COLORADO DEPARTMENT OF REGULATORY AGENCIES
OFFICE OF POLICY AND RESEARCH

CONTROLLED SUBSTANCE RECORD-KEEPING BY THE COLORADO DEPARTMENT OF HUMAN SERVICES

2001 SUNSET REVIEW

STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
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Bill Owens
Governor

October 15, 2001

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 controlled substance record-keeping function by the Colorado Department of Human Services. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2001 Legislative Committees of Reference. The report is submitted pursuant to §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 3 of Article 22 of Title 12, 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 statute is continued by the General Assembly.

Sincerely,

M. Michael Cooke

M. Michael Cooke
Executive Director

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Background

The Sunset Process

In accordance with §24-34-104, C.R.S., the Department of Regulatory Agencies (DORA) has reviewed the record-keeping functions of the Department of Human Services (Department) relating to controlled substances in accordance with Part 3 of Article 22 of Title 12, C.R.S. to determine whether these functions should continue in existence. The law currently specifies that the record-keeping functions will terminate on June 30, 2002 and will have one year from that date to conclude its affairs. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of this function administered by the Alcohol and Drug Abuse Division (ADAD) pursuant to §24-34-104(31.5)(a), C.R.S.

Methodology

The purpose of this review is to determine whether the record-keeping function should be continued for the protection of the public, and to evaluate the effectiveness of ADAD in carrying out the intention of the statute. During this review, ADAD must demonstrate that there is a need for the program's continued existence, and that regulation under the program is the least restrictive 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. A complete list of the sunset evaluation criteria can be found in Appendix A of this report.

This is the first review of the record-keeping functions relating to controlled substances. The sunset review process includes a review and analysis of applicable statutes and rules; interviews with ADAD staff; interviews with staff of the U.S. Drug Enforcement Administration (DEA); licensees including researchers, analytical laboratories, and police; and an assistant attorney general. Licensee files were reviewed for complaints and disciplinary actions and policy and procedure statements. To better understand the program, the author of this report accompanied an inspector on a visit to a licensed treatment facility, a licensed researcher, and a methadone clinic. Other states were contacted regarding their licensing requirements for the regulation of controlled substances. A survey was sent in February 2001 to the 188 licensees who were licensed at that time to determine the frequency of record inspections. An overview of federal law is also included within this report.

History of Regulation

Section 12-22-301, et. seq., C.R.S., entitled the Colorado Licensing of Controlled Substances Act (Act) incorporates the provisions creating the record-keeping functions of the Department. Laws regarding controlled substances were originally enacted in 1963 as Article 5 of Chapter 48, the State Narcotic Act. The State Narcotic Act was placed under the jurisdiction of the State Board of Health. In 1968, the state enacted the Colorado Dangerous Drug Act, under the jurisdiction of 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 Dangerous Drug Act, it was amended to require licensure by any wholesaler shipping dangerous drugs into Colorado or within Colorado (§12-22-304, C.R.S.).

In the early 1980's, the Colorado Prescription Drug Abuse Task Force was created to improve communication and cooperation in controlled substances licensing. This task force consisted of various state agencies including the Board of Pharmacy, the DEA, the Colorado Department of Health, ADAD, and other industry representatives.

In 1981, the Dangerous Drug Act and the State Narcotic Act were combined in a state Controlled Substances Act (Part 3 of Title 12, Article 22). Part 3 addresses licensure requirements for researchers, analytical laboratories, addiction programs, humane societies that euthanize animals, manufacturers who manufacture or distribute controlled substances, and wholesalers who 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. Record-keeping requirements for licensees were delineated, along with authorization for inspections, investigations, and reports necessary to determine compliance with the provisions of Part 3.

In 1984, the Controlled Substances Act resulted in ADAD assuming responsibility for controlled substances licensing of addiction programs, researchers, and analytical laboratories. The Act also resulted in the Board of Pharmacy assuming licensing responsibility for drug manufacturers, distributors, and pharmacists.

In 1992, Part 3 was changed to its current title, the Colorado Licensing of Controlled Substances Act. The Official Homeopathic Pharmacopoeia of the United States was added as a reference tool to determine recognized drugs in the United States and the term “wholesaler” was removed from the definition section of the Act and replaced with the term “distributor”. Furthermore, portions of the Act listing controlled substances Schedules I to V were repealed and the repealed sections were added to the Criminal Code (§18-8-203-207, C.R.S.).

Summary of Statute and Regulations

This section of the report provides an overview of the Colorado statute and regulations concerning the Colorado Licensing of Controlled Substances Act (Act). Several provisions of the Act reflect similar or the same wording as that of the federal Controlled Substances Act.

The General Assembly found that the strict control of controlled substances within Colorado is necessary for the public peace, health, and safety. Licensing, record-keeping, penalty and other provisions in Part 3 of Article 22 of Title 12, C.R.S., were deemed necessary to achieve this goal.

The Colorado Licensing of Controlled Substances Act is designed to limit and control access to drugs that are included in Schedules I to V of Part 2 of the Uniform Controlled Substances Act of 1992 of the C.R.S. Controlled substances are statutorily defined as "a drug, substance, or immediate precursor included in Schedules I to V of Part 2 of Article 18 of Title 18, C.R.S., including cocaine, marijuana, and marijuana concentrate. This classification creates a coordinated, codified system of drug control and regulation. The Act follows the federal Controlled Substances Act and lists all of the controlled substances in five schedules that are identical with federal law. The classification is flexible so that, as new substances are discovered or found to have an abuse potential, the Colorado General Assembly can add them to Schedules I to V. This flexibility allows the laws to respond to new trends in drug abuse and new scientific information.

Controlled Substances Standards and Schedules

Part 2 of Article 18 of Title 18, C.R.S., enumerates the five drug schedules that parallel the drugs classified at the federal level. Not only are heroin and cocaine controlled substances, but the mildest of prescription tranquilizers are as well. There are five schedules that are ranked by the potential for abuse and usefulness in medical treatment. Thus, Schedule I contains those drugs that have high potential for abuse and have no currently accepted medical use in treatment in the United States. Familiar substances such as heroin and cocaine fall into Schedule I drugs along with other synthetic opiates including any isomers, esters, ethers, and salts. Schedule II drugs that encompass opium and opium derivations also have a high potential for abuse but are currently used in medical treatment with severe restrictions. Schedule III substances have a potential for abuse less than those categorized in Schedules I and II and are currently used in medical treatment. Schedules IV and V have a low potential for abuse relative to Schedules I-III and are currently used in medical treatment in the United States.

Alcohol and Drug Abuse Division Licensing Responsibilities

The General Assembly declares the importance of strict control of controlled substances to preserve the public's peace, health, and safety and that the licensing and record-keeping are necessary for the achievement of such control. To achieve this goal, ADAD is directed to annually license researchers, analytical laboratories experimenting or testing any controlled substance, and addiction programs that administer or dispense a controlled substance. By licensing individuals dealing with controlled substances, the State will know who is responsible for a substance and who is dealing in these substances. The licensure requirements imposed are designed to eliminate many sources of diversion, both actual and potential.

Board of Pharmacy Licensing Responsibilities

The Board of Pharmacy (Board) issues licenses to manufacturers or distributors who distribute or manufacture a controlled substance in Colorado. In addition, the Board issues licenses to humane societies or animal control agencies which have been in existence for more than five years and euthanize injured, sick, homeless, or unwanted pets and animals.

Disciplinary Provisions

ADAD or the Board is authorized to deny, suspend, or revoke a license for fraudulent information supplied on an application, for conviction of a felony related to a controlled substance, for suspension or revocation of a federal registration, or for violations of the Act or rules or regulations. The Board and ADAD are also authorized to limit the license to a particular substance rather than revoking or suspending the entire license.

Record-keeping Requirements of Licensees

Persons licensed to manufacture, distribute, or dispense controlled substances under the Act are required to keep and maintain records and inventories relating to controlled substances. All records and inventories must be maintained for two years after the date of transaction. These records must include the date, name and address of person receiving and using the controlled substances, and the type and quantity of the controlled substance. Records must be kept of any controlled substance lost, destroyed, or stolen; the type and quantity of such substance; and the date of loss, destruction, or theft.

The records and inventories that licensees are required to maintain are confidential and only available for inspection by federal, state, county, and municipal officers authorized to enforce state and federal laws pertaining to controlled substances.

Enforcement and Cooperation with Governmental Entities

Peace officers and state district attorneys are authorized to enforce the provisions of the Act and to cooperate with all agencies that enforce state and federal laws regarding controlled substances. In addition, the Department is charged with enforcing state and federal laws relating to controlled substances by:

- communicating with other governmental officials concerning the use and abuse of controlled substances;
- maintaining a centralized unit to collect, analyze and report on statistics and provide this information to other local, state, and federal governmental entities;
- responding and acting upon complaints, referrals or information regarding possible violations;
- cooperating with state licensing boards regarding any violations of the Act;
- contracting with and conducting educational and research activities designed to prevent and determine misuse and abuse of controlled substances.

Rules and Regulations

Rules and regulations pertaining to the licensing and registration of researchers, analytical laboratories, and addiction programs using controlled substances (6 CCR 1008-2) were promulgated effective January 30, 1993. There are six pages of rules and regulations for standards relating to the control of controlled substances. These standards are divided into seven sections that include administrative procedures, definitions, licensing requirements, registration requirements, security controls and procedure requirements, maintenance of records and reporting requirements, and inspections.

Regulation in Other States

According to representatives from the DEA, Rocky Mountain Region, all 50 states have provisions for registering or licensing entities that handle controlled substances, however, not all states have enforcement powers. The agency/department responsible for registration or licensing varies among states ranging from the Bureau of Narcotics and Dangerous Drugs in Missouri, to the Board of Pharmacy in Wyoming, to the Board of Medical Examiners in Montana.

Uniform Controlled Substances Act

The Uniform Controlled Substances Act created and approved by the Uniform Law Commissioners in 1970, pertains to the control of narcotic drugs. It was originally adopted by 44 states. The states not adopting the uniform law included Alaska, Indiana, Maine, New Hampshire, Ohio, and Vermont. This act replaced the Uniform Narcotic Drug Act, approved by the Uniform Law Commissioners in 1932. The earlier act was adopted in all the states, and was the fundamental drug law in those adopting states until replaced by the Uniform Controlled Substances Act. In 1990, major revisions were made to the Uniform Controlled Substances Act to mirror the changes in federal law, however the basic structure of the act promulgated in 1970 remained the same. Three states including Colorado, Wisconsin, and Nevada have adopted the 1990 revisions.

This act endeavors to establish uniformity between federal law and state law, as well as uniformity between the states. The Uniform Controlled Substances Act significantly follows the federal Controlled Substances Act. Both the state and federal government have the ability to control narcotic drugs. The federal government enforces the federal law and state government enforces the state law. Proponents of the adoption of the uniform law argue that the advantage of a parallel law is concentration of both federal and state enforcement upon the same drugs, and the ability to cooperate in that enforcement.

The 1990 revisions to the Uniform Controlled Substances Act categorizes all applicable substances in the appropriate schedules developed or discovered since the act was originally approved. The narcotic and dangerous substances that are the subject of this act are organic chemicals. There are an infinite variety of such chemicals that are likely to be depressants, stimulants, analgesics and/or hallucinogens. Therefore, the initial mission of the Uniform Law Commissioners in revising the Uniform Controlled Substances Act was to include those substances that were discovered between 1970 and 1990.

The 1990 revisions further require a designated state agency to conduct a diversion control program that consists of preparing reports on distribution and diversion of controlled substances on a regular basis, engaging in agreements with other agencies to identify sources of diversion, and engaging in cooperative programs to "identify, prevent, and control" diversion. These functions are to be performed in addition to the registration requirements provided in the original act.

A full range of criminal penalties is a major aspect of the original Uniform Controlled Substances Act. The 1990 revisions enhanced the original act by the addition of criminal penalty provisions for "counterfeit" and "imitation" controlled substances, solicitation of any person to engage in a violation of the act, distribution of controlled substances in the vicinity of a school or college, using children in the distribution of controlled substances, and participating in laundering proceeds from traffic in illegal controlled substances.

In 1994, the Uniform Controlled Substances Act was amended to provide for both civil and criminal forfeiture actions. The new criminal forfeiture provision allows prosecutors to fold the forfeiture procedure into the criminal action. This new provision establishes a "preponderance of the evidence" standard of proof, which is the same as the standard for a civil forfeiture. It is not necessary to establish the right to seize forfeitable property "beyond a reasonable doubt."

Civil forfeiture is the subject of an entire new section. Regarding this section, the prosecutor may bring an administrative forfeiture action or begin a judicial proceeding. If the prosecutor chooses the administrative proceeding, the defendant may choose to convert the administrative action to a judicial action. In addition, the most dangerous controlled substances and dangerous materials associated with the manufacture of these dangerous controlled substances are subject to summary forfeiture. The objective of these choices is to give the prosecution maximum flexibility in conducting forfeiture actions, while protecting property owners' rights. Administrative proceedings are a less onerous burden than judicial proceedings.

Federal Laws and Regulation

Federal law that is relevant to the licensing of researchers, analytical laboratories, and addiction programs using controlled substances is the Controlled Substances Act, 21 U.S.C.A., Chapter 13.

Controlled Substances Act

The Controlled Substances Act is administered by the U.S. Department of Justice, Drug Enforcement Administration (DEA), Diversion Control Program. The DEA's Office of Diversion Control (Office) is responsible for two distinct problems: the diversion of controlled pharmaceuticals and the diversion of controlled chemicals. Many of the narcotics, depressants, and stimulants manufactured for legitimate medical uses are subject to abuse and have been brought under legal control. The goal of the Office is to ensure that these "controlled substances" are readily available for medical use, while preventing their distribution for illicit sale and abuse.

The Office consists of diversion investigators, special agents, chemists, pharmacologists, program analysts, and others. The Office's activities include field management oversight, coordination of major investigations, drafting and promulgation of regulations, advice and leadership on state legislation/regulation, legal control of drugs and chemicals not previously under federal control, computerized monitoring, and the tracking of distribution of certain controlled drugs.

Under federal law, all businesses that manufacture or distribute controlled drugs; all health professionals authorized to dispense, administer or prescribe them; and all pharmacies permitted to fill prescriptions must register with the DEA. Registrants must comply with regulatory requirements relating to drug security, records accountability, and adherence to standards.

Registration Requirements

Persons required to annually obtain a registration from the DEA pursuant to the federal Controlled Substances Act, Title 21, Section 822 include:

- manufacturers and distributors of controlled substances or list 1 chemicals;
- practitioners (including pharmacies) who dispense or conduct research with controlled substances;
- practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification.

According to the DEA, Rocky Mountain Region, there are 116 researchers, 39 analytical laboratories, and 13 addiction programs registered in Colorado.

Title 21, Section 823 outlines the requirements to obtain a DEA registration number and the factors that are reviewed to determine whether such registration is consistent with the public interest. Factors considered by the DEA include:

- maintenance of effective controls against diversion.
- compliance with applicable state and local law.
- promotion of technical advances in the art of manufacturing substances;

- prior conviction record (both state and federal) relating to the manufacture, distribution, or dispensing of such substances;
- past experience in the manufacture, distribution, conducting research, and/or dispensing of controlled substances;
- other factors that may be relevant to and consistent with the public health and safety.

The application requires the identification of drug schedules being dispensed; the type of activity, whether it is detoxification and/or maintenance; the state licensing number, information relating to conviction of drug offenses; and status of federal and state licenses.

The DEA relies on ADAD's assistance in controlled substances licensing given it's community understanding of local agency businesses, programming, and operations. The DEA office is a regional office and struggles with staffing resources to maintain databases; conduct licensing visits; process applications; and investigate complaints and critical incidents including overdoses, deaths, and diversion and theft of controlled substances.

Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA)

With the transfer of authority from the U.S. Food and Drug Administration (FDA) to SAMHSA in 2001, opioid clinics must be accredited in a manner similar to other health facilities. Clinics have two years to comply with the new rules and regulations. The FDA had inspected opioid clinics, but those inspections were widely criticized as inadequate.

Previously, opioid clinics were required to submit an application to the FDA which including program physician and other staffing information, number of daily intakes, and name of hospital for emergency treatment.

The new process implemented by SAMHSA entails a contractual agreement by the clinics with private organizations to inspect clinics and report those that meet government quality standards. The new regulations require that clinics that distribute methadone and other addiction-treating medication tailor therapy to addicts' differing needs, provide more physician supervision, and take other steps to improve quality.

Program Description and Administration

The Alcohol and Drug Abuse Division (ADAD) of the Department of Human Services administers the controlled substances licensing of addiction programs, researchers, and analytical laboratories.

Initial and annual license fees for addiction programs and researchers are currently $225. Revenue collected from licensing fees in fiscal year 2000 was $8,325, which was deposited into the General Fund. The cost of the program is absorbed by the Department.

This program has no FTE allocated for inspections or investigations. Rather, these activities are absorbed by existing staff of ADAD.

ADAD is responsible for formulating a comprehensive state plan for alcohol and drug abuse programs that includes:

- a survey of the need for the prevention and treatment of alcohol and drug abuse including a survey of health facilities needed to provide services;
- a plan for the development and distribution of facilities and programs throughout the state;
- a plan for programs to educate the public of the problems of alcohol and drug abuse;
- a survey of the need for trained teachers, health professionals, and others involved in the prevention and treatment of alcohol and drug abuse and a plan to provide necessary training;
- annual review and updating of the state plan.

Licenses

Section 305 of Title 12, Article 22 provides that upon application for a license by a researcher, analytical laboratory, or addiction program that experiments with, studies, tests, administers or dispenses a controlled substance and payment of a $225 fee, a license is issued. The applicant is required to submit a written description of policies and procedures for activities that involve developing, implementing, and maintaining security provisions to include:

- Detailed documentation of what controlled substances will be used;
- Protocols for use and/or administration of controlled substances;
- Who and/or what will be the subjects of the research using controlled substances;
- Controlled substances that the licensee intends to use and/or keep in inventory;
- Anticipated amounts of controlled substances kept in inventory;
- How and where controlled substances will be secured;
- Who has access to controlled substances;
- How licensees will account for amounts of controlled substances in inventory.

ADAD is authorized to determine whether the issuance of a license is consistent with the public interest. To determine whether the public interest is being served, ADAD considers the following factors:

- Maintenance of effective controls against diversion of controlled substances;
- Compliance with applicable state and local laws;
- Conviction under state or federal law for a crime relating to controlled substances;
- Falsification of an application;
- Suspension or revocation of federal registration.

There are currently 198 researchers, analytical laboratories, and addiction treatment centers that are licensed by ADAD to handle and use controlled substances.

Table 1

Entities Licensed by ADAD

Type of Facility	Total
Researchers	136
Addiction Treatment Centers	22
Analytical Laboratories	40
Total	198

Complaints/Disciplinary Actions

Complaints

One of the responsibilities of ADAD is the handling of complaints against researchers, analytical laboratories, and addiction program licensees. ADAD reports that addiction treatment providers and clients initiate the bulk of complaints. The complaints are usually the result of a consumer's perception that they received incorrect medication or dosing, addiction treatment provider's allegations of inappropriate use of controlled substances, reports of alleged theft or diversion of controlled substances, or reports of fraud in obtaining controlled substances.

Inspections

The successful implementation of a program often relies on periodic inspections of facilities to determine that they are in compliance with applicable laws and regulations. Since 1984 when ADAD assumed responsibility for controlled substances licensing of addiction programs, researchers, and analytical laboratories, it has not consistently conducted site visits of all controlled substance licensees and their facilities. Many of the controlled substance licensees have been licensed for such a long period of time that a decision was made not to conduct inspections upon renewal. Addiction programs are generally inspected every one to three years; although the researchers and analytical laboratories seldom receive an inspection. The inspection of addiction programs includes an interview with the director to discuss and review certain areas including the

licensing application, dispensing hours, number of clients, medications, dispensing, accountability (records, inventories, loss and waste), and security.

In addition, ADAD performs interviews with the dispensing staff to verify credentials and to assess general knowledge of addiction and methadone. The counseling staff is interviewed to determine their qualifications, credentials, and HIV, First Aid, and CPR training.

Disciplinary Actions

ADAD has a variety of enforcement mechanisms available to it that are created by statute. ADAD may take disciplinary action by denying, suspending, revoking, or limiting the authority of any licensee to prescribe, distribute, dispense, or administer controlled substances. If a license is suspended or revoked, ADAD may secure any controlled substance owned or possessed by the licensee. When a revocation order becomes final, the court may order the controlled substances forfeited to the state.

ADAD may suspend, without an order to show cause, any licensee upon finding that there is an imminent danger to the public health or safety. This suspension continues in effect until the conclusion of the proceedings, including judicial review, or until the case is dissolved by a court of competent jurisdiction.

There have been six instances since ADAD assumed statutory responsibility in which controlled substances licenses were revoked or not renewed as a result of illegal activity or statutory noncompliance. These instances are illustrated in Table 2 on the following page.

Table 2

Disciplinary Actions

Year	Incident	Investigation	Discipline Taken
1980s	Researcher diverted controlled substances for personal use.	Performed by DEA and ADAD. Substantiated allegations.	License revoked
1999	Employee of provisionally licensed addiction treatment center overdosed on methadone and died.	Performed by DEA and ADAD. Determined that substantial amounts of methadone had been diverted/unaccounted for.	Suspension of new admissions and more stringent measuring and accounting of methadone. Provisional license was not converted to a full license. Program was sold and was under new ownership.
1999	ADAD initially denied a license to a researcher for keeping high inventories of a drug popular on the illicit market. DEA was prepared to license facility.	ADAD identified concerns for public safety due to minimal security precautions.	Recommended security enhancements as a condition for licensing. Researcher complied and license was granted.
2000	Patient receiving methadone from physician in private practice alleged to have sold his methadone.	ADAD visited physician, area treatment providers, pharmacists, and pain specialists in the community.	Recommended that the physician no longer prescribe methadone to the patient and recommended referring the patient to an addiction treatment clinic.
2000	Physician prescribed methadone for son to take on an out-of-town trip.	ADAD contacted pharmacy and methadone treatment center. Determined that son had been over-prescribed by his father.	Contacted physician and pharmacy and referred to Medical Board. After an investigation, dismissed by the Medical Board.
2001	Physician prescribed a non-FDA approved drug to treat opiate addiction.	Contacted physician to inform him that this was outside his scope of practice.	Sent letter to DEA, the Medical Board, and the 11 licensed opioid programs in Colorado. The Medical Board initiated an investigation.

Record-keeping Function

The record-keeping requirements set forth in Colorado statute are very similar to the requirements found in federal law. The types of records kept include the following:

- Log for determining the dates and times when controlled substances are checked out and when returned. This would also include the weight of the substance;
- Internal inventory sheets;
- Lab reports;
- Chain of custody (transfer of substance to another location);
- Copies of order forms from manufacturers;
- Form that details who has access to which substances.

Currently, for the purpose of licensure, ADAD requires that applicants for renewal or for a new license submit their policies and procedures manual that addresses access to controlled substances, storage requirements, and distribution accountability. There is a requirement that ADAD be notified if there are any changes to the policies and procedures, personnel, or location, change of ownership, or if there is a loss by theft or destruction of controlled substances. If there is a change of ownership, a new license is issued.

It has only been in the past two years that the submittal of a policies and procedures manual has been mandatory. Previously, all that was required of an applicant was to complete the application form and submit the fee. At the present time, it is not uncommon to notify the applicant that the application is incomplete and additional information is warranted.

ADAD has maintained a close working relationship with the DEA in collaborative controlled substances licensing roles. The DEA will not complete controlled substances registrations unless applicants are first licensed by ADAD. The DEA regularly confirms licensure prior to registering initial and renewed applications.

In fact, during an interview with a DEA official, it was noted that Title 21 of the United States Code specifically requires a state license to obtain a federal registration number. ADAD and the DEA communicate regularly on any concerns regarding applicants as well as practices of applicants and coordinate licensing visits, complaint, and critical incident investigations.

Opioid addiction programs are required to submit monthly reports to ADAD. Compilation of the monthly report information is used to develop a picture of the provision of opioid treatment services for the state and identify trends in the population. For example, the following issues are analyzed: (1) Are there more young users? (2) Is there an increase in infectious diseases in this population? and (3) How many pregnant women are in opioid treatment? The following information is required for monthly submittal by the opioid treatment centers:

- Total number of patients;
- Monthly admissions and discharges;
- Pregnant patient status;
- Total number of current patients who are HIV seropositive, have clinically active TB, or Hepatitis B or C;
- Patient and dose amount (methadone) eligible for take-home status;
- Total number of patients testing positive for cocaine, morphine, other opiates, and benzos during a urine drug screen;
- Total number of patients on antabuse, flagyl, or naltrexone;
- Summary of critical incidents.

Survey Results

As part of this sunset review, a survey was developed and mailed in February 2001 to the 188 licensees who were licensed at that time: researchers (127), addiction programs (21), and analytical laboratories (40). This section of the sunset review provides a discussion of survey responses regarding the effectiveness of ADAD's oversight of record-keeping requirements. A copy of the survey may be found in Appendix B of this report.

Ninety-one survey responses were received representing a response rate of 48%. In addition to answering the questions posed in the survey, several respondents wrote comments. The purpose of the survey was to elicit such comments as well as to provide general information from the regulated community on its views of the effectiveness and necessity of the record-keeping requirements for the controlled substances regulatory program.

Discussion of Survey Results

ADAD grants licenses to three separate categories of entities that handle controlled substances: researchers, addiction programs, and analytical laboratories. Within these three categories are subcategories that further delineate the type of licensee. Table 3 below illustrates the type of license and the number of survey respondents.

Table 3

Breakdown of Survey Respondents

# of Researcher Respondents (60)	# of Addiction Program Respondents (10)	# of Analytical Laboratory Respondents (21)
Private Laboratory. – 9 Sheriff's Department. – 4 Police Department. – 2 State Agency – 1 University Based – 17 Canine Facility Sheriff - 8 Police – 15 State Agency – 1 Private - 3	Hospital Based - 3 Private Clinic - 5 Public Clinic - 2	Hospital Based – 1 Independent Laboratory – 9 Police Department – 6 State Agency – 4 Coroner - 1

The survey results clearly show a substantial split in the opinions of the licensees. Nearly half of the respondents felt that there is a duplication of efforts between the federal government registration program and the state licensing program and that the state licensing program should not be continued. Additionally, 58% of the respondents reported that they believe there would be no consequences if state licensing/record-keeping requirements were discontinued. Although almost two-thirds did not foresee consequences for discontinuance, half of the respondents recommended continuing the program. The common trend in the responses was that the analytical laboratories were most likely to proclaim that this regulation was ineffective.

Most of the rationale that accompanied the support of the program was centered on two issues. First, many respondents indicated that regulation is important because it is a motivating factor for persons who use controlled substances to properly store, handle, keep records of, and dispose of, controlled substances. Secondly, regulation gives the public the confidence that controlled substances are being adequately safeguarded. Most of the negative comments were centered on the issue that state licensing is a duplication of effort and paperwork that is submitted for a DEA license.

When asked whether ADAD had ever reviewed their onsite records, 97% of the researchers and 95% of the analytical laboratories responded in the negative, while 90% of the addiction programs responded in the positive.

Conclusion

The respondents to this survey represent about 49% of the total number of licensees in the Controlled Substances Program. There was considerable lack of consensus among the licensees about the necessity for this program. It is particularly revealing to note that addiction programs believed there would be consequences if the state regulation were discontinued, while most analytical laboratories anticipated there would be no consequences. Finally, the total percentage of licensed facilities that were inspected by ADAD was only 11%.

Analysis and Recommendations

Recommendation 1: The General Assembly should allow the record-keeping and licensing functions of the Alcohol and Drug Abuse Division relating to researchers and analytical laboratories to sunset on July 1, 2002.

It is the conclusion of this review that enforcement and inspection activities of this program offer little significant public protection. Second, the licensing activities of the Division are duplicated by the federal DEA and that agency is required by federal law to continue its registration program. Finally, the federal record-keeping requirement will remain in force absent state licensing and routine inspection requirements.

The original purpose of this program was to ensure strict control of controlled substances for the preservation of the public peace, health, and safety and that the licensing, record-keeping, and penalties are necessary for the achievement of such control. As evidenced in the Disciplinary Actions section of the report, there have only been six incidences of illegal activity investigated by ADAD since the 1980s. Additionally, there has only been one license revocation and one program suspension of new participants. Regarding inspections for facilities, there are not sufficient resources to adequately inspect all 198 licensees. The survey noted that only 3% of researcher licensees and 5% of analytical laboratories received an inspection subsequent to initial licensing.

Federal officials, who strongly support continuation of this licensing scheme, assert that state regulation is required by federal law. Support for this argument rests on Sections 822 and 823 of Title 21 of the United States Code. This is commonly known as the “Controlled Substances Act.” Essentially, the federal statute requires the DEA to issue registrations if doing so is in the public interest. In determining the public interest, the DEA must consider certain factors. One factor, found at Section 823(f)(4), is compliance by the applicant with applicable state, federal or local laws relating to controlled substances. It is not clear that this is a mandate to state legislatures that they must regulate the same entities regulated by the federal government.

In conclusion, absent a written legal opinion and given the plain meaning of the federal language, the report does not support the finding that the federal law requires state regulation. Rather, federal officials may take into account an applicant's compliance with state laws if such laws exist, as they do now.

Research conducted for this review, supported by the survey of licensees, indicates that the federal registration requirement and the state licensing requirement are duplicative regulation. As reported on page 21 of this review, nearly half of the respondents believe there is a duplication of efforts between the federal government registration program and the state licensing program and that the state licensing program should not be continued. Additionally, 58% of the respondents reported that they believe there would be no consequences if state licensing/record-keeping requirements were discontinued.

If regulation is continued, additional resources are needed to carry out the statutory mandates. ADAD is already understaffed and underfunded in relationship to the responsibilities that it must perform regarding the oversight of record-keeping functions for the Controlled Substances Program. For example, one of the primary problems of the operation of the controlled substances licensing program is the lack of personnel available to perform inspections of the facilities and their record-keeping requirements. To partially offset the expense of the program, it is recommended that the General Assembly designate the $225 licensee fee, collected by ADAD, to the Controlled Substances Program.

Furthermore, it is not clear from Colorado law that canine facilities should be licensed. In addition, we found no reference in federal law to canine facilities yet it also requires that these facilities have a DEA registration. Of the 57 licensed canine facilities in Colorado, 52 are law enforcement agencies and the remaining five are private canine facilities. Should regulation be continued, statutory clarification pertaining to regulation of canine facilities should be provided by the General Assembly.

Recommendation 2: The General Assembly should continue the record-keeping and licensing functions of the Department of Human Services in relation to addiction programs and set a new sunset date for 2007.

ADAD serves as an intermediary between the addiction programs and federal authorities to represent the interests of the State of Colorado on issues pertaining to controlled substance licensing and the use of scheduled controlled substances in addiction treatment. Examples include reporting to federal authorities when physicians are inappropriately prescribing medications for opiate addiction/detoxification and providing requested feedback to federal authorities on issues directly affecting opioid treatment. ADAD has the licensing authority to assure that its uniform standards for addiction programs are maintained to protect patients in treatment. It sets minimum standards for policies and procedures to be sustained in these programs and review critical incidents, dosage records, and security measures during inspections.

Addiction programs currently experience regulatory oversight by the State in the form of these inspections, contrary to the researchers and analytical laboratories that are very rarely inspected. Inspections entail a review of dispensing hours, number of clients, policies and procedures, provider credentials, fees, medication doses and dispensing, record-keeping, security, and staff licenses and credentials.

Within addiction programs, ADAD monitors trends in program enrollment, and is able to determine such things as anticipated need for referral resources, general changes in program demographics statewide, average daily dose for patients in the state, and the effect of communicable diseases within this population served.

The recommendation to perform a sunset review of this function in five years is based on Recommendation 1 that proposes the sunset of the licensing and record-keeping functions of ADAD in relation to researchers and analytical laboratories. At that time, the review will evaluate the effectiveness of the remaining state regulation of addiction programs.

Recommendation 3: Adopt the rules and revise them to reflect the amendments resulting from this sunset bill.

The regulatory oversight of this program was previously administered by the Colorado Department of Public Health and Environment (then known as the Department of Health). It was transferred to the Department of Human Services on July 1, 1994. However, the rules and regulations 6CCR 1008-2 effective January 30, 1993 were not subsequently transferred. This recommendation would eliminate the confusion that presently exists for licensees who might attempt to access the regulation.

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; and

(IX) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Appendix B – Controlled Substances Act Survey of Licensees

CONTROLLED SUBSTANCES ACT

SURVEY OF LICENSEES

Persons licensed to purchase, administer, store, use in research, dispense, or handle controlled substances controlled substances under the Controlled Substances Act are required to keep and maintain records and inventories relating to control substances (§ 12-22-318, Colorado Revised Statutes.). All records and inventories must be maintained for two years after the date of transaction. These records must include the date, name and address of person receiving and using the controlled substances, and the type and quantity the controlled substance. Records must be kept of any controlled substance lost, destroyed, or stolen, the type and quantity of such substance, and the date of loss, destruction, or theft.

Please respond to the following questions regarding the Alcohol and Drug Abuse Division's regulatory oversight of the licensee's (your) recordkeeping responsibilities.

Name (optional)_____ Place of Business (optional)_____

Please designate the type of license issued from the Alcohol and Drug Abuse Division (ADAD). Please check all that apply.

Researcher □	Addiction Treatment □	Analytical Laboratory □
K-9 facility □	Hospital Based □	Hospital Based □
Sheriff's Department □	Private Clinic □	Independent Lab □
Police Department □	Public Clinic □	Police Department □
University Based □		State Agency/Dept. □
Private Laboratory □		Coroner □
State Agency/Dept. □		

When was your state license originally issued?_____(Year)

Has ADAD ever reviewed your **onsite** records? Yes_____ No_____
If your answer is yes, how many times?_____

Has the Federal government ever reviewed your **onsite** records for compliance with Federal law?
Yes_____ No_____
If your answer is yes, how many times?_____

In your opinion, what would be the consequences, if any, if the state licensing/recordkeeping requirements program for controlled substances was discontinued? Please be as candid as possible.

Should the present state licensing program be continued? Why or why not?.

Appendix C – Colorado Licensing of Controlled Substances Act

12-22-301. Short title. This Part 3 shall be known and may be cited as the "Colorado Licensing of Controlled Substances Act"

12-22-302. Legislative declaration. The general assembly finds, determines, and declares that strict control of controlled substances within this state is necessary for the immediate and future preservation of the public peace, health, and safety and that the licensing, record-keeping, penalty, and other provisions contained in this Part 3 are necessary for the achievement of such control.

12-22-303. Definitions. As used in this Part 3, unless the context otherwise requires:

(1) "Addict" means a person who has a physical or psychological dependence on a controlled substance, which dependence develops following the use of the controlled substance on a periodic or continuing basis and is demonstrated by appropriate observation and tests by a person licensed to practice medicine pursuant to article 36 of this title.

(2) "Addiction program" means a program, licensed under this Part 3, for the detoxification, withdrawal, or maintenance treatment of addicts.

(3) "Administer" means to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject.

(4) "Agent" means an authorized person who acts on behalf of or at the direction of a person licensed or otherwise authorized under this Part 3. "Agent" does not include a common or contract carrier, a public warehouseman, or an employee of a carrier or warehouseman.

(5) "Board" means the state board of pharmacy.

(6) "Bureau" means the drug enforcement administration, or its successor agency, of the United States department of justice.

(6.5) "Cocaine" means coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this subsection (6.5).

(7) "Controlled substance" means a drug, substance, or immediate precursor included in schedules I to V of Part 2 of article 18 of title 18, CRS

(7.5) (a) "Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II and:
(I) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in schedule I or II; or
(II) With respect to a particular individual, which that individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in schedule I or II.
(b) "Controlled substance analog" does not include:
(I) A controlled substance;
(II) Any substance for which there is an approved new drug application;
(III) With respect to a particular person, any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the "Federal Food, Drug, and Cosmetic Act", 21 U.S.C. 355, as amended, to the extent that conduct with respect to the substance is pursuant to the exemption; or
(IV) Any substance to the extent not intended for human consumption before such an exemption takes effect with respect to the substance.
(8) "Deliver" or "delivery" means actual, constructive, or attempted transfer of a controlled substance whether or not there is an agency relationship. of a controlled substance whether or not there is an agency relationship.
(9) "Department" means the department of public health and environment.
(10) "Detoxification treatment" means a program for a short term of not more than three weeks for the administering or dispensing, in decreasing doses, of a controlled substance to an addict while he is receiving appropriate supportive medical treatment, with the immediate goal being to render the addict no longer dependent on the intake of any amount of a controlled substance.
(11) "Dispense" shall have the same meaning as set forth in section 12-22-102 (9).
(12) "Distribute" means to deliver a controlled substance other than by administering or dispensing.
(12.5) "Distributor" has the same meaning as that set forth in section 18-18-102 (12), CRS
(13) (a) "Drug" means any of the substances:

(I) Recognized as drugs in the official United States pharmacopoeia, national formulary, or the official homeopathic pharmacopoeia of the United States, or a supplement thereof;
(II) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals;
(III) Other than food, intended to affect the structure or any function of the body of individuals or animals; or
(IV) Intended for use as a component of any substance specified in subparagraph (I), (II), or (III) of this paragraph (a).
(b) "Drug" does not include devices or their components, parts, or accessories.
(13.5) Repealed.
(14) "Immediate precursor" means a substance which is a principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used, in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.
(15) "Maintenance treatment" means a program of more than six months' duration for the administering or dispensing of a controlled substance, approved for such use by federal law or regulation, to an addict for the purpose of continuing his dependence upon a controlled substance in the course of conducting an authorized rehabilitation program for addicts, with a long-term goal of decreasing the addict's controlled substance dependency and leading to his possible withdrawal.
(16) "Manufacturer" means a person who is licensed by this Part 3 and who, by compounding, mixing, cultivating, planting, growing, or other process, produces or prepares a controlled substance, but the term does not include a pharmacist who compounds controlled substances to be dispensed pursuant to a prescription, a practitioner who compounds controlled substances for dispensing in the course of his professional practice, or a researcher acting within the provisions of this Part 3.
(17) "Marihuana" or "marijuana" means all parts of the plant cannabis sativa L., whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin. It does not include fiber produced from the stalks, oil or cake made from the seeds of the plant, or sterilized seed of the plant which is incapable of germination, if these items exist apart from any other item defined as "marihuana" in this subsection (17). "Marihuana" does not include marihuana concentrate as defined in subsection (18) of this section.

(18) "Marihuana concentrate" means hashish, tetrahydrocannabinols, or any alkaloid, salt, derivative, preparation, compound, or mixture, whether natural or synthesized, of tetrahydrocannabinols.
(19) "Narcotic controlled substance" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(a) Opium or any opiate or any salt, compound, derivative, or preparation of opium or any opiate;
(b) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent to or identical with any of the substances referred to in paragraph (a) of this subsection (19) but not including the isoquinoline alkaloids of opium;
(c) Any opium poppy or poppy straw.
(20) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having an addiction-forming or addiction-sustaining liability. "Opiate" does not include, unless specifically designated as controlled under this Part 3, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts (dextromethorphan). The term does include its racemic and levorotatory forms.
(21) "Opium poppy" means the plant of the species papaver somniferum L., except its seeds.
(22) "Peace officer" shall have the same meaning as set forth in section 18-1-901 (3) (l), CRS
(23) "Person" means any individual, government, governmental subdivision, agency, business trust, estate, trust, partnership, corporation, association, institution, or other legal entity.
(24) "Peyote" means all parts of the plant presently classified botanically as lophophora williamsii lemaire, whether growing or not, the seeds thereof, any extraction from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or extracts.
(25) "Pharmacist" means an individual licensed pursuant to Part1 of this article to engage in the practice of pharmacy, as defined in section 12-22-102 (26).
(26) "Pharmacy" or "prescription drug outlet" shall have the same meaning as set forth in section 12-22-102 (30.2).
(27) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.
(28) "Practitioner" shall have the same meaning as set forth in section 12-22-102 (27).

(29) "Production" or "produces" means the manufacturing, planting, cultivating, growing, or harvesting of a controlled substance.
(30) "Remuneration" means anything of value, including money, real property, tangible and intangible personal property, contract rights, choices in action, services, and any rights of use or employment or promises or agreements connected therewith.
(31) "Researcher" means any person licensed by the department pursuant to this Part 3 to experiment with, study, or test any controlled substance within this state and includes analytical laboratories.
(32) (a) "Tetrahydrocannabinols" means synthetic equivalents of the substances contained in the plant, or in the resinous extractives of, cannabis, sp., or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity, such as the following:
(I) cis or trans tetrahydrocannabinol, and their optical isomers;
(II) cis or trans tetrahydrocannabinol, and their optical isomers;
(III) ,cis or trans tetrahydrocannabinol, and their optical isomers.
(b) Since the nomenclature of the substances listed in paragraph (a) of this subsection (32) is not internationally standardized, compounds of these structures, regardless of the numerical designation of atomic positions, are included in this definition.
(33) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use, for the use of a member of his household, or for use in administering to an animal owned by him or a member of his household.
(34) (Deleted by amendment, L. 92, p. 386, 5, effective July 1, 1992.)
(35) "Withdrawal treatment" means a program for an intermediate term, of more than three weeks but less than six months, for the administering or dispensing, in decreasing doses, of a controlled substance, approved for such use by federal law or regulation, to an addict while receiving rehabilitative measures as indicated, with the immediate goal being to render the addict no longer dependent on the intake of any amount of a controlled substance.

12-22-304. License required - controlled substances - drug precursors - fund created - repeal. (1) In accordance with Part 3 of article 18 of title 18, CRS, a license issued by the department shall be obtained annually for each place of business or professional practice located in this state by:
(a) Every researcher, including analytical laboratories, experimenting with, studying, or testing any controlled substance;

(b) Every addiction program which compounds, administers, or dispenses a controlled substance.

(2) In accordance with Part 3 of article 18 of title 18, CRS, a license issued by the board shall be obtained annually or biannually, if applicable, for:

(a) Every manufacturer in this state who manufactures or distributes a controlled substance;

(b) Every distributor who distributes a controlled substance in this state or who is doing business in this state.

(2.5) Repealed.

(3) (a) A license issued by the board shall be obtained annually by a humane society as provided in this subsection (3). The board shall, as provided in section 24-34-105, CRS, collect a fee and issue a license to a humane society as provided in this subsection (3).

(b) On and after July 1, 1979, a humane society which is duly registered with the secretary of state and has been in existence and in business for at least five years in this state as a nonprofit corporation or an animal control agency which is operated by a unit of government may apply to the board for a license for the sole purpose of being authorized to purchase, possess, and administer sodium pentobarbital, or sodium pentobarbital in combination with other noncontrolled prescription drugs which are medically recognized for euthanasia, to euthanize injured, sick, homeless, or unwanted pets and animals. Any society or agency so licensed shall not permit a person to administer sodium pentobarbital, or sodium pentobarbital in combination with other noncontrolled prescription drugs which are medically recognized for euthanasia, unless such person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering the drug. The board may issue a limited license to carry out the provisions of this subsection (3). The board shall issue such rules as it deems necessary to ensure strict compliance with the provisions of this subsection (3) and shall develop in conjunction with the state board of veterinary medicine criteria for training individuals in the administration of the drug. The board may suspend or revoke the license upon determination that the person administering sodium pentobarbital has not demonstrated adequate knowledge required by this subsection (3). Nothing in this subsection (3) shall be construed to apply to a licensed veterinarian.

(4) Persons licensed as required under this Part 3, or otherwise licensed as required by federal law, may possess, manufacture, distribute, dispense, administer, or conduct or do research with controlled substances only to the extent authorized by their licenses and in conformity with the provisions of this Part 3 and with article 18 of title 18, CRS
(5) The following persons need not be licensed by the department or by the board to lawfully possess controlled substances under this Part 3:
(a) to (d) (Deleted by amendment, L. 92, p. 387, 6, effective July 1, 1992.)
(e) (I) Employees of facilities who are administering and monitoring medications to persons under the care or jurisdiction thereof pursuant to the provisions of section 25-1-107 (1) (ee), CRS
(II) This paragraph (e) is repealed, effective July 1, 1998. Prior to such repeal, the exception to the licensure requirement set forth in this paragraph (e) shall be subject to review pursuant to the provisions of section 2-3-1201, CRS, by the sunrise and sunset review committee.
(5.5) and (5.6) Repealed.
(6) Any person who is required to be licensed and who is not so licensed may apply for a license at any time. No person required to be licensed shall engage in any activity for which a license is required until his application is granted and a license is issued to him by the department or the board.
(7) No license shall be issued under this Part 3 to a researcher, manufacturer, or distributor of marihuana or marihuana concentrate.

12-22-305. Issuance of license - fees - repeal. (1) The department or the board as provided in section 12-22-304 (1) or (2) shall issue the appropriate license to each manufacturer, distributor, researcher, and addiction program meeting all the requirements of this Part 3 unless it determines that the issuance of the license would be inconsistent with the public interest. In determining the public interest, the department or the board shall consider the following factors:
(a) Maintenance of effective controls against diversion of controlled substances into illegitimate medical, scientific, or industrial channels;
(b) Compliance with applicable state and local laws;
(c) Any conviction of the applicant under any federal or state law relating to a controlled substance;

(d) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;
(e) Any false or fraudulent information in an application filed under this Part 3;
(f) Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense a controlled substance as authorized by federal law; and
(g) Any other factors relevant to and consistent with the public peace, health, and safety.
(1.5) Repealed.
(2) Issuance of a license under subsection (1) of this section does not entitle a licensee to wholesale, manufacture, distribute, or professionally use controlled substances beyond the scope of his federal registration.
(3) (a) The initial and annual license fees are as follows:
(I) Addiction program $ 25.00
(II) Researchers $ 25.00
(b) Notwithstanding the provisions of paragraph (a) of this subsection (3), the fees collected by the board under this article shall be determined, collected, and appropriated pursuant to section 24-34-105, CRS
(4) Any person who is licensed may apply for license renewal not more than sixty days before the expiration date of his license.
(5) Neither the United States nor the state of Colorado or any of its political subdivisions shall pay any license fee required by this Part 3.

12-22-306. Disposition of fees. All moneys collected by the department shall be transmitted to the state treasurer, who shall credit the same to the general fund. The general assembly shall make annual appropriations from the general fund for the purposes authorized by this Part 3. Expenditures from such appropriations shall be made upon vouchers and warrants drawn pursuant to law.

12-22-306.1. Fees - drug precursors - refund. All moneys collected by the department of human services pursuant to section 12-22-305 from applicants and licensees who manufacture, transfer, possess, or transport drug precursors shall be refunded, before September 30, 1996, to the persons from whom such moneys were collected.

12-22-307. Qualifications for license. (1) An applicant for a license under this Part 3 must have adequate and proper facilities for the handling and storage of controlled substances and maintain proper control over such controlled substances to insure against their being illegally dispensed or distributed.
(2) Any person registered as a researcher by the federal government shall be presumed to possess the qualifications described in this section, so long as his federal registration is valid.
(3) No license shall be granted to any person who has been convicted within the last two years of a willful violation of this Part 3 or any other state or federal law regulating controlled substances.
(4) Except for fees, compliance by a registrant with the provisions of the federal law respecting registration entitles the registrant to be licensed under this Part 3.

12-22-308. Denial, revocation, or suspension of license. (1) A license issued under this Part 3 may be denied, suspended, or revoked by the department or by the board pursuant to article 4 of title 24, CRS, upon a finding that the licensee:
(a) Has furnished false or fraudulent information in an application filed under this Part 3;
(b) Has been convicted of, or has had accepted by a court a plea of guilty or nolo contendere to, a felony under any state or federal law relating to a controlled substance;
(c) Has had his or her federal registration to manufacture, conduct research on, distribute, or dispense a controlled substance suspended or revoked; or
(d) Has violated any provision of this Part 3 or the rules or regulations of the department or of the board.
(2) The department or the board may limit revocation or suspension of a license to the particular controlled substance which was the basis for revocation or suspension.
(3) If the department or the board suspends or revokes a license, all controlled substances owned or possessed by the licensee at the time of the suspension or on the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for making an appeal has elapsed or until all appeals have been concluded unless a court orders otherwise or orders the sale of any perishable controlled substances and the deposit of the proceeds with the court. Upon a revocation order's becoming final, all controlled substances may be forfeited to the state.

(4) The department or the board shall promptly notify the bureau and the appropriate professional licensing agency, if any, of all charges and the final disposition thereof and of all forfeitures of a controlled substance.

12-22-309. Controlled substances - schedule I. (Repealed)

12-22-310. Controlled substances - schedule II. (Repealed)

12-22-311. Controlled substances - schedule III. (Repealed)

12-22-312. Controlled substances - schedule IV. (Repealed)

12-22-313. Controlled substances - schedule V. (Repealed)

12-22-314. Unlawful acts - licenses - penalties. (Repealed)

12-22-315. Fraud and deceit. (Repealed)

12-22-316. Notice of conviction. (Repealed)

12-22-317. Exemptions. (1) The provisions of section 18-18-414, CRS, shall not apply to:
(a) Agents of persons licensed under this Part 3 or under Part 3 of article 18 of title 18, CRS, acting within the provisions of their licenses; or
(b) Officers or employees of appropriate agencies of federal, state, or local governments acting pursuant to their official duties.
(2) All combination drugs that are exempted by regulation of the attorney general of the United States department of justice, pursuant to section 1006 (b) of Public Law 91-513 (84 Stat. 1236), known as the "Comprehensive Drug Abuse Prevention and Control Act of 1970", on or after July 1, 1981, are exempted from the provisions of this Part 3 and from the provisions of Part 3 of article 18 of title 18, CRS
(3) The provisions of this Part 3 do not apply to peyote if said controlled substance is used in religious ceremonies of any bona fide religious organization.

(4) The provisions of section 12-22-318 shall not apply to a practitioner authorized to prescribe with respect to any controlled substance which is listed in schedules III, IV, or V of Part2 of article 18 of title 18, CRS, and which is manufactured, received, or dispensed by him in the course of his professional practice unless he dispenses, other than by direct administration, any such controlled substance to his patients and they are charged therefor either separately or together with charges for other professional services or unless he regularly engages in dispensing any such controlled substance to his patients.
(5) The exemptions set forth in this section shall be available as a defense to any person accused of violating the provisions of section 18-18-414, CRS
(6) It shall not be necessary for the state to negate any exemption or exception in this Part 3 or in Part 3 or 4 of article 18 of title 18, CRS, in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this Part 3 or under Part 4 of article 18 of title 18, CRS The burden of proof of any such exemption or exception is upon the person claiming it.

12-22-318. Records to be kept - order forms - repeal. (1) (a) Each person licensed or otherwise authorized under this Part 3 or other laws of this state to manufacture, purchase, distribute, dispense, administer, store, use in research, or otherwise handle controlled substances shall keep and maintain separate detailed and accurate records and inventories relating to controlled substances and retain all such records and inventories for a period of two years after the respective dates of such transactions as shown on such records and inventories.
(b) Repealed.
(2) The record of any controlled substance distributed, administered, dispensed, or otherwise used shall show the date, the name and address of person to whom, for whose use, the controlled substance was distributed, administered, dispensed, used, or otherwise disposed of, and the kind and quantity of such controlled substance.
(3) Manufacturing records of controlled substances shall include the kind and quantity of controlled substances produced or removed from process of manufacture and the dates of such production or removal from process of manufacture.
(4) The keeping of a record required by federal law, containing substantially the same information as set forth in subsections (1) to (3) of this section, shall constitute compliance with the record-keeping requirements of this Part 3.

(5) A record shall also be kept of any controlled substance lost, destroyed, or stolen, the kind and quantity of such controlled substance, and the date of such loss, destruction, or theft.
(5.5) Prescription drug outlets shall report thefts of controlled substances to the proper law enforcement agencies and to the board within thirty days after the occurrence of such thefts.
(6) Controlled substances listed in schedule I or II of Part 2 of article 18 of title 18, CRS, shall be distributed by persons licensed or otherwise authorized under this Part 3 or other laws of this state only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.
(7) to (11) Repealed.

12-22-319. Enforcement and cooperation. (1) Each peace officer and district attorney in this state shall enforce all the provisions of this Part 3 and shall cooperate with all agencies charged with the enforcement of the laws of this state, all other states, and the United States relating to controlled substances.
(2) The board shall make any inspections, investigations, and reports that may be necessary to determine compliance with the provisions of this Part 3 as they pertain to pharmacies, pharmacists, and manufacturers and distributors of controlled substances. The department shall cooperate with all agencies charged with the enforcement of the laws of this state, all other states, and the United States relating to controlled substances.
(3) The department of human services shall cooperate with all agencies charged with the enforcement of the laws of this state, all other states, and the United States relating to controlled substances. To this end, the department shall:
(a) Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances;
(b) Cooperate with the bureau and with local, state, and other federal agencies by maintaining a centralized unit to accept, catalogue, file, and collect statistics, including records of dependent and other controlled substance law offenders within the state, and make the information available for federal, state, and local law enforcement or regulatory purposes. It shall not furnish the name or identity of a patient or research subject whose identity could not be obtained under section 12-22-320.

(c) Respond to referrals, complaints, or other information received regarding possible violations and, upon notification of the appropriate licensing authority, if applicable, and upon a written finding by the executive director of the department that probable cause exists to believe that there is illegal distribution or dispensing of controlled substances, to make any inspections, investigations, and reports that may be necessary to determine compliance with the provisions of this Part 3 by all licensed or otherwise authorized individuals who handle controlled substances;
(d) Cooperate with and make information available to appropriate state licensing and registration boards regarding any violations of this Part 3 by persons licensed or registered by such boards;
(e) Enter into contracts and encourage and conduct educational and research activities designed to prevent and determine misuse and abuse of controlled substances.

12-22-320. Records confidential. Prescriptions, orders, and records required by this Part 3 and stocks of controlled substances shall be open for inspection only to federal, state, county, and municipal officers whose duty it is to enforce the laws of this state or of the United States relating to controlled substances or the regulation of practitioners. No officer having knowledge by virtue of his office of any such prescription, order, or record shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer to which prosecution or proceeding the person to whom such prescriptions, orders, or records relate is a party.

12-22-321. Rules and regulations. (1) 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, CRS
(2) (a) Repealed.

12-22-322. Department to promulgate rules and regulations. The department of human services shall promulgate rules and regulations for research programs and for the conduct of detoxification treatment, maintenance treatment, and withdrawal treatment programs for controlled substance addiction. Such rules and regulations shall be promulgated in accordance with the provisions of article 4 of title 24, CRS.

12-22-323. Authority to control drug precursors by rule and regulation. (Repealed)

12-22-324. Defenses. The common law defense known as the "procuring agent defense" is not a defense to any crime in this article or in title 18, CRS.