controlled substances with the goal of mitigating the abuse of prescription drugs. This is an opportunity to coordinate governmental efforts and protect the public.

Major Contacts Made During This Review

CARF International
Brandeis University PDMP Center of Excellence
Colorado Department of Human Services
Denver Health Medical Center
The Joint Commission
Maine Office of Substance Abuse
United States Substance Abuse and Mental Health Administration
West Slope Casa

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not 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:
Colorado Department of Regulatory Agencies
Office of Policy, Research and Regulatory Reform
1560 Broadway, Suite 1550, Denver, CO 80202
www.dora.colorado.gov/opr

Table of Contents

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 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 via DORA's website at: www.dora.colorado.gov/opr.

The regulatory functions of the Department of Human Services, Office of Behavioral Health (DHS and OBH, respectively) as enumerated in Part 2 of Article 80 of Title 27, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2014, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of the administration 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 under the Act should be continued for the protection of the public and to evaluate the performance of the DHS. During this review, the DHS must demonstrate that the regulation serves to protect the public health, safety or welfare, and that the regulation is the least restrictive regulation consistent with protecting the public. DORA's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, DORA staff attended licensee meetings and trainings, interviewed U.S. Substance Abuse and Mental Health Administration staff, interviewed DHS staff, reviewed licensee and DHS records including complaint and disciplinary actions, interviewed officials with state and national associations, interviewed addiction treatment providers, observed a facility audit, reviewed Colorado statutes and DHS rules, and reviewed the laws of the federal government.

Profile

The face of drug abuse has changed. No longer should people picture that the image of drug addiction is a skid-row vagabond. According to the Colorado Attorney General:

> Hundreds of Coloradans are dying each year from drug abuse. However, the drugs behind a growing number of these deaths usually are not being purchased on street corners or from drug dealers — the drugs are most commonly found in household medicine cabinets.[2]

Many of those prescriptions are opioid analgesics, used to reduce moderate to severe chronic pain.[3]

There are a number of broad classes of opioids: Natural, Semi-synthetic, and Fully-synthetic.[4]

- 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.
- Fully synthetic opioids include fentanyl, methadone, and tramadol.

[2] Colorado Department of Law, Attorney General John Suthers. Prescription Drug Abuse. Retrieved May 1, 2013, from http://www.coloradoattorneygeneral.gov/initiatives/prescription_drugs_abuse
[3] Web MD. *Pain Management Health Center*. Retrieved May 9, 2013, from http://www.webmd.com/pain-management/opioid-analgesics-for-chronic-pain
[4] Medical News. *Opioid Types*. Retrieved April 18, 2013, from http://www.news-medical.net/health/Opioid-Types.aspx

These lists are partial but consist mostly of medications found in medicine cabinets in many homes. The death rate in Colorado due to opioid poisoning, excluding heroin, is higher than that of cocaine, antidepressants, stimulants, and heroin itself.[5] Deaths involving the use of opioid analgesics nearly quadrupled from 2000 to 2011. In 2011, nearly twice as many people died in Colorado from opioid poisoning than in drunk-driving-related incidents.[6]

Programs that treat alcohol and drug addictions reduce the physical, social, and emotional dangers associated with addiction.

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:[7]

- *Outpatient detoxification*: person usually travels to a treatment facility daily. Outpatient detoxification programs may include provision of medically monitored medications used in the detoxification process.
- *Social detoxification*: provided in an organized, residential, non-medical setting delivered by an appropriately trained staff that provides safe, 24-hour medication monitoring, observation, and support in a supervised environment. Social detoxification is appropriate for individuals who are able to participate in the daily residential activities. Typically it is used as a less restrictive, nonmedical alternative to inpatient detoxification.
- *Inpatient detoxification*: 24-hour medical care and supervision provided by a professional staff in case treatment is needed for serious complications. The setting prevents access to alcohol and/or other drugs and offers separation from the substance-using environment. Inpatient detoxification is often provided to individuals with co-occurring health conditions.

For some individuals medication-assisted treatment is an option. The medications used in treatment include methadone and buprenorphine, which are approved by the Food and Drug Administration (FDA) for use in the treatment of opioid dependence. The aim of medication–assisted addiction treatment 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.[8]

Endogenous opioid peptides such as endorphins, enkephalins, dynorphins, and endomorphins are produced naturally in the body. That they occur naturally is important in understanding pharmacologically treated addiction.

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[5] Kristen Dixon, *Trends in Drug Abuse: What's Happening in Denver & Colorado*. State of Colorado, Office of Behavioral Health February 1, 2013, p.7.
[6] Peer Assistance Services. *Prescription Drug Abuse Prevention Program*. Retrieved May 1, 2013, from http://www.peerassistanceservices.org/prescription/drugabuse.php
[7] CARF International. *2013 Behavioral Health Program Descriptions.* Retrieved April 18, 2013, from http://www.carf.org/programdescriptions/bh/
[8] CARF International. *Opioid Treatment Program*. Retrieved April 18, 2013, from http://www.carf.org/Programs/OTP/

Briefly, the science behind this mode of 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 endogenous peptides such as endorphins on its own. Because the brain and body require the release of the peptides and the damaged brain can no longer produce them, opioid addiction 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 peptides becomes a permanent condition that an addict must live with 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 addict consumes the replacement medication, for example 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 therapy in conjunction with the medication.

Because treating addictions involves using controlled substances, the facilities are highly regulated. The federal Substance Abuse and Mental Health Services Administration (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 Colorado Licensing of Controlled Substances Act, also acts as the SOTA.

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, as part of 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 inserted into the statutes that govern the DHS and behavioral health. The reasoning behind the move was that it had been misplaced in the Colorado Revised Statutes for some time because the Act is implemented by the DHS and not the Pharmacy Board.

Current Regulation

The Act creates a state program that exists under the umbrella of federal regulation. Its purpose is to license addiction programs that compound, administer, or dispense controlled substances.[9] A license provides an exemption to the Uniform Controlled Substances Act of 1992, which regulates the use of controlled substances in Colorado, as long as the licensee acts within the scope of the license.[10]

[9] § 27-80-204(1)(a), C.R.S.
[10] § 27-80-209(1)(a), C.R.S.

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 the accreditation and licensing of opioid treatment programs. The ultimate purpose is to certify that practitioners are qualified to dispense opioid drugs in the treatment of opioid addiction. Eligibility for certification depends on an individual practitioner first obtaining an accreditation from a SAMHSA-approved accreditation body.[11]

Only a state governmental entity, a state political subdivision, or a private nonprofit organization may become an accreditation body.[12] Among other things, the application submitted to SAMSHA 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;[13]
- Description of the applicant's decision-making process;[14]
- Policies and procedures to avoid conflicts of interest by individuals associated with the accreditation body;[15]
- Experience and training requirements for the accreditation body's staff including a description of training policies;[16]
- Fee schedules with supporting data;[17]
- Assurances that the accreditation body will implement its responsibilities and a protocol for investigating complaints;[18]
- Policies and procedures to protect confidential information;[19] and
- Any other information SAMHSA may require.[20]

An accreditation body's term of approval cannot last more than five years.[21] An accreditation body must apply for renewal if it chooses to serve beyond its current term.[22]

[11] 42 C.F.R. § 8.1
[12] 42 C.F.R. § 8.3(a)
[13] 42 C.F.R. § 8.3(b)(3)
[14] 42 C.F.R. § 8.3(b)(4)
[15] 42 C.F.R. § 8.3(b)(5)
[16] 42 C.F.R. §§ 8.3(b)(6) and (b)(7)
[17] 42 C.F.R. § 8.3(b)(8)
[18] 42 C.F.R. § 8.3(b)(9)
[19] 42 C.F.R. § 8.3(b)(10)
[20] 42 C.F.R. § 8.3(b)(11)
[21] 42 C.F.R. § 8.3(g)
[22] 42 C.F.R. § 8.3(c)

Once approved, an accreditation body is accountable for implementation of SAMHSA rules concerning inspections, complaints, records and reporting, conflicts of interest, and accreditation practices.[23] SAMHSA will periodically evaluate an accreditation body.[24] If it deems that any accreditation body is out of compliance it may order corrective action or withdraw approval.[25]

SAMHSA has also promulgated rules that regulate program treatment and certification standards which lay out guidelines and standards for the treatment of individuals in opioid treatment facilities.[26] It likewise directs how the review of program certification suspension and adverse actions regarding withdrawal of approval of an accreditation body should proceed.[27]

There are two SAMHSA-approved organizations that provide accreditation for facilities in Colorado: CARF International and the Joint Commission.

Colorado Licensing of Controlled Substances Act

Once a facility is accredited by a SAMHSA-approved body, it is able to obtain a license to operate a treatment facility that uses controlled substances by the State of Colorado under the Act. The major thrust of the Act is to regulate treatment facilities in a manner that prevents diversion of controlled substances.

The Act allows licensees to possess, distribute, dispense, administer, or conduct research with controlled substances, subject to any limitations on their license and only pursuant to an order form, i.e., prescription.[28] 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,[29] who is qualified, to operate a treatment facility.

If a person has a valid federal government registration as a researcher, he or she is presumed to be qualified.[30] 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.[31] A person 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.[32]

[23] 42 C.F.R. § 8.4
[24] 42 C.F.R. § 8.5
[25] 42 C.F.R. § 8.6
[26] 42 C.F.R. Part 8, Subpart B.
[27] 42 C.F.R. Part 8 Subpart C.
[28] §§ 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.
[29] § 27-80-203(18), C.R.S.
[30] §§ 27-80-207(2) and (4), C.R.S.
[31] § 27-80-207(1), C.R.S.
[32] § 27-80-207(3), C.R.S.

The Colorado Department of Human Services (DHS) issues a license to every researcher and addiction program that meets the requirements of the Act unless it would be inconsistent with the public interest. In determining the public interest, the DHS must consider:[33]

- 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.[34]

The DHS may deny, suspend, or revoke a license upon a finding of the following violations:[35]

- 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 a 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 the DHS suspends or revokes a license, it may secure all of the licensee's controlled substances. The DHS cannot dispose of the substances until the time for making an appeal has lapsed 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.[36] The DHS has the option of limiting a revocation or suspension to the specific controlled substance that was the basis for the disciplinary action.[37]

The Act directs the DHS to "promptly" notify the U.S. Drug Enforcement Administration (DEA) and any applicable professional licensing agency, of all charges and forfeitures as well as the final disposition of the charges.[38]

[33] § 27-80-205(1), C.R.S.
[34] § 27-80-205(2), C.R.S.
[35] § 27-80-208(1), C.R.S.
[36] § 27-80-208(3), C.R.S.
[37] § 27-80-208(2), C.R.S.
[38] § 27-80-205(4), C.R.S.

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.[39] For its part the DHS must:[40]

- 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;
- Gather records of dependent and other controlled substance law offenders within the state, and make the information available for enforcement or regulatory purposes;
- 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.[41]

A licensee must maintain separate, detailed, accurate records and inventories and retain them for two years after each transaction.[42] The records must include the date distributed, the name and address of the person to whom it was distributed, and the kind and quantity of the controlled substance.[43]

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.[44]

Records made pursuant to the Act are to be kept confidential. 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 record can divulge what is known except in connection with a prosecution or proceeding in a court or before a licensing board.[45]

[39] § 27-80-211(1), C.R.S.
[40] § 27-80-211(2), C.R.S.
[41] § 27-80-210(3), C.R.S.
[42] § 27-80-210(1), C.R.S.
[43] § 27-80-210(2), C.R.S.
[44] § 27-80-210(4), C.R.S.
[45] § 27-80-212, C.R.S.

The record keeping provisions only apply if a licensee dispenses a Schedule III, IV, or V controlled substance to patients in a method other than by direct administration and charges the patient for other professional services; or the licensee regularly engages in dispensing a Schedule III, IV, or V controlled substance to his or her patients.[46]

The DHS 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.[47] The rules are available on its website.

[46] § 27-80-209(4), C.R.S.
[47] § 27-80-213, C.R.S.

Program Description and Administration

The Colorado Department of Human Services (DHS), Office of Behavioral Health (OBH) licenses addiction treatment programs under the Colorado Licensing of Controlled Substances Act (Act).

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, fiscal years 07-08 through 11-12. It also segregates the expenditure of dollars and FTE funded through the cash fund.

Table 1
Program Expenditures
Fiscal Years 07-08 through 11-12

Fiscal Year	Total Expenditures	Total FTE	Cash Fund Expenditures	Cash Fund FTE
07-08	$45,478	0.65	$3,340	0.06
08-09	$49,826	0.65	$3,961	0.06
09-10	$48,880	0.65	$4,504	0.06
10-11	$40,626	0.65	$2,753	0.06
11-12	$41,375	0.58*	$2,852	0.06

*The Controlled Substance Administrator position was vacant for a portion of fiscal year 11-12.

Table 1 indicates that approximately eight percent of the cash expenditures and 10 percent of the human resources were funded through the license fee cash fund during the period under review. The human resources committed to the program include 0.4 FTE of a General Professional V and 0.25 FTE of a Program Assistant. Table 1 also indicates a drop in expenditures of approximately 18 percent between fiscal years 09-10 and 10-11. OBH did not have an explanation as to why that was the case.

The Controlled Substances Administrator (Administrator), the General Professional V, is the principal of the program. The role is simultaneously regulatory and scientific. The actions and interactions made by the Administrator illustrate that while the specific statutes under sunset review concern the licensing of facilities, the program is charged with far more because of federal guidelines. Recall that the Colorado 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. However, the Administrator also works with the treatment programs advising and authorizing treatment doses, levels of treatment, patient complaints, patient transfers, and at times acts as an intermediary among facilities on specific cases when they have a common

interest or patient. All of these tasks are either explicit or implicit in the SAMSHA statutes and delegated to state programs.

This version of federalism has the Administrator, who is referred to as the State Opioid Treatment Authority (SOTA) in federal parlance, establish best practices for the state based on local experiences and issues. The Administrator/SOTA is entrusted to analyze data to determine types of addiction issues, drug traffic patterns, and gather input from patients and providers to develop solutions to those recognized problems.

Licensing

A license is required for each location where controlled substances are used to treat addiction or the withdrawal symptoms of addiction.[48]

To obtain the licenses necessary to operate an addiction treatment program, an applicant must submit a completed application, copies of necessary documentation, and license fees.

The license for a treatment program must also include a separate license as an entity authorized to dispense controlled substances. The license for the treatment program is issued for three years and carries a $200 fee.[49] The controlled substance license is renewed annually and is $75 for addiction programs and $25 for researchers.[50]

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 addiction and withdrawal.[51] In a general sense, the policies and procedures address the treatment being offered and the facility housing the program. Among those specific policies and procedures are:

- A description of the treatment philosophy, client populations, geographic service areas, services provided, and methods to retain clients in treatment;
- Knowledge of, and experience in both treatment and agency management;
- Documentation that counselors are qualified;
- Documentation that all staff members have undergone Colorado Bureau of Investigation and DHS name checks;
- Documentation that proposed treatment services address a community need;
- Copies of current property and professional liability insurance declaration pages;
- Copies of up-to-date fire inspection and health inspection reports when applicable; and
- Written evidence of compliance with local zoning ordinances.

[48] DHS Rule 22.320 B.
[49] Office of Behavioral Health (OBH) Combined Treatment License Application. p.6.
[50] § 27-80-205(3)(a), C.R.S.
[51] DHS Rule 22.330.

Most of the listed items are also required by SAMHSA.

Table 2 indicates that during the period under review, there were 21 active licensed facilities and no initial licenses issued.

Table 2
Active Licenses
Fiscal Years 07-08 through 11-12

Fiscal Year	Initial License	Renewal	TOTAL
07-08	0	21	21
08-09	0	21	21
09-10	0	21	21
10-11	0	21	21
11-12	0	21	21

Not all of the DHS-licensed treatment facilities employ modes of addiction treatment which require a controlled substance license. Some facilities handle detoxification patients short-term and some treat non-opiate addictions using non-controlled substance therapies. For example, when treating alcoholism pharmacologically, the medications employed in the treatment are typically not controlled substances. In those cases, a facility is required to be a DHS-licensed treatment facility but need not obtain the separate controlled substance license. However, if an individual who is treated for alcohol abuse needs a controlled substance short-term to better handle detoxification, the facility would need both a controlled substance license as well as a treatment license.

Inspections

At minimum, OBH conducts one inspection 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 U.S. Drug Enforcement Administration 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 get involved, and possibly other outside policing agency(s) as well.

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.

Complaints/Disciplinary Actions

The program 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.

OBH reports approximately two complaints filed per year. Based on what is anecdotally believed to be a high number of complaints fielded by staff on a day-to-day basis, the numbers reported appear to be very low. With all regulatory programs, triage is a large part of how complaints are handled. When complaints come into a program's administration it must be determined if there is jurisdiction over the issue and if a violation of the Act or associated rules has occurred. Still, the number reported appears low to both staff and analysts.

Like the complaint data, there is no simple, accurate, objective process for recording final agency actions. File examinations indicate that during the period under review, there was one license suspended and one license denied. Both actions concerned the same case in fiscal year 07-08 and the actions were eventually overturned on appeal.

Analysis and Recommendations

Recommendation 1 – Continue the Colorado Licensing of Controlled Substances Act for 11 years, until 2025.

The first sunset criterion asks whether regulation is necessary to protect the public health, safety, or welfare. Controlled substances are highly regulated, i.e., controlled, because while they can be therapeutic, they can also pose health and safety risks to the public.

Among those risks is the possibility of addiction. According to the Colorado Attorney General:

> Hundreds of Coloradans are dying each year from drug abuse. However, the drugs behind a growing number of these deaths usually are not being purchased on street corners or from drug dealers — the drugs are most commonly found in household medicine cabinets.[52]

Many of those prescriptions are controlled opioid analgesics which are used to reduce moderate to severe chronic pain.[53]

Records noting where, when, and to whom controlled substances have been prescribed, serve the public interest by limiting diversion. Drug diversion is the consumption of licit drugs, for illicit purposes. It involves taking drugs from legal and medically necessary purposes and using them for purposes that are illegal, not medically authorized, and/or necessary.[54]

Both state and federal governments have a degree of regulatory oversight of controlled substances.

The Colorado Licensing of Controlled Substances Act (Act) functions under the auspices of the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA sanctions state programs that license opioid addiction programs to treat addiction using controlled substances. The belief is that local regulators are better able to operate and adapt the programs, based on local distinctiveness and demands, than the federal government.

[52] Colorado Department of Law, Attorney General John Suthers. Prescription Drug Abuse. Retrieved October 1, 2013, from http://www.coloradoattorneygeneral.gov/initiatives/prescription_drugs_abuse
[53] Web MD. *Pain Management Health Center*. Retrieved October 1, 2013, from http://www.webmd.com/pain-management/opioid-analgesics-for-chronic-pain
[54] Drug War Facts.org. Diversion of Pharmaceutical Drugs. Retrieved July 1, 2013, from http://www.drugwarfacts.org/cms/Diversion#sthash.hdGX1ldR.dpbs

The state authority, housed in the Colorado Department of Human Services (DHS), Office of Behavioral Health (OBH), licenses and inspects the treatment facilities. Having a local authority that licenses and inspects the protocols, policies, and procedures of a facility to ensure all necessary precautions are in place benefits the public. In addition to an annual inspection, OBH has the authority to inspect a facility at any time. Therefore, it is possible that an inspector may visit a facility multiple times in a year.

If there were no local authority, treatment facility inspections would occur, and facility treatment records would be examined less often and quite sporadically. The agency that accredits a facility[55] inspects once every three years, when the facility is up for reaccreditation, SAMSHA rarely inspects, and the U.S. Drug Enforcement Administration typically goes to a facility only if a problem is reported to them. The lion's share of regulatory oversight is performed by OBH.

In conjunction with this sunset review, Department of Regulatory Agencies (DORA) staff accompanied the program administrator (Administrator) while conducting a treatment facility inspection. The inspection generally involved examining processes and procedures that prevent drug diversion. The Administrator spent time observing the dispensing and storage protocols and reviewed all the associated policies. The Administrator also spent extensive time examining the facility, interviewing patients and staff, reviewing facility records, and scrutinizing facility security.

To a large degree, the Administrator is also involved in patient treatment and assessment by approving treatment changes and deviations. More than one treatment facility director commented that it was extremely helpful having an Administrator with specific experience in this mode of treatment. The complexities of both the system and the treatment demand that an Administrator's bailiwick includes experience with both.

In addition to the facility inspections, the current Administrator performs educational roundtables around the state regarding addiction and treatment options. She also holds periodic conference calls with licensed facility directors. The facility directors interviewed for this sunset review expressed appreciation for this particular OBH staff outreach. They believed it was extremely helpful in determining what the current issues are, the Administrator's interpretation of laws and trends, and to network with other industry principals.

Beyond recordkeeping and diversion motives to reauthorize the Act, there are therapeutic reasons. Opioid replacement therapy may be controversial, but it is effective in treating addiction. The substances individuals become addicted to include morphine, codeine, hydrocodone, oxycodone, in addition to heroin. These substances can be found in many medicine cabinets in Colorado and therefore addiction appears in many walks of life.

[55] In Colorado either CARF International or the Joint Commission accredits treatment facilities.

Research has demonstrated that pharmacological treatment such as methadone is an effective treatment for prescription drug and heroin addiction. That efficacy can be measured by several conditions or means, including:[56]

- Reduction in the use of illicit drugs;
- Reduction in criminal activity;
- Reduction in human immunodeficiency virus infection rates and transmission;
- Reduction in commercial sex work;
- Reduction in the number of reports of multiple sex partners;
- Reduction in suicide;
- Reduction in lethal overdose;
- Improvements in social health and productivity;
- Improvements in health conditions;
- Retention in addiction treatment; and
- Cost-effectiveness.

Treating addiction pharmacologically is analogous to employing a controlled burn to fight fires. It works well and is a community asset under the right circumstances but can also be dangerous under some conditions. To protect the public from undue exposure to dangerous conditions such as drug diversion, it is necessary to regulate both treatment facilities and the treatments they provide. If the Act were to sunset and state regulation stopped, it is reasonable to conclude direct oversight of treatment and safety protocols would disappear and the institutional protections against drug diversion would slacken greatly.

Therefore, to protect the public interest, the General Assembly should continue the Act for 11 years, until 2025.

Recommendation 2 – Grant the DHS wider disciplinary discretion in implementing the Act.

Currently the DHS may deny, suspend, or revoke a license if the licensee:

- Submits false or fraudulent information in an application;
- Has been convicted or plead *nolo contendere* to a felony under any state or federal controlled substance law;
- Has had its federal controlled substances registration revoked; or
- Has violated the Act or State Board of Human Services Rules.

[56] National Institute on Drug Abuse. *Question 1: Is methadone maintenance treatment effective for opioid addiction?* Retrieved June 21, 2013, from http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b/question-1-methad

Typically, a program that licenses a business or occupation has the ability to act on violations with lesser degrees of discipline than license suspension or revocation. Both of those actions are, and should be, reserved for the most egregious violations.

For example, if an electrician uses false or misleading advertising it is a violation of his or her practice act and he or she can be fined. If a pharmacist violates his or her practice act, the State Board of Pharmacy (Pharmacy Board) has the option of issuing a letter of admonition rather than suspending the license.

Suspending the license and taking away the person's livelihood is always a major responsibility. However, if the licensee operates a drug addiction clinic the ramifications reverberate throughout the patient population and subsequently through the general public.

There are degrees of violations and most licensing statutes allow regulators a degree of discretion when issuing discipline. A major requirement of the Act is recordkeeping. Good records are vital in accomplishing the intent of Act. If a facility has scores of patients and the files of all but a few are in good order, the few that are not in good order constitute violations of the Act. Or, if a facility operates with a license that lapsed the day before, it too is technically in violation of the Act. In both of these hypotheticals the only alternatives currently available to the DHS are to suspend or revoke the facility's license to operate, or do nothing. It has no power to issue a letter of concern or admonition for the few files that were inadequate, or issue a fine or assess a late fee for a late license renewal.

Keeping adequate records and keeping a license up-to-date are important provisions in protecting the public or the General Assembly would not require that they occur. However, dependent on the degree of violation, the public interest may be far better served if an otherwise acceptable treatment facility is treating addicts, rather than the addicts being turned away to fend for themselves. It is not a stretch to state that in some cases it is a matter of life and death. Still, if a licensee violates the Act there should be action of some kind taken. There are few enough cases that come up for disciplinary review that having the Administrator weigh the circumstances surrounding an incident is appropriate prior to leveling discipline.

The actions on violations that are typically available to regulatory programs are:

- Dismissal;
- Dismissal with the issuance of a confidential letter of concern;
- Fine, up to $500;
- Letter of admonition;
- Probation;
- Stipulation; and
- Suspension or revocation.

These should be made available to the DHS in the Act. All actions would be subject to the State Administrative Procedure Act.

Therefore, to protect the public interest, the General Assembly should grant the DHS wider disciplinary discretion in implementing the Act.

Recommendation 3 – Expand prescription drug monitoring program access to the staff at facilities that treat addiction with controlled substances.

A prescription drug monitoring program (PDMP) is an electronic database that collects data concerning controlled substances dispensed or prescribed to individuals. As of October 2011, 37 states operated PDMPs and 11 more had enacted legislation to establish a PDMP, but they were not fully operational.[57] Though funded in part by the U.S. Department of Justice, each state implements its PDMP based on state law.

Colorado's PDMP is a function of the State Board of Pharmacy. Only licensed pharmacists, licensed prescribers, and the staff responsible for administering the PDMP for the Pharmacy Board may access the PDMP directly. Law enforcement may request data via a subpoena or court order if the patients are the subject of a bona fide investigation.

The PDMP and the Act have similar purposes. The General Assembly created the PDMP to give prescribers a way to monitor an individual patient's use of controlled substances with the goal of mitigating the abuse of prescription drugs. The Act states, "…that strict control of controlled substances within this state is necessary for the immediate and future preservation of the public peace, health, and safety…"[58]

It is clear that the goals of the two programs are similar, protecting the public from harm due to abuse of controlled substances through recordkeeping and oversight. It makes sense that the programs work together.

The nature of addiction is such that even those addicts who want to recover sometimes continue to use and lie about it while in recovery. The medical director of a nationally prominent addiction treatment facility put it this way:

> It seems nearly impossible to believe that people with addiction would continue to use drugs and alcohol to the point of death, but that is what people with addiction do: They deny both the consequences and the risks of using. As we continue to learn about addiction, we're understanding more about why addicted people behave the way they do….[59]

[57] U.S. Department of Justice. *State Prescription Monitoring Programs*. Retrieved July 17, 2013, from http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#4
[58] § 27-80-202, C.R.S.
[59] CNN Health; The Chart. *Addiction the Disease that Lies*. Retrieved July 18, 2013, from http://thechart.blogs.cnn.com/2011/07/26/addiction-the-disease-that-lies/

We can erroneously assume addicts can make rational decisions but in fact addicts have brain disease. It is not a matter of free will. This is why some addicts lie and sabotage their own recovery by continuing to use intoxicants.

Given this to be the case, if an individual is in treatment for addiction and gives permission to the staff at the treatment facility, the staff should be able to check a PDMP to see what prescribed controlled substances he or she is using or has recently used. Sharing information and verifying treatment will help the individuals control their addiction, help prevent drug diversion, and also help slow the practice of "doctor shopping." Doctor shopping is when an individual uses multiple doctors to acquire multiple prescriptions.

It is true that all licensed treatment facilities must have a licensed physician who acts as medical director. As a prescriber, the medical director has access to the PDMP. However, the medical director is the only person in the facility who has access to the PDMP. Access cannot currently be delegated to the facility staff by the medical director so there is no way to check on a patient when the medical director is not available or not on site.

It is also true that facilities randomly test patients for the presence of drugs; it is a federal requirement.[60] However, tests take more time and money compared to a quick search of a database. Access to the PDMP will not eliminate the need for tests. Access is a supplemental tool in treating a potentially deadly condition.

The public sometimes criticizes the lack of coordination among governmental entities, that each agency acts separately from others in regulating in its own corner of the world. Lawmakers and regulators have options when seeking more coordination between agencies but often do not use them. This is an opportunity to coordinate efforts and to further protect the public.

According to the Brandeis University PDMP Center of Excellence, there are four states that allow access of PDMP information by substance abuse treatment providers: Illinois, Maine, North Dakota, and South Carolina.

Key contingencies for any expanded PDMP access are that the medical director must be the responsible party for any facility queries and the patient must sign a written approval. If the patient denies consent then he or she does not meet the criteria for treatment.

The major justifications for allowing expanded PDMP access are that informed, coordinated management of the patients will lead to more positive outcomes and better public protection. The precedent has been set in other states and with prescription drug abuse on the rise in Colorado, all available tools should be used in building an effective solution.

[60] 42 C.F.R. § 8.12(6)

To facilitate coordinated treatment of addiction treatment, the General Assembly should expand PDMP access to the staff at facilities that treat addiction with controlled substances.

Recommendation 4 – Direct the OBH to provide secure online access to the central registry.

This Recommendation 4 is very similar to Recommendation 3. They both suggest facilitating access to centralized information, helping achieve the program's mission by preventing drug diversion, and making the treatment system more efficient.

To prevent drug diversion, OBH has instituted a central registry where all patients enrolled in treatment programs are listed. Prior to admitting a prospective patient to treatment, the treatment facility is required to submit information to OBH in "formats acceptable." No patient can be admitted to treatment when the registry shows him or her currently enrolled in another treatment program.[61] The "formats acceptable" are a hard copy of a document that is faxed by the treatment facility to OBH.

This is an antiquated way of doing business and has caused problems. For example, if OBH is closed due to bad weather or holiday, or staff is unavailable there is no way to get rapid access and approval. The only way to know if a patient is enrolled in another program is to call every other program in the state, ask if the individual is enrolled there, or turn the patient away until clearance 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 solution is to develop a secure online system to register individuals and verify eligibility for enrollment. The system should only be accessible to licensed facilities. This is similar to the PDMP database. Placing the central registry online will ensure that regardless of the circumstances, an individual will be enrolled in treatment regardless of any bureaucratic logjam.

An online system will also create administrative efficiencies because agency labor will be minimized. There will no longer be a need to have a person physically collect hard copies, record and file the information, and then access the information when it is requested. OBH can merely direct facilities to input and update the information as necessary.

As a result, the General Assembly should direct OBH to provide secure online access to the central registry.

[61] DHS Rule 15.223.9(E).

Recommendation 5 – Direct the DHS to administratively establish license fees for facilities regulated by the Act.

Section 204(1)(b)(II) of the Act states that the sunset review consider whether licensing should be combined with the licensing of any other drug and alcohol addiction treatment programs by the DHS. This has already been done.

When a person applies for a license to administer controlled substances in the treatment of addiction, the DHS requires that they first obtain a separate treatment facility license. The controlled substance license is more of an endorsement-like addendum on the treatment facility license.

Notwithstanding, DORA did uncover a connected problem that needs to be addressed by the General Assembly. DHS rules state that OBH issues a three-year license to treatment facilities.[62] The fee for the three-year license is $200. The Act sets the fee for an addiction treatment program that uses controlled substances at $75 per year.[63] So the initial license is $275 for the first year. Renewals for the next two years should be $75 for the controlled substance license only. The fourth year renewal for both licenses is $275, and then the sequence continues.

The problem is that OBH charges facilities $275 for initial licensing and $275 every year for license renewal.[64] This may have evolved because that is what the actual costs are to administer the program and it is supposed to be cash-funded. Whatever the justification or whether it was inadvertent, the policy runs counter to direction by the General Assembly.

The solution is to remove the controlled substances licensure fee specified in the Act. Because implementation costs are variable, the DHS needs the flexibility to evaluate and adjust fees so that the revenue generated from the fees approximates the direct and indirect costs of the regulating processes. Recall from page 14 of this sunset review, the cash fund currently does not come close to covering program expenditures. Setting fees administratively is generally the way fees are established for a cash-funded program.

Therefore, the General Assembly should direct the DHS to administratively establish license fees for facilities regulated by the Act.

[62] DHS Rule 15.211.3(A).
[63] § 27-80-205(3)(a), C.R.S.
[64] DHS Rule 22.340(A).

Administrative Recommendation 1 – Implement a formal, accurate, objective recordkeeping and tracking system for complaints and final agency actions

As noted in the Complaints/Disciplinary Actions section of this sunset review, located on pages 17 and 18, the program does not have a formal, accurate, or objective system to track and categorize incoming complaints, records of complaints, and final agency actions. In fact, it does not have a system at all.

Without such a system, the Administrator is unable to report complaint and disciplinary statistics without reviewing each individual file. Accurate records relating to complaints help the General Assembly, the public, and OBH itself determine whether the program is functioning properly and indeed protects the public's health, safety, and welfare. Better tracking and recordkeeping will also facilitate a determination of program efficacy.

To obtain data for this sunset review OBH staff had to examine individual files and subjectively determine into which complaint and discipline categories the few records they actually had, fit. An objective system removes any guess work and it becomes much easier to determine if and when patterns develop. Objective data also helps determine, without emotion, how successful an organization is at achieving goals.

Beyond measuring accountability, a formal system is more cost effective. Technology has streamlined processes making them far more cost effective than consideration and analysis of each individual file.

OBH should implement a formal, accurate, objective recordkeeping and tracking system for complaints and final agency actions to determine the effectiveness of the program and to enhance public protection.