COLORADO DEPARTMENT OF REGULATORY AGENCIES
OFFICE OF POLICY AND RESEARCH

# COLORADO DRUG PRECURSOR LICENSING PROGRAM

## 1995 SUNSET REVIEW

## *Joint Legislative Sunrise/Sunset Review Committee*
### *1995-1996 Members*

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June 30, 1995

The Honorable Richard Mutzebaugh, Chair
Joint Legislative Sunrise/Sunset Review Committee
State Capitol Building
Denver, Colorado 80203

Dear Senator Mutzebaugh:

The Colorado Department of Regulatory Agencies has completed the evaluation of the **Colorado Drug Precursor Licensing Program**. We are pleased to submit this written report, which will be the basis for my office's oral testimony before the Joint Legislative Sunrise/Sunset Review Committee. The report is submitted pursuant to §24-34-104 (8)(a), of the Colorado Revised Statutes, 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 such supporting materials as may be requested, to the Sunrise and Sunset Review Committee created by joint rule of the Senate and House of Representatives, no later than July 1 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 article 22 of title 12, C.R.S. The report also discusses the effectiveness of the division and staff in carrying out the intention of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Joseph A. Garcia
Executive Director

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# EXECUTIVE SUMMARY

The Colorado Department of Regulatory Agencies has completed its 1995 Sunset Review of the Colorado Drug Precursor licensing program. The program is administered by the Department of Health through the State Board of Pharmacy. The purpose of the drug precursor program is to prevent the unlawful diversion of drug precursors, substances that could be used in the manufacturing of illicit drugs, from legitimate sources for illegal uses. Colorado is one of only 4 states who have developed a drug precursor licensing program. The statute directs that licensing, reporting, and compliance penalties be established. The statute also excludes a number of individuals and businesses. The question central of this review is: **Do licensing, reporting and compliance penalties prevent the diversion of drug precursors for illegal uses?**

The Alcohol and Drug Abuse Division, within the Department of Public Health and Environment (CDPHE) reports that only one company, The Hach Company, is licensed and submits to the program requirements. The Department also reports that 26 other companies that would have been required to secure a license elected not to transact drug precursor business in Colorado. Furthermore, since the law's enactment, no complaints have be filed with the Department of Health. This sunset review makes the following recommendations intended to cause the termination of this regulatory program, while retaining legislative language prohibiting the diversion of drug precursors for illicit purposes. Specifically, the recommendations seek to (1) repeal the licensing program, (2) create a new part within the Controlled Substances Act of 1992, and (3) to amend references to the licensing program found within part 3 of article 18 of title 18., C.R.S.

1. The General Assembly should terminate the Colorado Drug Precursor licensing program as provided for under §12-22-301 et. seq., C.R.S.

2. The General Assembly should repeal §12-22-304 through §12-22-308, and §12-22-314(1)(I), C.R.S., that create the Drug Precursor Licensing program.

3. The General Assembly should amend or repeal provisions of §12-22-318, C.R.S., that contain unnecessary record keeping requirements.

4. The General Assembly should repeal §12-22-321, C.R.S., that directs the Department to create rules and regulations for the administration and enforcement of the Drug Precursor Licensing program.

5. The General Assembly should create a unique Part within §18-18-302 or 18-18-303., C.R.S., for the regulation of the manufacturing, distribution and dispensing of drug precursors.

6. The General Assembly should amend language within §18-18-414, C.R.S., to accommodate the elimination of the Drug Precursor Licensing program.

7. The General Assembly should amend language within §18-18-302(1), C.R.S., to accommodate the elimination of the Drug Precursor Licensing program.

# BACKGROUND

## The Sunset Process

Colorado law requires that the drug precursor licensing program administered by the CDPHE through the State Board of Pharmacy be terminated on July 1, 1996, unless continued by the General Assembly (§24-34-104, C.R.S.). The sunset review involves an analysis and evaluation of this regulatory program. The goal of this sunset review is to determine if licensing, reporting and compliance penalties help to prevent the diversion of drug precursors from legitimate to illegal drug activities. This review evaluates the form of regulation, the effectiveness of this approach in promoting public safety, and examines information on prosecutions and other legal actions taken against licensees. A complete list of the sunset evaluation criteria can be found in Appendix A of this report.

This is the first review of the Drug Precursor Licensing program. The review was originally scheduled for July 1993, but an extension was enacted during the 1992 regular session. It should be noted that several sections creating the drug precursor regulatory program call for repeal on July 1, 1995. Given that no sunset review has been conducted, this report is submitted to provide an official evaluation and list of recommendations regarding the Drug Precursor Licensing program. The analysis presented here includes a review of the current statute and rules. Interviews were held with the sole licensee, and the program director. Finally, letters were sent to the Colorado District Attorneys Council, the County Sheriffs of Colorado and the Colorado Bureau of Investigation, inviting their comments. A brief overview of federal law is also included within the report.

## Regulation of the Diversion of Drug Precursors

***History of Regulation***

Section 12-22-101, et. seq., C.R.S., entitled the Colorado Controlled Substances Act incorporates the provisions creating the Drug Precursor Licensing program within Part three. References to drug precursors and the need to license and regulate their usage is found as early as 1981. The act required licensing and provided that **the Department may** "promulgate reasonable rules necessary to implement the provisions of this article relating to the control of drug precursors, including rules specifying a common reporting form for substances that are drug precursors..." (§12-22-321(2)(a), C.R.S.). The department was also directed to create a list of drug precursors by rule, and the statute provided a detailed set of criteria for determining when a substance should be classified as a precursor. The program continued to operate in this fashion until 1992 when a significant change in regulatory approach was introduced. The 1992 legislation clarified the definition of a drug precursor, included the list of drug precursors within §12-22-303(13.5), C.R.S., and required that rules to implement a regulatory program be promulgated by July 1, 1992. The authority to control drug precursors by rule and regulation alone was repealed and a more formal licensing, reporting, and compliance penalty system was enforced.

***Historical Context of Federal Regulation***

In 1988, the U.S. Drug Enforcement Administration (DEA) reported a dramatic increase in the number of domestic clandestine laboratory seizures. Over 800 laboratories were discovered that used large amounts of precursor and essential chemicals necessary in the production of illegal drugs. The Chemical Diversion and Trafficking Act (CDTA) of 1988 attempted to address the diversion of these chemicals through a regulatory process. Authority and criteria for classifying precursor or immediate precursor chemicals were established. An annual registration and inspection process was introduced and a detailed system of reporting was implemented. Additional efforts to control the diversion of drug precursors were introduced through a series of 1989 amendments to the Controlled Substances Act of 1984. The DEA also encouraged states to develop similar programs. The Colorado statute lists many of the same drug precursors, creates a licensing and inspection process, and requires the same record keeping system.

# SUMMARY OF STATUTE

## Licensing and Recordkeeping Statutes

Drug precursors are chemicals that are used lawfully by persons in various legitimate manufacturing processes. They are also used by persons in clandestine drug manufacturing operations. Most illegal drugs are relatively simple to make. Many of the drugs can be made with easily obtainable chemicals with fairly unsophisticated laboratory equipment. No special training or facilities are required to produce illegal drugs. "Therefore, anyone motivated by the high profit potential can get involved in the illegal drug manufacturing business" (Proposed Guidelines For the Cleanup Of Clandestine Drug Laboratories, The Joint Federal Task Force, DEA, May 18,1989).

The CDPHE is directed to license and control the manufacture, possession, transfer, and transportation of drug precursors. The State Board of Pharmacy issues a license to those people and businesses who use controlled substances for legitimate purposes. The license authorizes the use of specific drug precursors and does not allow for the general use of any precursor chemicals. The Department is also responsible for promulgating regulations and charging reasonable fees for issuing a license. The license is an annual fee and is credited to the drug precursor cash fund. The current fee is established at $500 annually.

The following people are exempt from licensing under the drug precursor law:

1. Physicians, dentists, pharmacists, and veterinarians;

2. Agents of a licensed manufacturer of a drug precursor acting in the usual course of the principal's business or employment;

3. Employees of licensed common or contract carriers whose possession of a drug precursor is in the usual course of business;

4. Employees of licensed warehousemen whose possession of a drug precursor is in the usual course of business;

5. Students enrolled in a college chemistry class for credit and when the drug precursor is being used for educational purposes;

6. Officers and employees of appropriate federal, state, or local government agencies;

7. Officers and employees of law enforcement agencies acting according to their duties and;

8. Researchers who are experimenting, studying, or testing any drug analog who are already licensed by the department for controlled substances.

Additionally, the CDPHE may waive the need of a license for a manufacturer, "if it is consistent with the public health and safety" (§12-22-304(5.6)(a), C.R.S.). The criteria the Department must consider when granting a waiver include:

1. Maintenance of effective controls against diversion of drug precursors into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

3. Conviction of the applicant under federal or state laws relating to any controlled substance or drug precursor;

4. Past experience in the manufacture, possession, transfer, or transportation of drug precursors and the existence in the applicant's establishment of effective controls against diversion;

5. Whether the applicant has furnished false or fraudulent material on an application;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances or drug precursors as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

Section 12-22-318, C.R.S. requires that any person licensed to manufacture, possess, transfer, or transport a drug precursor must maintain, on a current basis, a complete and accurate record of each substance manufactured, possessed, transferred, or transported. The records must be maintained for at least two years after the date of the transaction.

This section is confusing as to whether it is subject to the sunset review. It states that most of the section is repealed effective July 1, 1995, and there is no mention of a sunset review prior to repeal. However, because one intent of licensing is to keep track of who is handling drug precursors and the record keeping is an essential component of regulating drug precursor activity, the record keeping requirements are included within this review. The reporting requirements are as follows:

Anyone selling, transferring, or otherwise furnishing a drug precursor to a manufacturer, wholesaler, retailer, or other person must, if the recipient does not represent a business:

1. Obtain the recipient's driver's license number or other photo personal identification certificate number, date of birth, and residential or mailing address;

2. Motor vehicle registration information for the vehicle owned or operated by the recipient;

3. The recipient's signature; and

4. A witness to the signature and identification of the recipient.

If the recipient represents a business, the recipient must present:

1. A letter of authorization from the business that includes the business license or comptroller tax identification number, address, area code and telephone number, and a complete description of how the substance is to be used;

2. The recipient's signature; and

3. A witness to the signature and identification of the recipient.

Manufacturers, wholesalers, retailers, or anyone who sells, transfers, or otherwise furnishes any drug precursor to a person must submit to the CDPHE a report of the transaction. This must be done at least 21 days before the delivery of the drug precursor, and it must be done on a Department form. The Department may authorize the regulated party to submit a comprehensive monthly report instead of the individual transaction reports if the Department determines that:

1. There is a pattern of regular supply and purchase of the drug precursor between the furnisher and the recipient; or

2. The recipient has established a record of utilization of the drug precursor solely for a lawful purpose.

Any theft or loss of any drug precursor must be reported to the Department within 3 days after the discovery. This is a requirement only for those regulated by part 3 of the statute (licensees of controlled substances and drug precursors).

If a manufacturer, wholesaler, retailer, or other person subject to any reporting requirements of part 3 receives a drug precursor from outside of Colorado, it must submit a report of the transaction to the Department. If such a report is not submitted, the person is guilty of a class 1 misdemeanor.

A drug precursor is defined as any substance, material, compound, mixture, or preparation listed in the statute or any of their salts, isomers, or salts of isomers. There are 35 designated drug precursors in the definition. Specifically exempted from the definition of drug precursor are those substances, material, compounds, mixtures, or preparations which are prepared for dispensing pursuant to a prescription or over-the-counter distribution. They must be generally recognized as safe and effective within the meaning of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 355. Also exempt are those substances that have been manufactured, distributed, or possessed in conformance with the provisions of an approved drug application or an exemption for investigational use within the meaning of the "Federal Food, Drug, and Cosmetic Act."

## Federal Law Regarding Drug or Immediate Precursors

Any person who distributes, imports, or exports certain drug precursors and essential chemicals must **register with the United States Drug Enforcement Agency (DEA).** Such persons must identify their customers, maintain retrievable records, report suspicious or unusual orders, and provide advanced notification of imports and exports. The federal law uses the term "immediate precursor" instead of "drug precursor."

## State Rules and Regulations for the Administration and Enforcement of the Drug Precursor Licensing Program

Rules and regulations pertaining to drug precursors are provided within 6 C.C.R. 1008-4, adopted as an emergency regulation on May 20, 1992. The rules were ultimately adopted without comment on July 15, 1992 and became effective on August 30, 1992. Contained within the first chapter is a restatement of definitions and the list of drug precursors identified within §12-22-303, C.R.S. Licenses are effective from July 1st through June 30th and provide authority for specific drug precursors identified by the applicant on forms provided by the Department. A requirement to conspicuously display the license is also included within the rules. Chapter 4.8 of the rules established the licensing fee for July 1,1992 to June 30, 1993 at a flat $500. Subsequent fee levels were to be established by the Department, through the State Board of Pharmacy, based on a cost analysis of administering the Drug Precursor licensing program. This analysis and evaluation of the fee amount was never completed, because only one applicant ever sought a license. The rule continues to restate language within §12-22-301 et. seq., C.R.S., regarding record keeping, required reports, and the Department's authority to conduct inspections.

## The Uniform Controlled Substances Act of 1992 - 18-18-101, C.R.S.

Three key references to the Drug Precursor licensing program are found within the Uniform Controlled Substances Act of 1992. The first reference found in §18-18-101, C.R.S. addresses the requirement for registration of "Every person who manufactures, distributes, or dispenses any controlled substance within this state...", and requires registration of persons doing business in this state "as set forth in parts 1 and 3 of article 22 of title 12, C.R.S.". Registration within this section is defined as licensed. The responsibility for registration is placed with the State Board of Pharmacy. A list of exempted persons is also provided within subsection 3, that is similar to those found in §12-22-304(5.5), C.R.S.

Within part 4, under §**18-18-414(1)(s), C.R.S.** it is stipulated that, “The knowing **manufacture by a licensee of a drug precursor** not authorized by his license, or the knowing **transfer of a drug precursor** not authorized by his license to another licensee or authorized person” is an unlawful act. **Paragraphs o, p, and q also state it is unlawful to: knowingly transfer drug precursors to an unauthorized licensee, to use a license number which is fictitious or that belongs to another person, and it is unlawful to acquire or obtain or attempt to acquire or obtain a drug precursor through any misrepresentation**. Subsection 5 further states that anyone who violates these paragraphs under subsection one commits a **class 4 felony**. A class 4 felony is punishable by **2-8 years of incarceration** at a state prison facility.

# SUNSET ANALYSIS

## Mission of Drug Precursor Program

The legislative declaration for Part 3 of the Colorado Controlled Substances Act found that strict control of controlled substances and drug precursors was "necessary for the immediate and future preservation of the public peace, health, and safety" (§12-22-302, C.R.S.). A program that incorporated licensing, record keeping, inspections, and a severe penalty for violating conditions of the Act were consequently enacted. The program manager also reports the program's goals were consistent with the Drug Enforcement Administration's interest in cracking down on clandestine drug laboratories throughout the United States. The program was originally enacted as early as 1981, but no enforcement or regulatory activity related to drug precursors arose until 1992.

## Is Public Health, Safety and Welfare at Risk?

***Who is Licensed?***

In 1990 and again in 1992, the CDPHE identified 27 Colorado businesses that were engaged in the manufacturing, possession, sale, or transfer of drug precursors. Each company was either visited or contacted by phone and provided information on the requirement for licensing and record keeping. Only one company, the **Hach Company of Loveland**, sought to comply with the licensing and record keeping requirements. The program manager reports that the **remaining 26 Colorado businesses made the decision to discontinue their drug precursor business in Colorado.** These companies either eliminated this service to their customers or simply moved these business transactions to offices in one of **46 other states without licensing requirements**. Two large and prominent companies from the industry that elected to discontinue this business in Colorado are Fisher Scientific and Dow Chemical, U.S.A.

***Actions Against a Licensee***

The program manager reports that **no penalties or other actions have been taken against the sole licensee** in over three years. A visit to the Hach Company, during this sunset review, also appears to support the program manager report. The license was conspicuously displayed in a public location at the site. The room and cabinet containing the drug precursors was locked, and access was limited to only 3 staff members. The company was also able to produce every report submitted since August 11, 1992. The licensee also stated that no theft or inappropriate sale of drug precursors had ever occurred at the company. The licensee further stated that any sales would be handled out of the company headquarters in Iowa. Additionally, no such sales would take place until the customer could demonstrate a legitimate need for the drug precursor materials. It was further suggested, by the licensee, that chemical manufacturers and other companies using drug precursors would have strict internal controls to prevent theft or inappropriate sale of drug precursors. Specifically, the licensee reports that industry customers tend to place routine orders. Any business or individual who significantly changes their routine order would likely be questioned or the incident reported to local law enforcement. The provision within statute to allow for a monthly report in lieu of transaction reports may be in response to the stable nature of drug precursor transactions.

***Other Prosecutions***

The program manager reports that he has never been asked to testify by a state district attorney or by any other court in Colorado, seeking to prosecute an individual for failure to comply with the Drug Precursor law. The Colorado Bureau of Investigations also reports that their office has never investigated, arrested, or had someone prosecuted under this law. The Colorado District Attorneys Council and the County Sheriffs of Colorado did identify **one criminal case** involving drug precursors. In the **People vs. Scott Allen Noland**, the defendant was convicted of attempted manufacture and possession of a schedule II controlled substance in the Douglas County District Court in 1987. The people argued that phenylacetoacetonitrile, present in the defendant's laboratory, if combined with sulphuric or phosporic acid could be used to produce, phenyl-2-propanone (P-2-P). The chemical P-2-P is not itself a drug, but if combined with methylamine could be used to synthesize "speed". The defendant argued that these chemicals were used to create perfume esters and that this was the legitimate purpose of his possessing these materials. The **conviction was reversed** by the Colorado Court of Appeals on the basis that "phenylacetoacetonitrile seized from the defendant's private chemical laboratory,...was insufficient to support conviction" [(See People v. Noland, 739 P.2d 906 (Colo. App. 1987)].

## Regulation or Criminal Investigation?

It appears that the Colorado Drug Precursor Licensing program is not efficiently nor effectively designed to prevent the diversion of drug precursors for illegal uses. Licensing is primarily intended to keep unqualified individuals from engaging in a harmful activity, and to prevent them from causing direct or indirect public harm. The focus of this regulatory program has been to license qualified individuals in an attempt to regulate an illegal activity. Clearly, the licensing and record keeping required under this act are not preventing unqualified persons from producing drug precursors, and they do not appear to promote public peace, health or safety. The most significant impact the program appears to have is the diversion of business from Colorado by companies that elected not to submit to drug precursor licensing and reporting requirements. This sunset review submits that a criminal investigation is a more efficient, effective and economical method to regulate the diversion for illegal uses of drug precursors.

Staffing time and resources used to implement the drug precursor program include no more than 10 percent of the efforts from an Administrative Officer and Secretary. These resources are used to collect one $500 licensing fee and to issue a licensing certificate to the sole licensee. An inspection/visit of the licensee facility is usually conducted when the licensing certificate is delivered. As reported earlier in this chapter, the licensee reports no theft or sale of drug precursors has occurred in over 3 years. The program manager also reports he has never been asked to testify on behalf of the state for the prosecution of anyone who was in violation of the drug precursor law. The one regulatory activity in nearly 15 years, since the law's enactment, involved the criminal investigation and prosecution of an individual with a private chemical laboratory. A criminal investigation is the method of regulation that seems most appropriate for the control of persons acting outside the law to produce illicit drugs. Both federal and state law provide for severe criminal penalties, when it is demonstrated that drug precursors were used for illicit or unlawful purposes.

This sunset review believes that it is necessary to preserve language that enforces severe penalties for the illegal use of drug precursors. Using a criminal investigation approach, medical professionals, chemical businesses, universities, and persons with private laboratories would all need to demonstrate their legitimate and lawful use of drug precursors when law enforcement officials suspected a problem. A representative from the County Sheriffs of Colorado reports that anyone using drug precursors illegally and without a license would not be prosecuted for failure to have a license, but would be prosecuted for engaging in a criminal activity. However, the Colorado District Attorneys Council argued that, "licensing provides an excellent tool for monitoring the transfer, distribution, and manufacturing of drug precursors." This review discovered that persons and businesses that have legitimate uses for drug precursors already maintain a series of internal and external sale and record keeping controls. Therefore, the need for licensing appears to be a duplication.

# RECOMMENDATIONS

## Should the Drug Precursor Licensing Program be Continued?

The stated purpose of the drug precursor program is to prevent the unlawful diversion of drug precursors, substances that could be used in the manufacturing of illicit drugs, from legitimate sources for illegal uses. The Colorado Drug Precursor licensing program does not appear to effectively achieve this purpose. The Colorado program seeks to license legitimate business activity in an attempt to regulate illegal persons and their illicit activities. The Colorado statute also excludes a number of individuals and businesses which also raises questions regarding the need for licensing. The net effect of this form of regulation appears to be the loss of state revenue from the business transactions of 26 chemical companies, who elected to eliminate or move their drug precursor business to another state. This sunset review suggests that licensing is not an appropriate form of regulation to achieve the stated purpose of this act. This sunset review also suggests that criminal investigations of suspected offenders is a more appropriate form of regulation. This sunset review makes the following recommendations intended to cause the termination of this regulatory program, while retaining legislative language prohibiting the diversion of drug precursors for illicit purposes.

***Recommendation 1 - The General Assembly should terminate the Colorado Drug Precursor licensing program as provided for under §12-22-301 et. seq., C.R.S.***

## Repeal Licensing Sections

***Recommendation 2 - The General Assembly should repeal §12-22-304 through §12-22-308 and §12-22-314(1)(l), C.R.S., that create the Drug Precursor Licensing program.***

In order to terminate the Drug Precursor licensing program it is recommended that the sections which directly create the licensing program be repealed. Section 12-22-304, C.R.S. establishes the requirement for licensing for each place of business or professional practice located in Colorado. This section also directs the CDPHE to promulgate regulations and charge reasonable fees related to the licensing requirement. A number of exceptions to the licensing requirement and authority for the Department to waive licensing are also provided within this section. Section 12-22-305, C.R.S. establishes guidelines for the issuance of licenses and authorizes the Department to issue all licenses under the Drug Precursor program. Section 12-22-306, C.R.S. addresses the financial disposition of licensing fees. Section 12-22-307, C.R.S. establishes the qualifications for licensing, and §12-22-308 authorizes the Department or Board to deny, revoke or suspend a license. Finally, §12-22-314(1)(i), C.R.S. makes it unlawful for the "failure to obtain a license as required by this part 3."

## Recordkeeping

***Recommendation 3 - The General Assembly should amend or repeal provisions of §12-22-318, C.R.S., that contain unnecessary record keeping requirements.***

It is recommended that the recordkeeping requirements of this section be either amended or repealed to eliminate references to a licensing requirement and to ensure that drug precursor activities are documented in sufficient detail to accommodate any criminal investigation of their illegal use or diversion. Specifically, **subsection (1)(b)(I) should be amended** to read, “Each person ~~licensed under section 12-22-304(2.5)~~ who manufactures, possesses, transfers, or transports a drug precursor shall maintain, on a current basis, a complete and accurate record AND INVENTORY of each substance manufactured, possessed, transferred, or transported" ~~by the licensee in accordance with regulations of the department~~. **Paragraph (c) of subsection (7) should be repealed** and thus eliminate the requirement to report drug precursor transactions to the Department at least 21 days prior to the transaction. This provision can hinder the normal conduct of business and does not account for existing internal and external sale and manufacturing controls already enforced by the industry. This provision is also a duplication of the record and inventory requirements already in force under this section. Lastly, it is recommended that **subsections (8) to (11) also be repealed**. These requirements are also a duplication of the existing record and inventory requirements.

## Rules and Regulations

***Recommendation 4 - The General Assembly should repeal §12-22-321, C.R.S., that directs the Department to create rules and regulations for the administration and enforcement of the Drug Precursor Licensing program.***

This sunset review recommends that §12-22-321, C.R.S. be repealed. In chapter 2 of this report, we report that the rules and regulations for the administration and enforcement of the Drug Precursor Licensing program largely repeated existing language within statute. These rules and regulations did not add any more significant direction on how this program should be administered, and they provided no more technical definition of what constituted a drug precursor. Additionally, the repeal of these rules and regulations is consistent with the recommendation to eliminate the Drug Precursor Licensing program.

## Regulation of the Manufacturing, Distribution and Dispensing of Drug Precursors

***Recommendation 5 - The General Assembly should create a unique Part within §18-18-302 or 303, C.R.S., for the regulation of the manufacturing, distribution and dispensing of drug precursors.***

This sunset review concludes that the purpose of preventing the diversion of drug precursors for illegal uses can more effectively be achieved through criminal investigation and not through licensing. This recommendation seeks to move the remaining sections of article 12, title 22 within a new part of the Uniform Controlled Substances Act of 1992. As stated in chapter 3 of this report, **it is necessary to preserve language that enforces severe penalties for the illegal use of drug precursors**. The remaining sections of the Drug Precursor law include: the short title and legislative declaration, definitions, a list of controlled substance schedules, a listing of unlawful acts and penalties, provisions prohibiting fraud and deceit, notice of conviction requirements, a list of exemptions to §12-22-314, C.R.S., the amended record keeping requirements, and provisions requiring the cooperation of persons and business with any investigations conducted by the Department or the Board. Retaining these sections under a new part entitled "REGULATION OF MANUFACTURE, DISTRIBUTION, AND DISPENSING OF DRUG PRECURSORS" should provide the necessary language to prosecute any offenders violating either federal or state laws, regarding drug precursors. This language should also provide for the prosecution of persons not engaged in a legitimate business who violate either federal or state laws, regarding drug precursors.

## Conforming Amendments

***Recommendation 6 - The General Assembly should amend language within §18-18-414, C.R.S., to accommodate the elimination of the Drug Precursor Licensing program.***

The 1992 amendments to the Drug Precursor Licensing program included references to §18-18-414, C.R.S., that require amended language. The Colorado District Attorneys Council report that "the licensing requirements under §12-22-304 are connected to the penalties in §18-18-414." They also identified that the class 4 felony penalties are linked by language with a licensing requirement. It is therefore recommended that **subsection (1)(j), (1)(p), and (1)(s) be repealed**. These provisions directly reference a licensing requirement and should be repealed if the drug precursor licensing program is terminated. It is further recommended that **subsection (1)(o) be amended** to read, "Knowingly transferring drug precursors except to ~~an authorized licensee;~~ A LEGITIMATE BUSINESS INTEREST." The **remaining language within subsection (1) still provides for a class 4 felony penalty** when a person: fails to comply with record keeping requirements, knowingly transfers drug precursors to an illegitimate business interest, or when a person knowingly attempts to or acquires a drug precursor through any misrepresentation.

***Recommendation 7 - The General Assembly should amend language within §18-18-302(1), C.R.S., to accommodate the elimination of the Drug Precursor Licensing program.***

The 1992 amendments to the Drug Precursor Licensing program also referenced Section 18-18-302, C.R.S that requires the registration, meaning the licensing, of "manufacturers, pharmacists, pharmacies, and humane societies located in this state,...or doing business in this state, by the state board of pharmacy as set forth in parts 1 and 3 of article 22 of title 12, C.R.S." It is recommended that **the reference to part 3 of article 22 of title 12, C.R.S. be repealed**. This would remove the requirement that persons doing drug precursor business in this state be registered or licensed as stated within this section. Again it is emphasized that the remaining language that is recommended for a new part under §18-18-302/303, C.R.S., should be sufficient to prevent the diversion of drug precursors for illegal uses.

# *APPENDICES*

## 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 of the Department of Regulatory Agencies 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 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 public interest.

# 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, C.R.S.

(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), C.R.S.

(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) "Drug precursor" means any substance, material, compound, mixture, or preparation as listed in this subsection (13.5), or any of their salts, isomers, or salts of isomers. "Drug precursor" specifically excludes those substances, materials, compounds, mixtures, or preparations which are prepared for dispensing pursuant to a prescription or over-the-counter distribution as a substance which is generally recognized as safe and effective within the meaning of the "Federal Food, Drug, and Cosmetic Act", 21 U.S.C. 355, as amended, or have been manufactured, distributed, or possessed in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of section 505 of the "Federal Food, Drug, and Cosmetic Act", 21 U.S.C. 355, as amended. The drug precursors are designated as follows:

(a) Phenyl-2-propanone;
(b) Methylamine;
(c) Ethylamine;
(d) D-lysergic acid;
(e) Ergotamine tartrate;
(f) Diethyl malonate;
(g) Malonic acid;
(h) Ethyl malonate;
(i) Barbituric acid;
(j) Piperidine;
(k) N-acetylanthranilic acid;

(l) Pyrrolidine;
(m) Phenylacetic acid;
(n) Anthranilic acid;
(o) Morpholine;
(p) Ephedrine;
(q) Pseudoephedrine;
(r) Norpseudoephedrine;
(s) Phenylpropanolamine;
(t) Propionic anhydride;
(u) Isosafrole;
(v) Safrole;
(w) Piperonal;
(x) Thionylchloride;
(y) Benzyl cyanide;
(z) Ergonovine maleate;
(aa) N-methylephedrine;
(bb) N-ethylephedrine;
(cc) N-methypseudoephedrine;
(dd) N-ethylpseudoephedrine;
(ee) Chloroephedrine;
(ff) Chloropseudoephedrine;
(gg) Nitroethane;
(hh) Hydriodic;
(ii) Benzaldehyde.

(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), C.R.S.

(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 part 1 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, choses 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, C.R.S., 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, C.R.S., 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) (a) The department shall, on or before July 1, 1992, promulgate regulations and charge reasonable fees relating to the licensing and control of the manufacture, possession, transfer, and transportation of drug precursors. The fees established under this subsection (2.5) shall be collected by the department and transmitted to the state treasurer, who shall credit the same to the drug precursor cash fund, which fund is hereby created.

(b) Every person who manufactures, possesses, transfers, or transports any drug precursor or who proposes to engage in the manufacture, possession, transfer, or transportation of any drug precursor must obtain, annually, a license issued by the department.

(c) Persons licensed by the department to manufacture, possess, transfer, or transport drug precursors may manufacture, possess, transfer, or transport those substances to the extent authorized by their licenses and in conformity with the other provisions of this part 3.

(d) This subsection (2.5) is repealed, effective July 1, 1995. Prior to said repeal, this subsection (2.5) shall be subject to review by the sunrise and sunset review committee pursuant to the provisions of section 2-3-1201, C.R.S.

(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, C.R.S., 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, C.R.S.

(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), C.R.S.

(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, C.R.S., by the sunrise and sunset review committee.

(5.5) (a) The following persons are not required to be licensed under subsection (2.5) of this section and may lawfully possess drug precursors:

(I) Physicians, dentists, pharmacists, and veterinarians;

(II) An agent of any licensed manufacturer of any drug precursor if he is acting in the usual course of his principal's business or employment;

(III) An employee of a licensed common or contract carrier or licensed warehouseman whose possession of any drug precursor is in the usual course of the licensed common or contract carrier or licensed warehouseman's business;

(IV) A student enrolled in a college chemistry class for credit if the student's use of the drug precursor is for a bona fide educational purpose and if the chemistry department of the educational institution otherwise possesses all the necessary licenses required by the department;

(V) Officers or employees of appropriate agencies of federal, state, or local governments and law enforcement agencies acting pursuant to their official duties;

(VI) Every researcher, including analytical laboratories, experimenting with, studying, or testing any drug analog who is licensed by the department pursuant to the requirements of subsection (1) of this section.

(b) This subsection (5.5) is repealed, effective July 1, 1995. Prior to said repeal, this subsection (5.5) shall be subject to review by the sunrise and sunset review committee pursuant to the provisions of section 2-3-1201, C.R.S.

(5.6) (a) The department may waive by regulation the requirement for licensing of certain manufacturers if it is consistent with the public health and safety.

(b) This subsection (5.6) is repealed, effective July 1, 1995. Prior to said repeal, this subsection (5.6) shall be subject to review by the sunrise and sunset review committee pursuant to the provisions of section 2-3-1201, C.R.S.

(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 except in accordance with part 9 of article 5 of title 25, C.R.S.