

WE—VIEW—THE—SUCS—6002

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

The Licensing of Addiction Treatment Programs Under the Colorado Licensing of Controlled Substances Act



October 12, 2006

STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
Office of the Executive Director
Tambor Williams
Executive Director

1560 Broadway, Suite 1550
Denver, CO 80202
Phone: (303) 894-7855
Fax: (303) 894-7885
V/TDD: (303) 894-7880



Bill Owens
Governor

October 12, 2006

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 Department of Regulatory Agencies has completed the evaluation of the licensing of addiction treatment programs under 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 2007 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 of addiction treatment programs provided under Part 3 of Article 22 of Title 12, C.R.S. The report also discusses the effectiveness of the staff of the Colorado Department of Human Services 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,

Tambor Williams

Tambor Williams
Executive Director

Table of Contents

Executive Summary	i
Background	1
<i>The Sunset Process</i>	<i>1</i>
<i>Methodology.....</i>	<i>1</i>
<i>Profile of the Program.....</i>	<i>1</i>
<i>History of Regulation.....</i>	<i>2</i>
Legal Framework.....	3
Program Description and Administration	8
<i>Licensing.....</i>	<i>8</i>
<i>Inspections.....</i>	<i>9</i>
<i>Complaints/Disciplinary Actions</i>	<i>11</i>
Analysis and Recommendations	14
<i>Recommendation 1 - Continue the licensing of addiction treatment programs under the Colorado Licensing of Controlled Substances Act for seven years, until 2014.....</i>	<i>14</i>
<i>Recommendation 2 – Direct ADAD to revise its rules pertaining to its controlled substances licensing functions to be effective no later than September 1, 2007, and make them available to controlled substances licensees and the public.....</i>	<i>17</i>
<i>Recommendation 3 – Remove from statute the establishment of any fees and authorize ADAD to set such fees administratively.</i>	<i>18</i>
<i>Administrative Recommendation 1 – Institute a records retention policy and retain all records for at least five years.</i>	<i>18</i>
Appendix A – Sunset Statutory Evaluation Criteria	20

2006 Sunset Review The Licensing of Addiction Treatment Programs Under the Colorado Licensing of Controlled Substances Act

Department of Regulatory Agencies

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Executive Summary

Quick Facts

What is Regulated? Addiction treatment programs that use controlled substances to treat individuals addicted to alcohol or controlled substances.

Who is Regulated? In fiscal year 04-05 there were 17 active licensees.

How is it Regulated? The Colorado Department of Human Services, Alcohol and Drug Abuse Division (ADAD) issues licenses to addiction treatment programs and requires licensees to maintain certain records, such as to whom controlled substances have been administered, the dosage and date of the administration and documentation of inventories of controlled substances, all in an attempt to curtail diversion.

What Does it Cost? In fiscal year 05-06, the license fee was \$225, which included the \$25-fee for licensure as an addiction treatment program authorized to use controlled substances and the \$200-fee for registration as an entity authorized to dispense controlled substances.

What Disciplinary Activity is There? During the five-year period of 2001 through 2005, ADAD's disciplinary proceedings consisted of:

Complaints Filed	7
Revocations	0
Suspensions	1
Surrender of Licenses	1
Provisional Licenses	5
License Denials	1
Dismissed	0
Other	2

Where Do I Get the Full Report? The full sunset review can be found on the internet at:

<http://www.dora.state.co.us/opr/oprpublications.htm>

Key Recommendations

Continue the licensing of addiction treatment programs under the Colorado Licensing of Controlled Substances Act for seven years, until 2014.

By their very nature, controlled substances pose both a health and safety risk to the public. Controlled substances are addictive, mind altering and, when taken in sufficient quantities, deadly. It is evident, therefore, that maintaining records that document to whom controlled substances have been administered and that document inventories, both of which serve to curtail diversion, serves the public interest.

Direct ADAD to revise its rules.

The rules that ADAD has promulgated pursuant to the Colorado Licensing of Controlled Substances Act (Act) contain obsolete language and have not been revised in over 13 years.

Authorize ADAD to establish fees administratively.

The Act establishes the controlled substances license fee for addiction treatment programs at \$25. Although ADAD's controlled substances licensing function is not explicitly cash funded, it is reasonable to conclude that \$25 is so insignificant an amount to fund this function that it costs more that it generates. Therefore, the fee should be removed from statute and ADAD should be authorized to set the fess administratively so as to cover, at a minimum, the cost of inspections.

Major Contacts Made In Researching the 2006 Sunset Review of Controlled Substances Licensing

Alcohol and Drug Abuse Division
Society of Addictions Counselors of Colorado
U.S. Drug Enforcement Administration

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 the public interest. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the rights of businesses to exist and thrive in a highly competitive market, free from unfair, costly or 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.state.co.us/opr

Background

The Sunset Process

The controlled substances licensing functions of the Colorado Department of Human Services, Alcohol and Drug Abuse Division (ADAD), with respect to addiction treatment programs, in accordance with Part 3 of Article 22 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2007, unless continued by the General Assembly. During the year prior to this date, it is the duty of the Department of Regulatory Agencies (DORA) to conduct an analysis and evaluation of ADAD pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the licensing of addiction treatment programs that use controlled substances in treatment should be continued for the protection of the public and to evaluate the performance of ADAD. During this review, ADAD must demonstrate that there is still a need for the licensing function and that current regulation is the least restrictive form of regulation consistent with the public interest. DORA's findings and recommendations are submitted via this report to the legislative committee of reference of the Colorado General Assembly. Statutory criteria used in sunset reviews may be found in Appendix A on page 20.

Methodology

As part of this review, DORA staff interviewed representatives of ADAD, licensees, professional associations and the U.S. Drug Enforcement Administration (DEA), and reviewed ADAD records, including complaint and disciplinary actions, Colorado laws and rules, and the laws of other states.

Profile of the Program

All addiction treatment programs that treat individuals addicted to alcohol or controlled substances and that are 1) required by statute, 2) receive public funds to provide substance abuse treatment or 3) provide substance abuse treatment to patients whose referral sources (i.e., insurance companies) require treatment at a licensed entity, must obtain an addiction treatment license from ADAD. ADAD establishes standards and treatment protocols for such programs that must be followed in such treatment.

If an addiction treatment program uses one or more controlled substances, including methadone or buprenorphine, in its treatment of patients, then that addiction treatment program must also obtain a second license from ADAD. This second license is commonly referred to as the controlled substances license and it is the sole subject of this sunset review.

Addiction treatment programs that use one or more controlled substances in treatment must comply with certain recordkeeping and physical security requirements, as promulgated by ADAD and DEA.

History of Regulation

Colorado first enacted laws regarding controlled substances in 1963, in the form of the State Narcotic Act, which was administered by the State Board of Health. In 1968, Colorado enacted the Colorado Dangerous Drug Act, which was administered by the Board of Pharmacy. Dangerous drugs were defined as non-narcotic substances, such as stimulants, depressants, hallucinogens, and tranquilizers. Two years after the enactment of the Colorado Dangerous Drug Act, it was amended to require licensure of any wholesaler shipping dangerous drugs into Colorado or within Colorado.

In 1981, the Colorado Dangerous Drug Act and the State Narcotic Act were combined into the Colorado Licensing of Controlled Substances Act (Act), which was codified at Part 3 of Title 12 of Article 22, C.R.S. The Act addressed licensure requirements for researchers, analytical laboratories, addiction programs, humane societies that euthanize animals, manufacturers that manufacture or distribute controlled substances, and wholesalers that distribute controlled substances. 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 were also outlined. 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 ADAD. Additional amendments to the Act resulted in the Board of Pharmacy assuming licensing responsibility for drug manufacturers, distributors, and pharmacists.

Following a Department of Regulatory Agencies' recommendation in the 2001 sunset review of ADAD's controlled substances licensing program, the General Assembly, through House Bill 02-1229, repealed the controlled substances licensing requirements for researchers and analytical laboratories.

Legal Framework

Colorado and federal laws and regulations pertaining to the licensing of addiction treatment programs that use controlled substances in treatment overlap to a great extent.

Any person who dispenses any controlled substance must be registered with the U.S. Drug Enforcement Administration (DEA)¹ and be licensed by the Colorado Department of Human Services, Alcohol and Drug Abuse Division (ADAD) if the controlled substances are dispensed to conduct addiction treatment.²

ADAD-issued licenses are valid for one year from the date of issuance,³ and the annual license fee is \$25.⁴ In addition, all ADAD licensees must also register with ADAD under the Uniform Controlled Substances Act of 1992, and pay the annual registration fee of \$200.⁵

A separate license must be obtained for each location maintained by an addiction treatment program.⁶ In issuing such a license, ADAD must consider:⁷

- Maintenance of effective controls against the diversion of controlled substances;
- Compliance with applicable state and local laws;
- Any controlled substances-related conviction of the applicant;
- Any false or fraudulent information in the license application;
- Suspension or revocation of the applicant's DEA registration; and
- Any other factors relevant to and consistent with the public peace, health and safety.

Each application for licensure by ADAD must be accompanied by a copy of the addiction treatment program's policies and procedures for treatment using controlled substances,⁸ as well as any other documentation requested by ADAD.⁹

¹ 21 C.F.R. § 1301.11(a).

² §§ 12-22-304(1)(b) and 18-18-302(1), C.R.S., ADAD Rule 3.1, and 21 C.F.R. § 1301.13.

³ § 12-22-304(1), C.R.S., and ADAD Rules 3.1 and 3.5.

⁴ § 12-22-305(3)(a)(I), C.R.S., and ADAD Rule 3.6.

⁵ ADAD Rule 4.3.

⁶ ADAD Rule 3.4.

⁷ § 12-22-305(1), C.R.S.

⁸ ADAD Rule 3.8.

⁹ ADAD Rule 3.9.

ADAD may deny, suspend or revoke a license upon finding that the applicant or licensee, as the case may be, has:¹⁰

- Furnished fraudulent information in the license application;
- Been convicted of, or has pleaded guilty or *nolo contendere* to any controlled substances-related felony;
- Had its DEA registration suspended or revoked; or
- Violated any provision of Part 3 of Article 22 of Title 12, Colorado Revised Statutes (C.R.S.), or any rules promulgated thereunder by ADAD.

In addition, addiction treatment programs that offer opioid replacement therapy must also obtain a certification from the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA),¹¹ which requires the addiction treatment program to obtain and maintain a valid accreditation from an accreditation body designated by SAMHSA.¹² Such certifications are valid for up to three years.¹³ If the accrediting body revokes the addiction treatment program's accreditation, SAMHSA may conduct an investigation,¹⁴ which can result in SAMHSA suspending or revoking the certification of the addiction treatment program.¹⁵ In such a case, SAMHSA must immediately contact DEA so that the addiction treatment program's DEA registration may be suspended.¹⁶

Schedule II narcotics that are used by an addiction treatment program must be stored in a secure safe, vault or steel cabinet,¹⁷ and access to the controlled substances must be limited to a minimum number of addiction treatment program employees.¹⁸ The DEA regulations concerning the requirements of such a storage device are quite detailed.

Additionally, addiction treatment programs that offer opioid replacement therapy must maintain a diversion control plan to reduce the possibility of diversion of controlled substances.¹⁹

Upon initial registration, and at least every two years thereafter, a DEA-registered addiction treatment program must take a complete inventory of all controlled substances on hand.²⁰

¹⁰ § 12-22-308(1), C.R.S., and ADAD Rule 3.10.

¹¹ 42 C.F.R. § 8.11(a)(1).

¹² 42 C.F.R. § 8.11(a)(2).

¹³ 42 C.F.R. § 8.11(a)(3).

¹⁴ 42 C.F.R. § 8.13(a).

¹⁵ 42 C.F.R. § 8.14.

¹⁶ 42 C.F.R. § 8.14(d).

¹⁷ 21 C.F.R. § 1301.72(a).

¹⁸ 21 C.F.R. § 1301.72(d), and ADAD Rule 5.2.

¹⁹ 42 C.F.R. § 8.12(c)(2) and ADAD Rule 5.1.

²⁰ 21 C.F.R. §§ 1304.11(a) and (c).

Each time a controlled substance is dispensed by an addiction treatment program to a patient, DEA requires a record containing the following information to be created:²¹

- Name of the substance dispensed;
- Strength of the substance dispensed;
- Dosage form;
- Date dispensed;
- Identification of the patient;
- Amount consumed by the patient;
- Amount and dosage form taken home by the patient, if applicable; and
- The dispenser's initials.

While Colorado law requires that such records contain only the name and amount of the controlled substance, the patient's name and address and the date the controlled substance was dispensed,²² adherence to the DEA's more stringent requirements is deemed to be compliance with Colorado's requirements.²³ All such records must be maintained for two years.²⁴

Addiction treatment programs that offer opioid replacement therapy may dispense the controlled substances methadone and buprenorphine during the course of treatment.²⁵ In general, initial doses of methadone for new patients may not exceed 30 milligrams.²⁶

Such programs are also required to provide adequate medical, counseling, vocational, educational and other assessment and treatment services,²⁷ including requiring each patient to undergo a complete physical evaluation before the patient is admitted to the program.²⁸ Such programs must also have specific policies and procedures for addressing the special needs of pregnant patients.²⁹

For patients in long-term opioid addiction treatment, the addiction treatment program must conduct monthly drug tests.³⁰

²¹ 21 C.F.R. § 1304.24(a).

²² § 12-22-318(2), C.R.S.

²³ § 12-22-318(4), C.R.S.

²⁴ § 12-22-318(1)(a), C.R.S.

²⁵ 42 C.F.R. § 8.12(h)(2).

²⁶ 42 C.F.R. § 8.12(h)(3)(ii).

²⁷ 42 C.F.R. § 8.12(f)(1).

²⁸ 42 C.F.R. § 8.12(f)(2).

²⁹ 42 C.F.R. § 8.12(f)(3).

³⁰ ADAD Rule 15.223.6(D)(2).

Opioid addiction treatment programs may provide patients with take-home doses of their medications for each day that the addiction treatment program is closed for business.³¹ Additional take-home doses may be approved by the addiction treatment program, based on the following criteria:³²

- Absence of recent abuse of drugs or alcohol;
- Regularity of clinic attendance;
- Absence of serious behavioral problems at the clinic;
- Absence of known recent criminal activity;
- Stability of the patient's home environment and social relationships;
- Length of time in comprehensive maintenance treatment;
- Assurance that take-home medication can be safely stored within the patient's home; and
- Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

If these criteria are satisfied, take-home doses may be provided, based upon the length of time the patient has participated in the addiction treatment program:³³

- Days 1 through 90 – one take-home dose per week, plus one dose for each day the clinic is closed.
- Days 91 through 180 – two take-home doses per week, plus one dose for each day the clinic is closed.
- Days 181 through 270 – three take-home doses per week, plus one dose for each day the clinic is closed.
- Days 271 through 365 - maximum of six take-home doses per week.
- After one year – maximum of two-week supply of take-home doses per month.
- After two years – maximum of one-month supply of take-home doses per month, but the patient must make monthly visits to the clinic.

³¹ 42 C.F.R. § 8.12(i)(1).

³² 42 C.F.R. § 812(i)(2).

³³ 21 C.F.R. § 8.12(i)(3).

DEA may inspect the premises of any DEA-registered addiction treatment program.³⁴ All controlled substances records are confidential, but may be inspected by federal, state, county and municipal officers whose duty it is to enforce laws relating to controlled substances,³⁵ as well as by ADAD personnel.³⁶ ADAD may establish separate fees to cover the costs of its inspections.³⁷

DEA-registered addiction treatment programs may not employ, as an employee with access to controlled substances, any person who has been convicted of a felony relating to controlled substances, who has surrendered a DEA registration or who had a DEA registration denied or revoked.³⁸ Opioid addiction treatment programs must also ensure that their employees have sufficient education, training and experience to perform their assigned functions.³⁹

Upon the discovery of any theft or significant loss of any controlled substances, a DEA-registered addiction treatment program must notify DEA,⁴⁰ and within three days, ADAD must also be notified.⁴¹

Any person in possession of a controlled substance may request the assistance of the DEA in disposing of the controlled substance.⁴²

By rule, ADAD has adopted all DEA rules regarding inventories, records and reports.⁴³ All records must be retained for two years.⁴⁴

³⁴ 21 C.F.R. § 1301.31.

³⁵ § 12-22-320, C.R.S.

³⁶ ADAD Rule 7.1.

³⁷ § 25-1-1102(1), C.R.S.

³⁸ 21 C.F.R. § 1301.76(a).

³⁹ 42 C.F.R. § 8.12(d).

⁴⁰ 21 C.F.R. § 1301.76(b).

⁴¹ ADAD Rule 6.3.

⁴² 21 C.F.R. § 1307.21(a).

⁴³ ADAD Rule 6.2.

⁴⁴ ADAD Rule 6.1.

Program Description and Administration

The Colorado Department of Human Services, Alcohol and Drug Abuse Division (ADAD) administers the licensing of addiction treatment programs under the Colorado Licensing of Controlled Substances Act (Act).

No full-time equivalent (FTE) employees or funds are specifically allocated to ADAD for the administration of this program. Rather, ADAD has absorbed the costs of administering the program, and has assigned 1.1 FTE toward this end. Of these, 1.0 FTE constitutes the Controlled Substances Administrator (General Professional V), who conducts inspections, investigates complaints, works with the addiction treatment programs licensed to use controlled substances, advising on and authorizing treatment doses, levels of treatment, licensing issues, patient complaints and patient transfers from one addiction treatment program to another. The remaining 0.1 FTE constitutes the Provider Liaison (General Professional III), who processes initial and license renewal applications for addiction treatment programs using controlled substances.

Licensing

An addiction treatment program seeking a license to use controlled substances in its treatment program must submit a completed application form to ADAD, along with payment of the \$225-license fee. Although the form does not so state, the license application form, as well as the fee, actually encompass two applications: 1) an application for licensure as an addiction treatment program authorized to use controlled substances (\$25-fee); and 2) an application for registration as an entity authorized to dispense controlled substances (\$200-fee).

The application form solicits information as to the name of the addiction treatment program and its address and phone number; the name, title and license number of the physician in charge of the program; the types of controlled substances to be used in treatment (i.e., methadone, buprenorphine, librium, valium or ativan); the applicant's current U.S. Drug Enforcement Administration (DEA) registration number; and certifications that the applicant has never been convicted of a controlled substances-related felony or ever had a controlled substances license or registration denied, revoked or suspended.

In addition, the application must be accompanied by a narrative, or copies of the applicant's policies and procedures, describing:

- How patients will be assessed to be appropriate for the use of the indicated controlled substances;
- What controlled substances will be dispensed;
- Protocols for how the controlled substances will be dispensed;
- Where the controlled substances will be stored;
- How the controlled substances will be accounted for; and
- Who will have access to the controlled substances.

Table 1 illustrates the number of controlled substances licensees for fiscal years 00-01 through 04-05.

**Table 1
Licensing Information**

Fiscal Year	Total Active Licenses
00-01	52
01-02	67
02-03	19
03-04	18
04-05	17

Until the beginning of fiscal year 02-03, ADAD licensed not only addiction treatment programs that use controlled substances, but also researchers and analytical laboratories that used controlled substances. The statutory provisions regarding researchers and analytical laboratories were repealed during the 2002 legislative session, following a recommendation contained in the 2001 sunset review of this program. This explains the significant decrease in the number of licensees between fiscal years 01-02 and 02-03.

Ten of the 17 licensees in fiscal year 04-05 offered opioid replacement therapy.

Inspections

ADAD conducts routine, unannounced and targeted inspections, as well as audits, which are more focused than inspections, of controlled substances licensees. ADAD staff attempts to conduct at least one unannounced inspection each year of controlled substances licensees that offer opioid replacement therapy.

Table 2 illustrates the number of inspections and audits ADAD conducted for calendar years 2001 through 2005.

Table 2
Routine Inspection & Audit Information

Calendar Year	Number of Inspections	Number of Audits
2001	Not Available	Not Available
2002	Not Available	Not Available
2003	3	3
2004	6	6
2005	14	14

Figures for 2001 and 2002 are unavailable because, according to a representative of ADAD, records for those years had been destroyed prior to the Department of Regulatory Agencies' (DORA's) request for the information.

During the course of an audit, which typically lasts an entire day, ADAD staff reviews program files and records pertaining to the licensee's medication records, including:

- Daily dispensing logs for a period of at least six months;
- Medication logs for a period of at least six months;
- Number of patients with take-home dosing privileges;
- Pump calibration;
- Daily medication records for the length of stay in treatment;
- Program physician orders to determine assessment of addiction;
- Medical standing orders;
- Medication management and administration; and
- Number of critical incidents that pertain to controlled substances.

In addition, ADAD staff assesses the security of the storage of the controlled substances.

The breadth and scope of an inspection depends entirely on the reason for the inspection. On a license renewal inspection, for example, ADAD staff will conduct a comprehensive review of all of the licensee's records, files, processes, procedures and other relevant items. If, on the other hand, the inspection is driven by a complaint, ADAD staff may limit its review to the relevant files and records of the individuals involved in the issue upon which the complaint is based. Finally, a routine or unannounced inspection may include an audit.

Additionally, since controlled substances licensees also hold separate addiction treatment licenses, ADAD staff frequently conserves resources and conducts inspections for the purposes of both licenses at the same time.

Complaints/Disciplinary Actions

In addition to routinely inspecting addiction treatment programs that are licensed to use controlled substances, ADAD also conducts investigations of such licensees when it receives complaints. Table 3 illustrates the number and nature of complaints ADAD received concerning such licensees between calendar years 2001 and 2005.

**Table 3
Complaint Information**

Nature of Complaints	2001	2002	2003	2004	2005
Practicing w/o a License	1	Not Available	0	0	0
Standard of Practice	Not Available	Not Available	1	1	2
Scope of Practice	1	Not Available	0	0	1
Sexual Misconduct	Not Available	Not Available	0	0	1
Substance Abuse	Not Available	Not Available	0	0	1
TOTAL	2	Not Available	1	1	5

With one exception, figures for 2001 and 2002 are unavailable because, according to a representative of ADAD, records for those years had been destroyed prior to DORA's request for the information.

The exception to this pertains to the complaints in 2001, the substance of which the current Controlled Substances Administrator has personal knowledge. Both complaints in 2001 related to the same individual who failed to renew his controlled substances license, but continued writing prescriptions and claiming to be licensed by ADAD.

Table 4 illustrates, for calendar years 2001 through 2005, the number of disciplinary actions ADAD has taken against controlled substances licenses.

Table 4
Final Agency Actions

Type of Action	2001	2002	2003	2004	2005
Revocation	Not Available	Not Available	0	0	0
Surrender of License	Not Available	Not Available	0	1	0
Suspension	Not Available	Not Available	0	0	1
Provisional License	Not Available	Not Available	0	0	5
License Denied	Not Available	Not Available	1	0	0
Dismiss	Not Available	Not Available	0	0	0
Corrective Action	Not Available	Not Available	0	1	1
TOTAL DISCIPLINARY ACTIONS	Not Available	Not Available	1	2	7

Figures for 2001 and 2002 are unavailable because, according to a representative of ADAD, records for those years had been destroyed prior to DORA's request for the information.

The license that was denied in 2003 was actually a renewal application. The renewal was denied because the licensee failed to report the loss of a significant amount of controlled substances (2,306 mg) and because the licensee failed to correct a number of deficiencies identified by ADAD during previous inspections.

Both actions in 2004 pertained to the same licensee. ADAD placed the licensee on a corrective action plan due to deficiencies in patient dosing, patient files, patient urine testing procedures, documentation requirements, and employee files. Ultimately, DEA suspended the licensee's DEA registration for recordkeeping errors that indicated the licensee was missing 30 bottles of methadone (approximately 30,000 mg). The licensee subsequently surrendered its ADAD license and closed.

All but one of the cases in 2005 pertain to the same company that holds multiple controlled substances licenses. Similarly, all but two of the complaints reported for 2005 in Table 3 (the two pertaining to standard of practice), also pertain to this same company.

The allegations involved in this case included, but were not limited to employees performing services beyond the scope of their training, improper standing orders pertaining to increasing doses without prior physician approval, unacceptable employee-patient ratios, and sexual misconduct. The provisional licenses that ADAD issued to this company are listed here, although they pertained to the underlying treatment licenses, not the controlled substances licenses. However, since the controlled substance license is based upon the treatment license, the fact that the treatment license was provisional, the controlled substances licenses were, in reality if not legally, provisional as well.

Finally, when investigating licensees, ADAD has historically worked closely with DEA, when such cooperation has been appropriate.

Analysis and Recommendations

Recommendation 1 - Continue the licensing of addiction treatment programs under the Colorado Licensing of Controlled Substances Act for seven years, until 2014.

The first sunset criterion asks whether regulation is necessary to protect the public health, safety or welfare. By their very nature, controlled substances pose both a health and safety risk to the public. Controlled substances are addictive, mind altering and, when taken in sufficient quantities, deadly.

In 2001, the White House Office of National Drug Control Policy estimated that there were approximately 980,000 individuals addicted to heroin in the United States, only about 20 percent of whom received methadone or levomethadyl acetate as part of an addiction treatment program.⁴⁵

Based on such statistics regarding only those addicted to heroin and not including other addictive substances, it is clear that there is a large street market for the controlled substances used in addiction treatment. Indeed, according to one estimate, the cost of a single dose of methadone varies from between \$10 and \$40.⁴⁶

It is evident, therefore, that maintaining records that document to whom controlled substances have been administered and that document inventories, both of which serve to curtail diversion, serves the public interest.

As a result, both the state and federal governments have enacted statutes and promulgated rules governing nearly every aspect of controlled substances. Indeed the requirements placed on addiction treatment programs that dispense controlled substances by the U.S. Drug Enforcement Administration (DEA) and the Colorado Department of Human Services, Alcohol and Drug Abuse Division (ADAD) by virtue of the Colorado Licensing of Controlled Substances Act (Act) are virtually identical to one another since ADAD, by rule, has adopted the requirements of DEA.

The real question, then, becomes whether the licensing functions of ADAD under the Act are necessary to protect the public when there is so much federal oversight as well, or whether regulation by ADAD is overly duplicative.

⁴⁵ U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration press release dated January 17, 2001, downloaded on April 14, 2006, from www.samhsa.gov/news/newsreleases/010117nrmeth.htm.

⁴⁶ Presentation by D. Curry, U.S. DEA Office of Diversion Control, April 23, 2006.

Recall that an addiction treatment program that dispenses controlled substances must be:

- Accredited by a U.S. Substance Abuse and Mental Health Services Administration (SAMHSA)-approved accrediting agency;
- Approved by SAMHSA;
- Registered with DEA;
- Registered with ADAD under the Uniform Controlled Substances Act; and
- Licensed by ADAD under the Act.

Each of these agencies inspects controlled substances licensees periodically. The frequency and focus of those inspections, however, is the key to the differences between these various agencies.

SAMHSA-approved accrediting agencies typically inspect controlled substances licensees once every three years. The focus of such inspections typically involves ensuring that the controlled substances licensee has in place appropriate treatment protocols, policies and procedures.

DEA attempts to inspect controlled substances licensees once every two years, though in reality such inspections are typically conducted less frequently. Indeed, based on interviews with representatives of controlled substances licensees and DEA, DEA's focus is to respond to major incidents involving the loss or theft of controlled substances, not compliance inspections.

Regardless, the focus of DEA inspections, when they occur, typically revolves around the security of the controlled substances. DEA verifies that proper inventory and dispensing records are maintained; that the controlled substances are stored in a secure location within the controlled substances licensee's facility and that the facility itself is secure.

ADAD inspects controlled substances licensees at least once a year. ADAD has the authority to inspect a controlled substances licensee at any time and inspections typically occur in conjunction with the inspections that ADAD conducts pursuant to the requirements of the other ADAD-issued licenses held by the controlled substances licensee such as the controlled substance registration and the addiction treatment license.

As a result, ADAD inspectors may visit a controlled substances licensee multiple times in a given year. Some of the records that are reviewed during these inspections may encompass multiple licenses, so the controlled substances licensee may not always be aware that an inspection of the controlled substances license is even taking place.

The focus of an ADAD controlled substances license inspection encompasses those elements of an accrediting agency inspection and a DEA inspection. Additionally, ADAD inspectors typically take the time to observe the actual dispensing of controlled substances, which can reveal deficiencies or other problems.

During the course of this sunset review, a representative of the Department of Regulatory Agencies (DORA) accompanied an ADAD inspector on one such inspection. The ADAD inspector spent a considerable amount of time observing the dispensing of controlled substances, during which several relatively minor problems were identified. Additionally, the ADAD inspector examined the controlled substances licensee's policies and protocols, dispensing and inventory logs, dispensing equipment and processes and the security of the facility and the controlled substances within the facility. The inspection appeared to be relatively comprehensive in nature.

Perhaps more importantly, however, was the comfort level of the staff of the controlled substances licensee. The staff knew and was familiar with the ADAD inspector and throughout the course of the inspection, asked the ADAD inspector questions about various issues. Similarly, the ADAD inspector pointed out problems during the course of the inspection and proposed potential solutions, rather than simply imposing discipline on the controlled substances licensee after the inspection. Fear seemed to play very little role and, as a result, problems were identified and addressed in a solution-oriented manner. There is no assurance that DEA would conduct inspections in a similar manner.

Furthermore, according to representatives of controlled substances licensees and DEA, DEA tends to focus on major losses of controlled substances. This is important because, while the regulations administered by DEA and ADAD may be highly duplicative, it is primarily ADAD, not DEA, that enforces compliance with them.

If ADAD's licensing function were allowed to sunset, it is reasonable to conclude that the enforcement of the laws intended to prevent diversion of controlled substances from addiction treatment programs would become considerably more lax, thereby endangering the public health and safety.

Since drugs like methadone need to be controlled and since ADAD inspects controlled substances licensees more frequently and with more of a solution-oriented attitude than the other agencies that play a role in controlled substances regulation, the licensing of addiction treatment programs by ADAD under the Act should be continued for seven years, until 2014.

Recommendation 2 – Direct ADAD to revise its rules pertaining to its controlled substances licensing functions to be effective no later than September 1, 2007, and make them available to controlled substances licensees and the public.

Section 12-22-321(1), C.R.S., states:

The department of human services *shall* promulgate rules and regulations to implement the provisions of this part 3 pursuant to the procedures of article 4 of title 24, C.R.S. (emphasis added)

While the Department of Human Services, through ADAD, has promulgated rules, these rules have not been updated since 1993 and contain many obsolete provisions.

In its 2001 sunset review of the controlled substances licensing functions of ADAD, DORA recommended that ADAD update its rules. Not only has ADAD not implemented this recommendation, but ADAD also did not amend its rules after the licensing of researchers and analytical laboratories was repealed during the 2002 legislative session.

As a result, ADAD's current rules contain at least 15 obsolete provisions and should be amended.

More problematic, however, is the availability of the rules on ADAD's website -- only the first page of the rules appears. This is problematic for two reasons. First, unless an individual searching for the rules knows better, that individual may conclude that that single page is the extent of the rules. Second, regardless of their age and relative obsolescence, controlled substances licensees are required to comply with the rules. Although controlled substances licensees are provided a copy of the rules at the time of license issuance, if that copy of the rules is lost or destroyed, the rules cannot be easily replaced via the Internet.

This issue first came to DORA's attention on February 3, 2006, and was mentioned to representatives of ADAD who assured representatives of DORA that the problem would be corrected. However, as of October 5, 2006, the problem had not been addressed and only the first page of the rules was available on ADAD's website.

Ordinarily, this type of recommendation would be administrative in nature. However, since a similar recommendation was made once before and not implemented, this recommendation advocates that ADAD promulgate new rules no later than September 1, 2007, in order to place direct pressure on ADAD to comply.

Since many of ADAD's rules are obsolete and have not been revised in over 13 years and since only a portion of ADAD's rules are available on its website, the General Assembly should direct ADAD to promulgate new rules, to be effective no later than September 1, 2007, and to make a complete set of those rules available on its website.

Recommendation 3 – Remove from statute the establishment of any fees and authorize ADAD to set such fees administratively.

Section 12-22-305(3)(a)(l), C.R.S., establishes the controlled substances license fee for addiction treatment programs at \$25. However, section 25-1-1102(1), C.R.S., authorizes ADAD to establish the fees to be charged for required inspections.

As a result, ADAD charges \$225 for a controlled substances license, and this fee also includes the application fee for registration as an entity authorized to dispense controlled substances.

Although ADAD's controlled substances licensing function is not explicitly cash funded, it is reasonable to conclude that \$25 is so insignificant an amount to fund this function that it costs more than it generates.

Therefore, the fee should be removed from statute and ADAD should be authorized to set this fee administratively so as to cover, at a minimum, the cost of inspections.

Since the statute sets the license fee for a controlled substance license at \$25 and since this sum is insignificant in comparison to the actual costs associated with running the program, the General Assembly should remove the fee from statute and authorize ADAD to establish the license fee administratively.

Administrative Recommendation 1 – Institute a records retention policy and retain all records for at least five years.

Throughout this report, data for the years prior to 2003 were generally unavailable because, according to a representative of ADAD, such records were destroyed, in accordance with ADAD's records retention policy, prior to DORA's request for such information.

While this is certainly frustrating from a data reporting and analysis point of view, it could also cause legal problems for ADAD. Without such records, ADAD would be unable to defend itself should any of its actions prior to 2003 be challenged.

Admittedly, the Uniform Records Retention Act, in section 6-17-104, C.R.S., permits state agencies to destroy records after three years. However, as this sunset review discovered, three years may not be long enough in some cases. Those records may have contained valuable information that could have been used by policy- and decision-makers in the future.

Indeed, like controlled substances licensees, pharmacies licensed by the State Board of Pharmacy (Pharmacy Board) also must retain records for only two years.⁴⁷ However, the Pharmacy Board's own internal records retention policy is more expansive. For example, license applications and documentary evidence of any final agency action are considered permanent records that are never destroyed.

Since ADAD has destroyed records after only three years and this situation is unacceptable from a variety of standpoints, ADAD should immediately implement a records retention policy that requires such documents to be retained for at least five years.

⁴⁷ § 12-22-131(1)(a), C.R.S., and Pharmacy Board Rule 11.00.00.

Appendix A – Sunset Statutory Evaluation Criteria

- (I) 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;
- (II) 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;
- (III) 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;
- (IV) Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- (V) 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;
- (VI) The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- (VII) 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;
- (VIII) Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;
- (IX) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.