COLORADO DEPARTMENT OF REGULATORY AGENCIES
OFFICE OF POLICY AND RESEARCH

COLORADO STATE BOARD OF PHARMACY

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 **State Board of Pharmacy**. 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 Section 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 Department of Regulatory Agencies has concluded its Sunset Review of State Board of Pharmacy. After independent research, interviews with Board members, the regulated community, and other interested parties, DORA recommends continuing the regulatory authority of the Board. The report makes several specific recommendations, both statutory and administrative, to modify the program if it is continued.

Abuse of prescription drugs is prevalent in Colorado and nation wide. Reporting the distribution of controlled substances at the consumer level is a weak link in drug abuse enforcement. A key recommendation of the report is a centralized reporting system for controlled substances by prescription drug outlets.

The National Association of Boards of Pharmacy (NABP), has developed a national Model Pharmacy Act (MPA). NABP is recommending member states adopt the MPA to develop consistency between state programs. Several of the recommendations in the report were based on language and recommendations from the MPA.

The MPA contains provisions giving licensed pharmacists limited prescriptive authority. A complete analysis of this provision is beyond the scope of this report. However, no evidence was presented which indicated a risk to the public by continuing the current restrictions on pharmacists releasing drugs by prescription order only. Therefore, the report does not include a recommendation for prescriptive authority. It is expected that members of the profession will discuss the issue in detail during the Sunset Hearing.

Another provision in the MPA, endorsed by the Board, is the ability to levy civil fines on practitioners as a disciplinary option. Some occupational boards in Colorado, such as Accountancy, Outfitters, Veterinary, and the Gaming Commission, have the ability to use fines as a disciplinary option. Use of fines is appropriate when the damage caused is economic. In health care professions, the primary concern is physical harm, not economic. For this reason, the report does not recommend fines as a disciplinary option.

BACKGROUND

The State Board of Pharmacy, in the Division of Registrations, Department of Regulatory Agencies (DORA) shall be terminated July 1, 1996 unless continued by the general assembly. During the year prior to this date it is the responsibility of DORA to conduct an analysis of the program in compliance with § 24-34-104, C.R.S.

The purpose of this review is to determine whether the State Board of Pharmacy should be continued for the protection of the public health, safety and welfare. The report also evaluates the performance of the Division of Registrations in relation to this program. During this review, the Division must demonstrate that there is still a need for the program and that the regulation is the least restrictive regulatory structure consistent with the public interest. DORA's findings and recommendations are submitted to the Sunrise and Sunset Review Committee of the Colorado General Assembly. Statutory criteria used in the sunset review is found in the appendix of this report.

The Sunset Review process includes an analysis of the statute, interviews with state authorities, Board of Pharmacy members, professional and trade association representatives, and regulated individuals. Every effort is made to elicit information and comments from all interested parties.

SUMMARY OF STATUTE

The Colorado Pharmacy Act is contained in § 12-22-101 *et seq*., C.R.S. The Act defines the scope of the practice of pharmacy, creates the State Pharmacy Board (Board), and establishes the framework for the promulgation of regulations by the Board. The Board consists of five licensed pharmacists and two public members, all appointed by the governor. The Act specifies geographical diversity, by congressional district. The Board is required to meet at least three times per year and elect its own officers. Section 108 of the Act gives the Board broad authority to promulgate regulations necessary for the administration of the Act.

Definitions are contained in § 102 of the Act. The Act defines prescription drug outlet (PDO) as "any outlet where prescriptions are filled or compounded, and are sold, dispensed, offered, or displayed for sale." Outlet is defined as "... any prescription drug outlet, hospital, institution, nursing home, rural health clinic, convalescent home, extended care facility, family planning clinic, wholesaler, manufacturer, mail order vendor, other than a pharmacist, with facilities in this state who engages in the dispensing, delivery, distribution, manufacturing, wholesaling, or sale of drugs or devices."

Section 110 contains the powers and duties of the Board which includes:

- Inspection of pharmacies and investigation of violations of the Act or regulations promulgated under the Act;
- Administration of examination for licensure;
- The ability to apply to the courts for restraining orders and injunctions to enjoin violations of the Act;
- The power to grant licenses and renewals;
- The power to deny, revoke or suspend licenses, for cause; and

- The ability to impound and destroy adulterated or misbranded drugs and devices at a prescription drug outlet.

All pharmacists are required to fulfill a Board approved internship prior to licensure in Colorado. The internship must be supervised and evaluated by a Board approved licensed pharmacist (preceptor). The Board has regulatory authority over the requirements for internship, including the areas of study, evaluation and preceptor approval. Guidelines for the Board are contained in § 12-22-111, C.R.S.

The Board is responsible for the control and regulation of drugs under § 12-22-112, C.R.S. This includes the regulation of retail sales, purity and quality of drugs, the procedures, equipment, environment and supplies necessary to compound or dispense drugs, and the control of the sale of medical devices requiring a prescription.

Insurance companies licensed to sell malpractice insurance to pharmacists in Colorado must report malpractice claims to the Board. The Board may consider information provided by the insurance company malpractice settlement in disciplinary hearings and may review such information in closed session as provided for in § 12-22-113.5, C.R.S.

The regulation of pharmacists and PDOs is a cash funded program. Fees are established and collected in accordance with § 24-34-105, C.R.S. Fees for the licensing of pharmacists, interns, PDOs, pharmacy managers, changing pharmacy names or managers, and issuing duplicate licenses for any licensee are authorized by § 12-22-114(1), C.R.S. Any pharmacist licensed by the state for fifty years or more is exempt from the payment of fees for continued licensure.

Under § 12-22-115, C.R.S., The Board has the ability to use the resources of any recognized accrediting organization in determining the approval of a school or college of pharmacy for meeting the educational requirements for licensure in Colorado. The Board must maintain a list of approved schools of pharmacy from which graduation is necessary to obtain a license to practice pharmacy in Colorado.

The Act, in §§ 12-22-116 - 118, C.R.S., outlines the application procedures for licensure as an intern, pharmacist, outlets, manufacturer, or wholesaler. The Act identifies four classes of pharmacist licenses and provides an exemption from licensure for hospital residency programs. Applicants for professional licensure must pass a Board approved written examination. Graduates from foreign pharmacy schools may be required to demonstrate proficiency in the English language. The Board is required to issue a license by endorsement to a licensee from another jurisdiction with substantially similar licensing requirements, provided the licensee's disciplinary record is satisfactory.

All PDOs must register with the Board and must be managed by a licensed pharmacist. A pharmacist may manage only one PDO. The pharmacy owner must notify the Board of management or ownership changes. PDOs owned by political subdivisions of the state are exempt from the registration provisions of §12-22-119, C.R.S.; however, they must obtain a certificate of compliance from the Board. Section 119 also allows a licensed pharmacist to delegate certain pharmacist functions (such as the compounding, dispensing, labeling, delivery, storage, and distribution of drugs and devices and the maintenance of proper records) to a non licensed person under the licensed pharmacist's direct and immediate supervision. Certain outlets recognized in section 120 are exempt from the provisions for the management by a pharmacist by § 12-22-119(3)(b), C.R.S. Such outlets must have written protocols for the dispensing of drugs, prepared by a consulting pharmacists and approved by the Board. The Board has regulations on the frequency of protocol review, and regulates the supervision of these outlets by licensed pharmacists.

Section 120 provides the Board with the authority to register various types of drug outlets, including manufacturing facilities. The section requires the Board to accept nursing, residential and intermediate care facility licenses issued by the **Health Facilities Division of the Colorado Department of Public Health and Environment**, as registration. Non prescription drugs are exempted from the Pharmacy Act in this section. Section 120(1)(e) identifies an "other" category of PDOs. These are usually community health clinics, jails or prisons, planned parenthood clinics, and animal shelters. These outlets may dispense prescription drugs under approved protocols without the immediate and direct supervision of a licensed pharmacist.

Section 121 contains provisions that govern the compounding, dispensing and sale of prescription drugs and devices. Dispensing provisions exempt authorized emergency room personnel and licensed practitioners from regulation by the Board when dispensing to patients. Section 12-22-121(14), C.R.S., requires the Board to promulgate regulations quantifying the number of non-licensed persons a pharmacist may supervise when the pharmacist and non-licensed person are engaged in dispensing. Pharmacies are authorized to provide emergency medical kits to specifically identified licensed health care facilities.

All licensed pharmacists are authorized by Section 122 to issue medications without a valid prescription under very limited circumstance. These situations are limited to providing small amounts of medication under previously authorized prescriptions when the prescriber cannot be contacted and, in the professional judgment of the pharmacist, the medication is necessary for the patient.

Section 123 contains labeling requirements for medications dispensed pursuant to a prescription order. Section 124 allows pharmacist to recommend and substitute generic drugs for the prescribed medication with the patient's permission, unless specifically prohibited by the prescriber.

Disciplinary authority for the Board is contained in Section 125. This includes the ability to suspend, deny, revoke or place limitations on a license or registration issued by the Board. Licensees or registrants are afforded a hearing in accordance with the State Administrative Procedure Act before disciplinary actions take effect. The Board may issue a formal "Letter of Admonition" in situations where violations are determined to be insufficient to warrant more severe action. Disciplinary actions are subject to judicial review under § 12-22-125.5, C.R.S.

Sections 126 and 127 prohibit certain acts, such as obtaining or dispensing drugs by fraud, deceit, or subterfuge. First offenses of the Act are considered class 2 misdemeanors. Second and subsequent offenses are classified as class 6 felonies.

Under § 128, new drugs are prohibited from sale or distribution, until approved by federal law for interstate sale. Exceptions are provided for research by persons qualified to conduct safety and effectiveness tests.

Prescription drug outlets may advertise prescription drug prices. Section 129 requires advertisements of drugs by brand or proprietary name to include the generic drug name.

Part Two of the Act regulated the working hours of licensed pharmacists. This part two was repealed in 1981. Part Three of the Act is also known as the "Colorado Controlled Substances Act". Part Three authorizes the Colorado Department of Public Health and Environment (CDPHE) to regulate substance abuse programs and provides for the licensing of persons manufacturing, transporting, possessing, or transferring a drug precursor by CDPHE. The licensing of drug precursors is the subject of a separate sunset report by DORA.

Part Five of the Act concerned the control of drug paraphernalia. This part was repealed in 1992. Part Six of the Act contains provisions for the Pharmacy Peer Health Assistance Diversion Program. Part Six was established in 1991 and amended extensively in 1993.

Regulation Review

The regulations promulgated by the Board are contained in the Colorado Code of Regulations (CCR) 3 CCR 719-1 (1993). The regulations were last modified in June of 1992, effective July 30, 1992.

The Board has rules establishing a professional code of conduct. Included in this code of conduct are requirements forbidding the practice of pharmacy while employed by a person authorized to prescribe drugs, or to participate in any plan which detrimentally affects a patient. The code requires pharmacists to advise patients on the proper use and affects of a prescription when requested, or when in the pharmacist's judgment it is in the best interest of the patient. The code outlines a standard of confidentiality regarding patient information.

The next sections of the regulations concern prescription orders and dispensing of prescription drugs or devices. Regulations specify who may issue and receive orders, the format in which orders must be received, procedures to follow when prescriptions are transferred between pharmacies, recordkeeping requirements for controlled substances, and labeling requirements for dispensed prescriptions.

The Board has regulations for the licensing and evaluation of pharmacy interns, and the approval of intern preceptors (supervisors). The Board licenses four classes of pharmacists. A Class I licensee is a person licensed in Colorado prior to July 2, 1979; Class IV licenses are granted to applicants applying for licensure by examination in Colorado (licensure by examination includes a Board administered jurisprudence examination); Class V is a license granted by endorsement; and a Class VI license is issued to a graduate of a foreign school of pharmacy who meets the licensing requirements in Colorado (including a Board approved English proficiency examination).

Board regulations concerning prescription drug outlets are extensive. The regulations require registration of all outlets, notification and approval of changes in ownership or management, and controlled substance inventories in the event of ownership or management changes. The Board has procedures for the closing of a pharmacy to ensure patients are notified and that their records are available for transfer to another pharmacy.

The regulations detail, in section 5.01.41 through 5.01.65, physical requirements for a prescription drug outlet. Because of the importance of the compounding area, where ingredients are mixed, weighed, or otherwise prepared, emphasis is placed on stringent standards in this area. Regulations specify the size of the counter top in the drug compounding area, required equipment, ventilation, the availability of a reference library, requirements for compounding sterile parnteral products and security requirements. Regardless of who owns the building or business where the outlet is operated, the pharmacist has control and responsibility for the drug compounding area.

The Board must approve written protocols for compounding, dispensing and recordkeeping by outlets, prior to registration approval. Non-pharmacy outlets, such as community clinics, jails, schools, and county health departments, must have approved protocols provided by a consulting pharmacist. The consulting pharmacist must periodically visit the facility, specified by a schedule in the regulations, to ensure compliance with protocols and applicable laws.

The Board regulates the contents and access to emergency medical kits provided to health care facilities specified in the Act. Kits contain small amounts of prescription drugs. These are generally a 12-72 hour supply of the drugs, such as nitroglycerin tablets, antinfectives, analgesics and tranquilizers, commonly in an emergency. Kits must be registered with the Board and the pharmacy supplying the kit maintains ownership and responsibility for the drugs contained in the kit. Pharmacies must maintain separate records for each kit and inspect them at least annually. Facilities opening a kit must notify the pharmacy within 72 hours and provide a written prescription for any of the contents removed.

Section 11 of the Pharmacy Regulations contain the requirements for the use of computers or automated data processing systems in the practice of pharmacy. New and refill prescription order transactions must be entered into the system at the time of the transaction. Daily printouts of prescription drug transactions must be maintained and available for inspection by Board representatives. Board regulations include detailed requirements on the information that must be included in the daily printouts. Transactions involving controlled substances must be specifically identified.

Nuclear pharmacies deal with the preparation and delivery of radioactive material used in medical procedures. They have special requirements to comply with, contained in section 12 of the regulations. In addition to the requirements for licensure as a pharmacist, nuclear pharmacists must complete a minimum of 200 hours of instruction in radiopharmaceutical service from an approved program. The Board has developed special record keeping requirements with which nuclear pharmacies must comply. These are in addition to those which are standard for prescription drug outlets. Nuclear pharmacies must also comply with regulations of the Colorado Department of Public Health and Environment regarding radiation control.

The Board has established procedures for any individual to petition the Board for a declaratory order to clarify the applicability of any statutory or regulatory provision enforced by the Board. This is commonly used by persons establishing new procedures in a pharmacy who want to make sure they are in compliance with Board regulations. The procedures for requesting a declaratory order are detailed in section 13 of the regulations.

Section 14 of the regulations is devoted to recordkeeping requirements for outlets. Inventory records must be kept a minimum of two years. The regulations specify which records must be maintained on site and which must be made available upon request by the Board or its representative. The recordkeeping requirements are more stringent for controlled substances. They incorporate by reference sections of the federal code of regulations applying to controlled substances.

The Board has specific regulatory requirements for drug wholesalers and drug manufacturing facilities. These are contained in sections 15 and 16 of the regulations. Recordkeeping and security issues are a high priority, in order to prevent the unlawful distribution of controlled substances.

The final section of the Board regulations deal with the use of electronic transfer orders (ETO), including facsimile (fax) machines for transmitting prescriptions. The regulations cover the receipt of both original and transfer prescriptions. The dispensing of controlled substances via an ETO prescription is prohibited.

of five licensed pharmacists with at least five years of experience in the state of Colorado and two public members. All are appointed by the governor. No Board member may serve more than two consecutive four year terms. At least one member must reside in each congressional district and no more than four members shall belong to the same political party. The Board elects its own officers from the appointed members. The Board is required by § 12-22-107, C.R.S. to meet at least three times per year; however, in practice, it meets more frequently.

The investigations, inspections and administrative functions of the Board are performed by classified state employees of the Department of Regulatory Agencies, Division of Registrations. Oversight of the administrative staff is provided by a Program Administrator. This Program Administrator also supervises the staff of the Veterinarian and Optometric Boards. The Program Administrator oversees three full-time licensed pharmacists to conduct inspections and investigate complaints. DORA also employs 2.5 full-time equivalent (FTE) clerical support staff to process license and registration applications, renewal applications, and to provide administrative support to the Board.

The regulatory program for pharmacists is cash funded by the licensing and registration fees of the regulated individuals and businesses. Colorado currently has 740 registered pharmacies and 4,900 licensed pharmacists. The Board has also issued licenses to 50 wholesalers and 5 manufactures. There are approximately 1,400 other special licenses or registrations issued by the Board each year for interns, preceptors, limited licenses (animal shelters), or other outlets (prisons, community health clinics). The fees for licensing and registration are adjusted each year based on the prior years expenses in relation to the number of licensees. The relatively large number of licensees provides a sufficient base to absorb expenses without extreme variations in fees. The licensing fee has remained less than $200 per two year cycle for the past several years (see Table 1 for a partial list of related fees).

The Board of Pharmacy consists

Table 1

NABP Examination processing	25
Jurisprudence	35
Examination score transfer	60
Intern license	26
PDO (1 year renewal)	125
PDO (new)	250
PDO ownership transfer	250
PDO location transfer	100
Other Outlet	75
Controlled substance distributor	250
Controlled substance manufacturer	250
Wholesaler outlet	250
Manufacture outlet	250
Endorsement processing fee	175**
Pharmacist renewal	196*
Pharmacist reinstatement	75

* 1995-96 projected fee

** Persons obtaining a license by endorsement also pay the renewal fee.

Under the provisions of 12-22-603 (3)(b) C.R.S., the Board is required to establish a fee for each licensee, not to exceed $25 biannually, for the administration of the Peer Assistance Program. The maximum fee for any licensee is currently $22 biannually.

The regulation of prescription drugs is a shared responsibility of the federal and state governments. The federal government, through the “Federal Food, Drug and Cosmetic Act”, Food and Drug Administration, Drug Enforcement Administration, and the “Comprehensive Drug Abuse Prevention and Control Act” has extensive authority to control various chemical compounds that have therapeutic benefits.

While the federal government has extensive control and recordkeeping requirements over what may be dispensed, individual states have broad latitude over who may administer, dispense and prescribe controlled substances. In Colorado, as in most states, prescription drug control is divided along two lines. The first is those who may prescribe controlled substances. Traditionally, this has been limited to licensed medical professionals, physicians, dentists and veterinarians, although recent trends have expanded prescriptive authority.

The second, dispensing has with few exceptions, been the exclusive domain of pharmacists. Colorado has been licensing pharmacists since the State Board of Pharmacy was created as an independent licensing authority in 1887. Original licensing requirements were (1) graduation from a school of pharmacy and two years of experience or (2) two years of experience and a passing score on a Board administered examination.

The authority of the Board, and regulatory requirements for pharmacists, has changed several times in the 108 years since its creation. The makeup of the Board has been changed from only licensed pharmacists selected by the Pharmacy Association to a mixture of public and professional members appointed by the governor. In 1968, administration of the Board was transferred to the DORA, Division of Registrations by a Type 1 transfer under the Administrative Organization Act. It was not until 1979 that persons without a degree in pharmacy were excluded from obtaining a pharmacist license.

SUNSET ANALYSIS

The Board has a satisfactory mix of public and professional members. In making recommendations for appointments for new members, professional organizations recognize the need to diversify the professional members by areas of specialization, i.e. retail pharmacist, nuclear pharmacist, hospital pharmacist. The requirement that at least one person on the Board must be from each congressional district sometimes limits the pool of candidates making it difficult to achieve the desired practice representation.

The original intent of the regulation of pharmacists was to ensure minimum qualifications of those compounding prescription drugs. However, national and state regulatory requirements are now focused on two main objectives.

The first, is to ensure the public receives the quality and strength of medications prescribed by medical practitioners. The public has an expectation that when a medical professional prescribes drug therapy to resolve a medical condition that the course of treatment is correct. They also expect that when they receive a prescription from a licensed pharmacist, it is the correct drug and the proper dosage. Not receiving the correct drug, or dosage, may have serious consequences for the patient. Under utilization of drug therapy may result in prolonging the illness or only masking a serious condition. Overdoses of controlled substances may lead to severe injuries or even death. Even an overdose of antibiotics may cause liver or kidney damage, or send the patient into toxic shock. While the Board investigates several complaints each year of mislabeled prescriptions, the number, in relation to the number of prescriptions issued, is insignificant.

The second objective is to reduce the abuse of drugs by limiting access to controlled substances. In this area, regulatory efforts have been less than successful. According to the U.S. Drug Enforcement Administration (DEA), 15 of the top 20 abused drugs, and over 30% of all illegally sold drugs are prescription drugs (see Table 2). Prescription drug abuse is the cause of more injuries and deaths than all other illegal drugs combined, according to the Colorado Prescription Drug Abuse Task Force.

Table 2

TWENTY MOST ABUSED CONTROLLED SUBSTANCES
(Bolded substances are legal prescription drugs)

1. **Cocaine**
2. Heroin
3. Marijuana
4. **Alprazolam (Xanax)**
5. **Diazepam (Valium)**
6. **Lorazepam (Ativan)**
7. **Clonazepam (Klonopin)**
8. **Methamphetamine (Desoxyn)**
9. **Codeine combinations**
10. **Unspecified Benzodiazepines**
11. **D-Propoxyphene (Darvon, Darvocet)**
12. PCP & PCP combinations
13. **Hydrocodone (Vicodin, Locet, Lortab)**
14. **Amphetamine**
15. Hashish
16. **Temazepam (Restoril)**
17. **Oxycodone (Percodan, Percocet, Tylox, Roxicodone)**
18. LSD
19. **Chlordiazepoxide (Librium, Libritabs)**
20. **Methadone**

Information obtained from the Colorado Prescription Drug Abuse Task Force indicates that while Colorado has made improvements in reducing prescription drug abuse, it is still a problem (see Table 3). Table 4 below tracks the reduction in Colorado's ranking in abuse of some of the most commonly abused prescription drugs. Colorado ranked in the top ten states in per capita consumption of five of the abused prescription drugs. By 1989, Colorado no longer ranked in the top ten in per capita consumption of any of the most abused prescription drugs.

Table 4

DRUG	1982 RANK	1986 RANK	1989 RANK
Hydromorphone (Dilaudid)	9	18	20
Oxyodone (Percodan, Percocet, Tylox)	9	16	24
Methadone	7	18	30
Methamphetamine	11	32	25
Phenmetrazine (Preludin)	12	38	40
Pentobarbital	6	3	13
Cocaine	2	11	13
Alphaprodine	11	10	No longer produced

Source: Prescription Drug Abuse Task Force

Table 3
NUMBER OF PEOPLE ENTERING DRUG TREATMENT IN DENVER
(Within first three years of use)

YEAR	HEROIN	COCAINE	MARIJUANA	OTHER DRUGS
1986	89	289	283	201
1990	114	493	465	273
1994	144	864	1,544	521

Source: Colorado Drug/Alcohol Coordinated Data System

Schedule II drugs are those which are most likely to be abused and therefore have the strictest controls. The tracking of these drugs is very complex and is the shared responsibility of manufacturers, wholesalers, and retailers. Each time controlled substances are transferred between one of these entities, DEA order forms are generated and sent to the DEA. Pharmacy inspectors routinely review controlled substance records and verify DEA order form information when conducting pharmacy inspections. This system is labor intensive and mostly manually operated. Information concerning potential abuse of controlled substances is frequently exchanged between DEA, Pharmacy Inspectors, and other appropriate licensing boards in DORA.

Pharmacies and other outlets registered by the Board conduct regular "self inspections", essentially self audit reporting, using inspection forms sent by, and returned to, the Board. Prior to 1993, inspectors conducted complete inspections of all PDO every eight months and also periodically "visited" PDO. Personnel reductions, combined with increased numbers of licensees, has reduced the number and frequency of complete inspections.

Current Board regulations to implement § 12-22-121(14), C.R.S., have established a one to one ratio for unlicensed persons supervised by a pharmacist engaged in dispensing. Some individuals contacted for this report indicated a belief that this is an overly conservative ratio in some settings. Variations in the skill and experience levels of both the non-licensed personnel and the pharmacist may justify a higher ratio in some instances. However, the Act specifies a uniform standard for all pharmacists. The General Assembly may want to consider giving the Board some flexibility in this area.

The Act specifically identifies "nuclear pharmacy" as a specialized prescription drug outlet. This is the only specialized outlet identified in the Act. The practice of pharmacy has changed over the years giving rise to a variety of specializations within the profession, such as consultant pharmacist, intravenous pharmacist, collaborative practice, hospital pharmacy, and others. Some states, such as Texas and California, have recognized this trend and have by statute, authorized regulatory authorities to establish specialized licenses under their pharmacy acts.

The current definition of PDO does not address a large hospital complex that may have several dispensing points under a single pharmacy license. There are a variety of options to address this situation. The Board could require a separate license for each dispensing point. This would be unnecessarily burdensome on the complex. The Board has proposed, in the MPA, defining separate distribution points as satellites of the licensed PDO. This appears to be the most reasonable alternative reviewed.

The American Council on Pharmaceutical Education is the accrediting organization that sets standards for pharmacy schools and the standards for continuing pharmaceutical education. The University of Colorado, Health Sciences Center operates the only accredited pharmacy school in Colorado.

The National Association of Boards of Pharmacy (NABP) is the nationally recognized entity for setting standards for testing and licensing pharmacists. The NABP administers the national examination for pharmacists. California is the only state not using the NABP examination for licensure by examination.

NABP also operates a national clearing house for disciplinary actions and licensing transfers. Colorado is one of only four states not requiring use of the NABP clearing house for licensing transfers. This saves applicants transferring to Colorado the $250 fee charged by NABP for processing the paperwork. However, it increases the administrative burden to the Board. Individuals applying directly to the Board for licensure by endorsement are not subject to a NABP search of disciplinary actions in other states. The applicant is required to sign a statement to the effect that all information concerning other state licensing and disciplinary actions is complete and accurate. False or incomplete information on the application is grounds for license revocation, however, it is unlikely such information would come to the attention of the Board.

The Board issues licenses to new applicants by three methods: examination, endorsement through the Board, and endorsement through a clearing house. Individuals requesting licensure by examination submit a complete application to the Board for evaluation. Application materials documenting minimum requirements for licensure, include information about education, internship, and employment history must be submitted to the Board. The applicants must pass a Board administered written jurisprudence examination in addition to the national examination. Currently, the Board uses the NABP examination as the approved national examination. Test scores are submitted directly to the Board by NABP. Once application information is verified the Board and satisfactory examination scores are confirmed by NABP, the license is issued. The Board then approves the license at its next regular meeting

Pharmacists licensed and in good standing in another state(s) who wish to become licensed in Colorado may apply to the Board for licensure by endorsement. In this situation, the applicant submits an application containing information about education, current state licensing status and disciplinary actions directly to the Board. The Board, then verifies the information with current state(s) of license. Since most states use the NABP clearinghouse, they are either not equipped to, or are reluctant to provide information on licensees to other states except through the clearing house. Pharmacists applying for licensure by endorsement generally obtain a license as soon as qualifications and current license status is verified. Because of the difficulty in verifying information from other states, this sometimes takes 4-6 weeks from the time the completed application is received by the Board. The license is ratified at the next regular meeting of the Board following verification of information.

The third method for obtaining a license is by endorsement through an approved clearing house. Currently, the Board uses the NABP clearing house. According to NABP, 78% of the applicants using the NABP Transfer of Pharmacist License Clearinghouse Program result in completed, verified information transmitted to the appropriate regulatory authorities in five weeks or less. The majority of those applications taking longer than five weeks are applicants licensed in multiple states, resulting in extended time to research disciplinary actions in several states. Colorado relies on individual applicants not using the clearing house to self report multiple state licenses.

Based upon which method was used to obtain a license, and when the license was obtained, an applicant is granted one of four classes of pharmacy license. As previously stated, a Class I licensee is a person licensed in Colorado prior to July 2, 1979; Class IV licenses are granted to applicants applying for licensure by examination in Colorado; Class V is a license granted by endorsement, and a Class VI license is issued to a graduate of a foreign school of pharmacy who meets the licensing requirements in Colorado. There are no practice limitations placed on a pharmacist based upon the class of license issued. Applicants applying for licensure by endorsement are exempted from taking the Colorado jurisprudence examination.

All licenses and registrations issued by the Board expire in accordance with the provisions of § 24-34-102(8), C.R.S. This allows the Director of the Division of Registrations to stagger expiration dates to smooth out the administrative work involved in processing renewals. Licensees must submit a renewal fee on or before the expiration date of the license to maintain licensure. Licensees missing the renewal date may apply for reinstatement for the remainder of the renewal period.

The Act does not require an evaluation of competency, continuing education or a demonstration of actual practice to renew a license. The Board does require a passing score on an out of practice examination and jurisprudence examination for licensees applying for reinstatement, if they can not document at least 400 hours in the practice of pharmacy during the year prior to the application for reinstatement. Some representatives of the pharmacy community have indicated a desire for Mandatory Continuing Education (MCE) to maintain licensure. The report does not endorse MCE for licensed pharmacists.

The Board administers the jurisprudence examination four times per year. Two of the examinations are linked with the NABP examinations to allow applicants to complete both examination requirements at one time. In the 1985 Pharmacy Sunset Report, DORA recommended the Board use an open book, mail in jurisprudence examination to reduce the burden on out of state applicants. The General Assembly instead eliminated the examination requirement for licensure by endorsement, under the assumption that licensees in another state passed that states jurisprudence examination. There is no statistical information available on the relationship between successful completion of the jurisprudence examination and competency in the practice of pharmacy.

The Board has the authority, under § 12-22-125, C.R.S. to deny, suspend, or revoke any license or registration issued under the Act. The Board may also issue a Letter of Admonition when an investigation discloses an instance of misconduct that does not warrant more severe action by the Board. The Board occasionally issues confidential Letters of Concern when investigations reveal no violations, but practice conditions exist where violations could potentially occur. Since the Board has no statutory authority for Letters of Concern, they cannot be considered a formal disciplinary action.

Violations of Board regulations are discovered through a variety of channels; self reporting, inspections, consumer complaints, professional complaints, other agency referrals, and malpractice insurance reports. Table 5 details investigatory actions for the past three years. Malpractice insurance claims in this fiscal year have increased dramatically. This is due to new Board regulations requiring self insured pharmacies to report claims. Because the statute only requires licensed insurance companies to report, there is concern that the Board lacks the ability to enforce the regulation on self insured pharmacies.

TABLE 5

Investigations	1992	1993	1994
Investigations initiated by Board or via Complaint	68	75	64
Investigations initiated via insurance settlements	14	11	12
Dismissed, no violation found	33	16	26
Letter of admonition issued	20	30	21
Referred to Attorney General (AG)	23	22	12
Stipulated settlement through AG	22	17	3
License denied	0	2	0
Licensed suspended or revoked	0	2	2

A review of complaint investigations by the Board revealed some inconsistencies in the disciplinary actions for similar offenses. Some of this may be attributed to a concern of the Board on the welfare of the public served in rural areas. Suspending the license of the only pharmacist in a small town may result in patients being forced to travel long distances to obtain medications. The Board avoids this action unless the continued operation of the pharmacy clearly endangers the public. However, actions based on this concern create inequities among licensees.

A major issue has been raised in regard to the enforcement and disciplinary responsibilities of the Board. The Board has used the provisions of § 12-22-110(2), C.R.S., "such other duties, power, and authority as may be necessary to the enforcement..." as implied investigative subpoena powers. The Board has not been challenged on this issue, but the possibility exists. Other professional licensing boards have specific subpoena powers contained in their statutory authority.

Other issues related to enforcement powers of the Board were: (1) the inability to discipline out of state pharmacists, (mail order firms); (2) the ability to issue punitive fines as a disciplinary option; (3) expansion of Board authority to seize or embargo drugs at non outlet locations, and (4) creation of a mechanism to collect legal expenses from those disciplined licensees. Each of these concerns were evaluated, but the report is not making recommendations to change the current status of Board authority in these areas.

The Act, in § 12-22-119, C.R.S., requires prescription drug outlets to register with the Board, and obtain Board approval before commencing operation. The Act exempts prescription drug outlets operated by government entities from registration but requires them to obtain a certificate of compliance from the Board. Holders of a certificate of compliance must comply with all regulatory requirements of the Board, but are exempted from paying registration fees.

The terms license and registration are used inconsistently throughout the Act. The Act gives the Board authority to license pharmacists, then refers to licensed pharmacists as "Registered Pharmacists" such as in 12-22-110 (1)(a) C.R.S.

Section 10 of the Board regulations implement § 12-22-121(13), C.R.S., regarding the placement of emergency kits in licensed Nursing, Intermediate Health and Residential Care Facilities. As health care has evolved over the years, new types of health care facilities have been identified and regulated by the Health Facilities Division of the CDPHE. The identification of three specific licensed facilities in the Act limits the placement of emergency drugs in other recognized facilities, such as hospices. The General Assembly should consider authorizing the Board determine which facilities are appropriate for the placement of an emergency kit.

Recent trends in health care have expanded the prescriptive authority of some health care professionals. The Colorado General Assembly recently granted prescriptive authority to advance practice nurses, operating under a collaborative agreement with a licensed physician. Several states have enacted legislation extending prescriptive authority to pharmacists.

The State of Washington has what is considered to be one of the most innovative models for pharmacist prescriptive authority. The Washington Pharmacy Act includes in the definition of practice of pharmacy "the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs;". The Washington Board of Pharmacy reports 400 pharmacists and 2,000 physicians are participating in the program.

The Colorado Act provides limited authority for pharmacists to dispense or prescribe drug therapy. Under § 12-22-122(2), C.R.S., a pharmacist may provide a 72 hour refill for a previously authorized prescription without the prescriber's authorization. This may only be done when efforts to contact the prescriber have failed and in the professional judgment of the pharmacist, the refill is necessary for the patient. Under § 12-22-124, C.R.S., a pharmacist may, with the patients permission, substitute an equivalent drug product if the product is the same generic drug type. Pharmacists may not substitute drugs if the prescriber or patient indicate no substitutions are to be made.

Pharmacists by education and training are qualified to evaluate drug therapies and interactions. In fact, pharmacists have more required education in pharmacology and drug therapy than most prescribers. However, most pharmacists do not have education and experience in diagnoses of medical conditions. States that have extended prescriptive authority to pharmacists have done so under pre-approved protocols or in a collaborative or coordinated arrangement with a prescriber. Colorado physicians and pharmacists report that some informal collaborative arrangements occur. However, the Act does not define collaborative practice and the Board does not regulate the practice.

During the course of researching this report, several individuals and groups have recommended expanding the scope of practice for pharmacists to include some type of prescriptive authority. Valid arguments have been presented as to the qualifications for pharmacists in the areas of drug therapy monitoring and dosage modification. However, information presented did not demonstrate a potential harm to the public if the current system is maintained. For this reason, the report is neutral on the issue of prescriptive authority for licensed pharmacists.

The Board contracts with a private company to operate the Peer Assistance Program. There are currently 12 participants in the program. Public safety is ensured through monitored drug screens, treatment provider reports, and mandatory attendance at self help groups, among other services. The contractor provides quarterly reports to the Board.

Current language in the Act requires the Board to use the Peer Assistance Program as an alternative to disciplinary action. The legislative declaration for the Pharmacy Peer Assistance provision is more restrictive on the Board than language in other health related peer assistance legislation.

RECOMMENDATIONS

Continue the Licensing of Pharmacists and Pharmacies

The value of properly prescribed and administered drug therapy is accepted in the medical community and by the general public. The proliferation of new prescription drugs has benefited many people by providing innovative therapies for previously untreatable illnesses. There is sufficient evidence of potential harm to the public caused by the dispensing of improper drug dosages or improper medications. Limiting access to controlled substances serves to protect the public health, safety and welfare. A system for regulating the prescribing, storage, and dispensing of drugs is a necessary function of state government.

Recommendation 1 - The General Assembly should continue the licensing of pharmacists and pharmacies for the protection of the public health, safety and welfare.

Remove Restrictions

The current Act requires that one member of the Board reside in each congressional district, and no more than four members of the Board may represent the same political party. Efforts should be made to obtain geographic diversity in Board membership. However, requiring membership by congressional district unnecessarily limits the pool of qualified applicants. It is more important for the regulated community to have diverse representation by practice specialty and pharmacy type than by geographic considerations. The interests of an independent pharmacy in an urban area will be better represented by an independent pharmacist in a rural area than they will be by a hospital pharmacist in his or her own congressional district.

The public and the regulated community would be best served by a Board made up of qualified, interested individuals, regardless of political party affiliation. The function of the Board is to establish and administer a regulatory program for pharmacists and pharmacies. Qualifications based on experience, education, and interest are more important than political party affiliation.

RECOMMENDATION 2 - Remove the restrictions on Board membership.

Clarify Terms

The terms license and registration are used inconsistently, and in some cases incorrectly throughout the Act. Qualified pharmacists are commonly referred to as “Registered Pharmacists”. However, the Act properly grants the Board authority to license pharmacists, then refers to registered pharmacists in various sections, such as § 12-22-110(1)(a), C.R.S. Likewise, PDOs are required to register with the Board and display their registration prominently at their place of business. However, the registration would more properly be defined as a license.

Recommendation 3 - Correct inconsistent use of the terms "license and registration".

Consolidate Classes of Licenses

The Act currently identifies four classes of licensed pharmacists. The different classes pay the same licensing fees, and are not differentiated in their scope of practice. They are different only in the method they obtained or in the length of time of licensure in Colorado. Differentiating between classes of licensees does not serve a public protection function and should be eliminated.

Recommendation 4 - Consolidate the four classes of pharmacist licensees.

Centralize Data Collection

The abuse of prescription drugs is a serious problem in Colorado. While per capita consumption has decreased, the number of admitted abusers has continued to increase. The problem crosses a broad spectrum of society and has direct and indirect impacts and costs to taxpayers in this state. Sources for obtaining the abused substances vary. Among the common sources are over prescribing or abusive prescribing by practitioners; abuse or theft by pharmacy or hospital personal; and "doctor shopping" by persons addicted to prescription drugs. In a doctor shopping scenario, an individual may visit several physicians complaining of identical symptoms and obtain prescriptions for controlled substances from each physician. Individuals utilizing this technique often use different pharmacies to fill the prescriptions. This makes it virtually impossible for prescribers or pharmacists to identify abusers.

Oklahoma and New Mexico have recently implemented computer tracking systems for controlled substances distributed at the consumer level, using federal grants as a funding source. These systems are currently being evaluated by regulatory authorities. However, preliminary information indicates success in identification of prescription drug abusers.

Recommendation 5 - The General Assembly should consider implementing a system to centralize data collection on the dispensing of controlled substances, similar to the system in Oklahoma.

Examinations

The General Assembly eliminated the requirement for a jurisprudence examination on licensure by endorsement effective 1988 [§ 12-22-116.5(1)(e), C.R.S.]. However, under the provisions of § 12-22-116.5(2), C.R.S., the Board has been requiring jurisprudence examinations for some applicants applying for reinstatement of an expired license.

Also under the reinstatement provisions of § 12-2-116.5(2), C.R.S., the Board requires an "out-of-practice examination" for individuals applying for reinstatement of an expired license who have not been employed as a pharmacist for at least 400 hours in the previous year. However, a licensed pharmacist who applies for renewal of a current license does not need to document employment as a pharmacist for any period of the two year licensing cycle. This creates an equity issue for licensees. If an out of practice examination is necessary to protect the public, applicants for renewal should be required to demonstrate 400 hours of employment as a pharmacist or be subject to an out-of-practice examination.

Recommendation 6 The General Assembly should provide clear and consistent guidance to the Board on the issue of out-of-practice and jurisprudence examinations.

Malpractice Claims

Licensed insurance companies are required, pursuant to § 12-22-113.5, C.R.S. to report malpractice claims against a Colorado licensed pharmacist. The Board has promulgated regulations requiring self insured pharmacies to report claims also. Some large retail chains have indicated a reluctance to comply with the regulations, asserting that they are not licensed insurance companies.

The intent of the malpractice reporting requirement was to provide the Board with information about practices which violate provisions of the Act or Board regulations. Instances of negligence and malpractice need to be investigated to protect the public regardless of whether the entity in question is self insured or insured by a private carrier.

Recommendation 7 - The General Assembly should require self insured pharmacists and pharmacies to report malpractice claims to the Board.

Identification of Health Care Facilities Eligible for the Placement of Emergency Kits

As the national health care system changes, new types of health care facilities are developed and utilized by a population requiring specialized care. The Act currently limits emergency kits to nursing care, intermediate health care and residential care facilities. The Board should have the ability to establish regulations providing emergency supplies of drugs to health care facilities licensed or regulated by the Health Facilities Division of the CDPHE.

Recommendation 8 - The General Assembly should delegate to the Board the responsibility for identification of health care facilities eligible for the placement of emergency kits.

Licensure by Examination Requirements

According to § 12-22-117(1)(d), C.R.S., in order for an applicant to obtain licensure by examination in Colorado, the applicant must pass a written examination approved by the Board. Colorado, as with 48 other states uses the NABP examination as the state approved exam. To speed up the examination process, the NABP is considering implementing a computerized examination. The Board should have the flexibility to approve this innovative process when it is satisfied it accurately evaluates the qualifications of examinees.

Recommendation 9 - The General Assembly should change the licensure by examination requirement from a written examination to a Board approved examination.

Subpoena Powers

The ability to subpoena witnesses and information is a necessary tool for the investigation of regulatory violations. The Board has assumed subpoena powers based on its broad statutory authority. While this assumption has not been challenged, it is certainly open to such a challenge. Providing explicit authority for subpoenas in the Act will eliminate any question as to the Boards ability in this area.

Recommendation 10 - Formalize the investigative subpoena powers of the Board.

Permitting Provision

Among the permits, registrations, and licenses the Board approves is a permit, to destroy drugs, contained in § 12-22-121(10), C.R.S. This was intended as a method to monitor the disposition of drugs when they expire or become contaminated. As a practical matter, PDOs return outdated or contaminated drugs to the distributor or manufacture. The Board has not issued a permit to destroy drugs in many years. Therefore, the provision is unnecessary and should be eliminated.

Recommendation 11 - Eliminate unused permitting provision.

Letters of Concern

The Board occasionally issues confidential Letters of Concern in situations where an investigation reveals practices that are not violations, but could lead to violations of the Act or Board regulations. The practice of issuing letters has been challenged because the Board does not have specific statutory authority to issue them. Placing authority in the statute will eliminate any doubt for the Board and licensees as to the validity of the letter as a disciplinary measure.

Recommendation 12 - Add confidential Letters of Concern as a disciplinary option for the Board.

Licensure by Endorsement

Applicants for licensure by endorsement currently may apply directly to the Board or use the NABP clearinghouse. On applications not using the clearinghouse, the Board is dependent upon the applicant to reveal all past disciplinary actions and state licenses held. Applications presented directly to the Board clearly increase the administrative burden on the Board. However, there is insufficient evidence that the public is endangered by this option.

Requiring applicants to use the NABP clearinghouse is in effect requiring them to support a private enterprise. In order for this report to make a recommendation to this effect there would have to be overwhelming evidence of increased benefit to the public. The current clearinghouse process is not demonstrably more efficient than direct application to the Board. NABP is developing a system for on-line, computerized background checks on credentials and disciplinary records of applicants. Although this would seem to add to the public protection, the system is not operational so an evaluation is not possible.

Recommendation 13 - Maintain the current option to apply directly to the Board for licensure by endorsement.

Peer Assistance Program

The General Assembly has recently amended language relating to peer assistant and drug diversion programs in the Medical Practices and Nurse Practice Acts. The Pharmacy Act should be amended to be consistent with other health related occupations. "In determining appropriate disciplinary action, the Board shall first consider sanctions that are necessary to protect the public. Only after the Board has considered such sanctions may it consider and order requirements designed to rehabilitate the licensee."

Recommendation 14 - Change language for the PEER Assistance Program to be consistent with other health related occupational licensing programs.

Large hospital complexes frequently have multiple areas for the storage and distribution of pharmaceuticals. Regulation of these points under the current Act is burdensome on both the complex and the Board. A definition for a satellite distribution point would allow the Board to regulate these areas efficiently.

RECOMMENDATION 15 - The General Assembly should adopt a definition for a satellite distribution point.

Administrative Recommendations

Board regulations currently prohibit accepting a controlled substance prescription order by fax or other electronic means. Technology is available to safeguard prescription orders transmitted electronically. There is no evidence that electronically transmitted orders are more susceptible to fraud than verbal or handwritten prescriptions. The Board should promulgate regulations that allow practitioners and pharmacists to utilize all reasonably secure methods to authorize the dispensing of medications.

Recommendation 1 - The Board should reevaluate its regulatory prohibition on accepting prescription orders for controlled substances by electronic means.

Printed, or hardcopy reports, are useful, and even necessary, when a PDO is being inspected. This is not an everyday occurrence, and even when it does occur, PDOs have notice. Many outlets generate these reports only to comply with Board regulations. Other, more efficient techniques can be used to backup and store records. Some of these methods, such as offsite data transmissions, are actually more effective in the event of a computer failure than daily hardcopy reports.

Recommendation 2 - The Board should eliminate the requirement for a daily printout of computer reports.

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.

Pharmacy Act

12-22-101. Public interest. The practice of pharmacy is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is a matter of public interest and concern that the practice of pharmacy, as defined in this part 1, merits and receives the confidence of the public and that only qualified persons be permitted to practice pharmacy in this state. This part 1 shall be liberally construed to carry out these objects and purposes. Pursuant to these standards and obligations, the state board of pharmacy may adopt, by rule and regulation, rules of professional conduct.

12-22-102. Definitions. As used in this part 1, unless the context otherwise requires:

(1) "Administration" means the giving of medication to a patient by a pharmacist qualified to administer drugs by authorization of a physician.

(2) "Advertise" means to publish or display information about prescription prices or drugs in any medium.

(2.5) "Anabolic steroid" has the same meaning as that set forth in section 18-18-102 (3), C.R.S.

(3) Repealed, L. 81, p. 706, 26, effective July 1, 1981.

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

(5) "Casual sale" means a sale to a corporation, individual, or other entity, other than a consumer, entitled to possess prescription drugs; except that the amount of drugs sold in such manner by any registered prescription drug outlet shall not exceed five percent of the total amount of drugs sold annually by such outlet.

(6) "Compound" means to mix, weigh, or otherwise prepare ingredients, as specified in the prescription order of a practitioner, in accordance with the statutes and regulations of pharmacy and to insure that a label is prepared in accordance with the prescription order and placed on or securely attached to the container meeting compendia standards.

(7) "Delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(8) "Device" means an instrument, apparatus, machine, contrivance, or implant or a similar or related article other than a drug, including any component part or accessory which is:

(a) Recognized in the official compendia or any supplement thereto;

(b) Intended for use in the diagnosis, treatment, or prevention of disease or other conditions in humans and animals; and

(c) Required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

(9) "Dispense" means to prepare a drug or device pursuant to a lawful prescription order of a practitioner, together with an appropriate label, in a suitable container for subsequent administration to or use by a patient or other individual entitled to receive the prescription order.

(10) "Distribution" means the delivery of a drug or device other than by administering or dispensing.

(11) (a) "Drug" means:

(I) Substances recognized as drugs in the official United States pharmacopoeia, national formulary, or the official homeopathic pharmacopoeia of the United States, or any supplement to any of them;

(II) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals;

(III) Substances (other than food) intended to affect the structure or any function of the body of individuals or animals; and

(IV) Substances 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.

(12) "Generic drug type" means the chemical or generic name, as determined by the United States adopted names (USAN) and accepted by the federal food and drug administration (FDA), of those drug products having exactly the same active chemical ingredients in exactly the same strength and quantity.

(13) "Habit-forming drug" means any drug or medicine which is required under the state food and drug law or the federal "Food, Drug, and Cosmetic Act" to be labeled as a habit-forming drug.

(14) "Hospital" means a general hospital or specialty hospital having a license or certificate of compliance issued by the department of public health and environment.

(15) "Intern" means a person who is attending, or who is in good standing with, an accredited school of pharmacy or who has graduated from an accredited school of pharmacy and is completing an internship to satisfy board requirements for licensure.

(16) "Labeling" means the process of preparing and affixing a label to any drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation.

(17) "Manufacture" means to cultivate, grow, or prepare by other process drugs for sale to wholesalers or other persons entitled to purchase drugs other than the ultimate user, but "manufacture" does not include the dispensing of a prescription drug pursuant to a prescription order.

(18) and (19) Repealed, L. 86, p. 622, 36, effective July 1, 1986.

(20) "Nonprescription drug" means a medicine or drug which may be sold without a prescription which is prepackaged for use by the consumer, prepared by the manufacturer or producer for use by the consumer, properly labeled and unadulterated in accordance with the requirements of the state food and drug law and the federal "Food, Drug, and Cosmetic Act". The term shall not apply to any drug that is designated under any law or regulation of this state or federal law or regulation as a habit-forming drug or a controlled substance, as defined in section 12-22-303 (7).

(21) "Nuclear pharmacy" means a specialized pharmacy which deals with the preparation and delivery of radioactive material as defined in section 25-11-101, C.R.S.

(22) "Official compendia" means the official United States Pharmacopeia or any supplement thereto.

(22.5) "Order" means:

(a) A prescription order which is any order, other than a chart order, authorizing the dispensing of drugs or devices written or transmitted by other means of communication by a practitioner and which includes the name or identification of the patient, the date, and sufficient information for compounding, dispensing, and labeling; or

(b) A chart order which is an order for inpatient drugs or medications to be dispensed by a pharmacist, or pharmacy intern under the direct supervision of a pharmacist, which is to be administered by an authorized person only during the patient's stay in a hospital facility. It shall contain the name of the patient and of the medicine ordered and such directions as the practitioner may prescribe concerning strength, dosage, frequency, and route of administration.

(23) "Outlet" means any prescription drug outlet, hospital, institution, nursing home, rural health clinic, convalescent home, extended care facility, family planning clinic, wholesaler, manufacturer, mail order vendor, other than a pharmacist, with facilities in this state who engages in the dispensing, delivery, distribution, manufacturing, wholesaling, or sale of drugs or devices.

(24) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.

(25) Repealed, L. 81, p. 706, 26, effective July 1, 1981.

(26) "Practice of pharmacy" means:

(a) An initial interpretation, selection of ingredients and final evaluation of each prescription order or chart order, the participation in drug selection and drug utilization reviews, the participation in administration of drugs, the advising and providing of information concerning utilization of drugs and devices in the treatment of an injury and the treatment and prevention of disease, and the offering or performing of those health services, operations, or transactions necessary in the conduct, operation, and control of a prescription drug outlet by a pharmacist;

(b) The responsibility for the compounding, dispensing, labeling (except nonprescription drugs), delivery, storage, and distribution of drugs and devices and the maintenance of proper records thereof;

(c) (Deleted by amendment, L. 81, p. 696, 1.)

(27) "Practitioner" means a person authorized by law to prescribe any drug or device, acting within the scope of such authority.

(28) Repealed, L. 81, p. 706, 26, effective July 1, 1981.

(29) "Prescription" means the finished product of the dispensing of a prescription order in an appropriately labeled and suitable container.

(30) "Prescription drug" means a drug which, prior to being dispensed or delivered, is to be labeled with the following statement: "Caution: Federal law prohibits dispensing without a prescription." or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.".

(30.2) "Prescription drug outlet" means any outlet where prescriptions are filled or compounded, and are sold, dispensed, offered, or displayed for sale.

(30.3) "Refill" means the dispensing of any drug by a practitioner pursuant to a previously executed order.

(31) Repealed, L. 81, p. 706, 26, effective July 1, 1981.

(32) "Sample" means any prescription drug given free of charge to any practitioner for any reason except for a bona fide research program.

(33) "Therapeutically equivalent" or "equivalent" means those compounds containing the identical active chemical ingredients of identical strength, quantity, and dosage from and of the same generic drug type, which, when administered in the same amounts, will provide the same therapeutic effect as evidenced by the control of a symptom or disease.

(34) "Wholesaler" means a corporation, individual, or other entity with facilities in this state which buys drugs or devices for resale and distribution to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers.

12-22-103. State board of pharmacy - creation - subject to termination - repeal of article. (1) The responsibility for enforcement of the provisions of this part 1 is vested in the state board of pharmacy, which is hereby created. The board shall have all of the duties, powers, and authority specifically granted by and necessary to the enforcement of this part 1, as well as such other duties, powers, and authority as may be granted by statute from time to time. Except as otherwise provided to the contrary, the board shall exercise all its duties, powers, and authority in accordance with the "State Administrative Procedure Act", article 4 of title 24, C.R.S.

(2) The board shall exercise its powers and perform its duties and functions specified by this part 1 under the department of regulatory agencies and the executive director thereof as if the same were transferred to the department by a type 1 transfer, as such transfer is defined in the "Administrative Organization Act of 1968", article 1 of title 24, C.R.S.

(3) (a) The provisions of section 24-34-104, C.R.S., concerning the termination schedule for regulatory bodies of the state unless extended as provided in that section are applicable to the state board of pharmacy created by this section.

(b) This article is repealed, effective July 1, 1996.

12-22-104. Membership. The board shall be composed of five licensed pharmacists, each having at least five years' experience in this state and actively engaged in the practice of pharmacy in this state, and two nonpharmacists who have no financial interest in the practice of pharmacy. All appointments shall be made by the governor. The term of office of each member shall be four years. Persons holding office on June 15, 1987, are subject to the provisions of section 24-1-137, C.R.S. In the case of any appointment to fill a vacancy, the appointee shall complete the unexpired term of the former board member. No member of the board may serve more than two consecutive full terms. Appointments shall be made so that at least one member shall reside in each congressional district. A vacancy on the board occurs whenever any member moves out of the congressional district from which he was appointed. A member who moves out of such congressional district shall promptly notify the governor of the date of such move, but such notice is not a condition precedent to the occurrence of the vacancy. The governor shall fill the vacancy as provided in this section. No more than four members of the board shall be members of the same major political party. Appointments made to take effect on January 1, 1983, shall be made in accordance with section 24-1-135, C.R.S. The pharmacist members shall be appointed so that the term of one member shall expire July 1 each year, and board members serving on January 1, 1980, shall serve until the July 1 next following the date on which their terms would otherwise expire. Of the two nonpharmacist members whose terms are scheduled to expire on July 1, 1986, the governor shall select one and extend the term of that member to July 1, 1987. Persons holding office on June 15, 1987, are subject to the provisions of section 24-1-137, C.R.S.

12-22-105. Removal of board members. The governor may remove any board member for misconduct, incompetence, or neglect of duty.

12-22-106. Compensation. Each member of the board shall receive the compensation provided for in section 24-34-102 (13), C.R.S.

12-22-107. Meetings. Meetings of the board shall be held at least once every four months at such times and places as may be fixed by the board. One meeting shall be for the purpose of electing officers, who shall be a president and a vice-president. A majority of the members of the board shall constitute a quorum for the conduct of business, and, except as otherwise provided in this part 1, all actions of the board shall be by a majority of a quorum. Full and timely notice of all meetings of the board shall be given pursuant to any requirements of state laws. All board meetings and hearings shall be open to the public; except that the board may conduct any portion of its meetings in executive session closed to the public, as may be permitted by law.

12-22-108. Rules and regulations. The board shall make, adopt, amend, or repeal such rules and regulations as may be deemed necessary by the board for the proper administration and enforcement of the responsibilities and duties delegated to the board by this article, including those relating to prescription drug outlets dealing with the prescription and delivering of radioactive materials as defined in section 25-11-101, C.R.S. All rules adopted or amended by the board on or after July 1, 1979, shall be subject to sections 24-4-103 (8) (c) and (8) (d) and 24-34-104 (9) (b) (II), C.R.S.

12-22-109. Administrator. (Repealed)

Repealed, effective July 1, 1986.

12-22-110. Powers and duties. (1) The board shall:

(a) Inspect, or direct inspectors who are registered pharmacists to inspect, all outlets and investigate violations of this part 1;

(b) Prescribe forms and receive applications for licensure and registration and grant and renew licenses and registrations;

(c) Deny, suspend, or revoke licenses or registrations;

(d) Apply to the courts for and obtain in accordance with the Colorado rules of civil procedure restraining orders and injunctions to enjoin violations of the laws which the board is empowered to enforce;

(e) Administer examinations to applicants for licensure;

(f) Keep a record of all licenses, registrations, renewals, suspensions, and revocations, and of its own proceedings;

(g) Collect all fees prescribed by this part 1.

(2) The board shall have such other duties, powers, and authority as may be necessary to the enforcement of this part 1 and to the enforcement of rules and regulations made pursuant thereto.

(3) The board may adopt a seal to be used only in such manner as may be prescribed by the board.

(4) (a) Whenever a duly authorized agent of the board finds or has probable cause to believe that in any prescription drug outlet any drug, nonprescription drug, or device is adulterated or misbranded within the meaning of the "Colorado Food and Drug Act", part 4 of article 5 of title 25, C.R.S., he shall affix to such article a tag or other appropriate marking giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the board, its agent, or the court. No person shall remove or dispose of such embargoed article by sale or otherwise without the permission of the board or its agent or, after summary proceedings have been instituted, without permission from the court.

(b) If the embargo is removed by the board or by the court, neither the board nor the state shall be held liable for damages because of such embargo in the event that the court finds that there was probable cause for the embargo.

(c) When an article detained or embargoed under paragraph (a) of this subsection (4) has been found by an agent to be adulterated or misbranded, such agent shall petition the judge of the district court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. When such agent finds that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.

(d) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the owner thereof under the supervision of such agent, and all court costs and fees, storage, and other proper expense shall be borne by the owner of such article or his agent; except that, when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid by the owner of such article and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may, by order, direct that such article be delivered to the owner thereof for such labeling or processing under the supervision of an agent. The expense of such supervision shall be paid by the owner. Such bond shall be returned to the owner of the article on representation to the court by the board that the article is no longer in violation of the embargo and that the expenses of supervision have been paid.

(e) It is the duty of the attorney general or the district attorney to whom the board reports any violation of this subsection (4) to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Nothing in this paragraph (e) shall be construed as requiring the board to report violations whenever the board believes the public interest will be adequately served in the circumstances by a suitable written notice or warning.

12-22-111. Internship. (1) All applicants for licensure by examination shall obtain practical experience in the practice of pharmacy. The board shall establish standards necessary to qualify an applicant for the licensure examination and shall determine the necessary qualifications for a preceptor.

(2) The board shall develop a manual for use by interns and preceptors for the purpose of establishing criteria for the intern program and its evaluation. The criteria shall be related to the practical experience necessary for a competent pharmacist to practice in a manner consistent with the health and safety of the public. Such criteria shall include training in, at least, the following areas to be gained by the intern prior to becoming a licensed pharmacist:

(a) Knowledge of the legend and controlled substances distribution cycles from ordering by the prescriber to administration by the patient, including receiving prescription orders, reading prescriptions, analyzing legality and safety of prescription orders, filling and filing orders, packaging, storing, and labeling prescription medications, and utilizing professional judgment in advising customers about medications;

(b) Knowledge and skills in monitoring drug utilization and detecting drug interactions through a review of patient profiles, records, charts, histories, and other relevant information;

(c) Knowledge and skills necessary for the safe and accurate preparation of products requiring compounding; and

(d) Knowledge of the various legal requirements and procedures applicable to different pharmacy settings, such as hospitals, nursing homes, or other types of practice settings.

(3) The board shall require any licensed pharmacist who applies to be a preceptor to list those areas in which he will provide training to interns. The board shall require each intern to evaluate the areas of training and quality of training provided by his preceptor, and it shall remove the approval of any preceptor it deems to be providing inadequate training experience or who does not comply with evaluation requirements of the board. The board shall not prohibit an otherwise qualified pharmacist licensed in another jurisdiction from becoming a preceptor. The evaluation by the intern shall not be subject to the provisions of article 72 of title 24, C.R.S.

(4) The board shall require each preceptor to complete an evaluation of each intern to evaluate the areas of training and performance of the intern. The evaluation of the performance of the intern shall be used solely to assist the intern and shall not be subject to the provisions of article 72 of title 24, C.R.S.

(5) Repealed, L. 89, p. 650, 2, effective April 12, 1989.

12-22-112. Drugs, devices, and other materials. (1) The board shall be responsible for the control and regulation of drugs, including the following:

(a) The regulation of the sale at retail and the dispensing of drugs;

(b) The specification of minimum professional and technical equipment, environment, supplies, and procedures for the compounding or dispensing of medications and drugs;

(c) The control of the purity and quality of drugs.

(2) The board shall be responsible for the control and regulation of the sale of devices at retail.

12-22-113. Report - publications. The board may prepare and transmit, in the form and manner prescribed by the heads of the principal departments pursuant to the provisions of section 24-1-136, C.R.S., a report accounting to the governor and the general assembly for the efficient discharge of all responsibilities assigned by law or directive to the board. Publications of the board circulated in quantity outside the executive branch shall be issued in accordance with the provisions of section 24-1-136, C.R.S. Publications of the board shall be circulated to all registered prescription drug outlets which will be directly affected by the publications.

12-22-113.5. Reporting - malpractice claims. (1) Each insurance company licensed to do business in this state and engaged in the writing of malpractice insurance for licensed pharmacists shall send to the board, in the

form prescribed by the board, information relating to each malpractice claim against a licensed pharmacist which is settled or in which judgment is rendered against the insured.

(2) The insurance company shall provide such information as is deemed necessary by the board to conduct a further investigation and hearing.

(3) Claims reports and information provided by insurance companies shall be exempt from the provisions of any law requiring that the proceedings of the board be conducted publicly or that the minutes or records of the board be open to public inspection unless there is final disciplinary action taken. The board may use such information in any formal hearing involving a licensee.

12-22-114. Fees. (1) Fees shall be determined and collected pursuant to section 24-34-105 for the following licenses:

(a) For certifying to another state the grades of a person who has taken the pharmacist examination in this state;

(b) Repealed, L. 81, p. 706, 26, effective July 1, 1981.

(c) For the initial licensure, upon examination, as a Class IV pharmacist, as provided in section 12-22-117 (1) (d);

(d) For the initial licensure, without examination and upon presentation of evidence of licensure in another state, as a Class V pharmacist, as provided in section 12-22-117 (1) (e);

(e) For the renewal of a license as a licensed pharmacist, as provided in section 12-22-118 (2);

(f) For reinstatement as a licensed pharmacist, as provided in section 12-22-118 (2);

(g) For the transfer of a prescription drug outlet registration to a new owner, as provided in section 12-22-119 (2);

(h) For the transfer of a manager's name, as provided in section 12-22-119 (1);

(i) For the issuance of a duplicate certificate to a licensed pharmacist;

(j) For the initial licensure as a pharmacy intern;

(k) For the issuance of a duplicate license of a pharmacy intern;

(l) Repealed, L. 84, p. 411, 3, effective February 17, 1984.

(m) For the transfer of a prescription drug outlet registration to a new location, as provided in section 12-22-119 (2);

(n) For reissuing a prescription drug outlet registration in a new store name, without change of owner or manager, as provided in section 12-22-119 (2);

(o) For the initial registration or the renewal of the registration of a prescription drug outlet, as provided in section 12-22-119 (2);

(p) For the initial certificate evidencing licensure for all classes of pharmacists;

(q) For the initial and renewal registration of all other outlets under section 12-22-120 not covered in this section.

(2) Any licensed pharmacist licensed in Colorado for fifty years or more as a licensed pharmacist shall be exempt from the payment of fees under this part 1 but shall be allowed to practice as a licensed pharmacist.

12-22-115. Approval of schools. (1) A school or college of pharmacy which is approved by the board as a school or college of pharmacy from which graduation is required in order for the graduate thereof to be an applicant for licensure as a pharmacist shall meet the requirements set forth by the board.

(2) The board may utilize the facilities, reports, requirements, and recommendations of any recognized accrediting organization in determining the requirements for a school or college of pharmacy.

(3) A list of approved schools or colleges shall be maintained by the board at its office.

12-22-116. Licensure or registrations - applicability - applications. (1) The provisions of this part 1 shall apply to all persons in this state engaged in the practice of pharmacy and to all outlets in this state engaged in the manufacture, production, sale, and distribution of drugs, devices, and other materials used in the treatment of injury, illness, and disease.

(2) Every applicant for a license under this part 1 shall be able to read and write the English language, or a partnership each of whose members meet said qualifications, or a Colorado corporation in good standing, or a foreign corporation qualified to do business in this state.

(3) Every applicant for a license or registration under this part 1 shall make written application in the manner and form prescribed by the board, setting forth his name and address, his qualifications for said license or registration, and other information required by the board. Every application shall be accompanied by the fee specified, and, if the applicant is required to take an examination, he shall appear for examination at the time and place fixed by the board.

(4) Repealed, L. 81, p. 706, 26, effective July 1, 1981.

(5) No applicant shall exercise the privileges of licensure or registrations until the license or registration has been granted by the board.

(6) The board may require any applicant for licensure to display written or oral competency in English. The board may utilize a standardized test to determine language proficiency.

(7) A person licensed by examination and in good standing in another state may apply directly to the board for licensure by endorsement. The board shall provide procedures for direct application and may designate a clearinghouse for those applicants who choose not to apply directly.

(8) The board shall adopt such rules and regulations as may be deemed necessary by the board to ensure that any person who manufactures drugs, as defined in section 12-22-102 (17), and any wholesaler of drugs, as defined in section 12-22-102 (34), possesses the minimum qualifications required for wholesale drug distributors pursuant to the federal "Prescription Drug Marketing Act of 1987", 21 U.S.C. sec. 353, as amended.

12-22-116.5. Exemption from licensure - hospital residency programs. The board shall have the authority to approve hospital residency programs in the practice of pharmacy. Persons accepted into an approved hospital residency program who are licensed to practice pharmacy in another state shall be exempt from the licensing requirements of this part 1 so long as their practice is limited to participation in the residency program.

12-22-117. Classes of pharmacists. (1) A licensed pharmacist is defined to be:

(a) Class I. A person licensed in this state as a licensed pharmacist on July 1, 1979;

(b) and (c) Repealed, L. 79, p. 459, 1, effective June 30, 1981.

(d) Class IV. Any person who has graduated from a school or college of pharmacy approved by the board, who satisfactorily passes an examination before the board, which examination shall be in writing and shall be fairly designed to test the applicant's knowledge of pharmacy and other related subjects, and who has completed an internship as prescribed by the board;

(e) Class V. Upon the payment of a fee as established pursuant to section 24-34-105, C.R.S., any person who is licensed by the board by reason of his licensure in some other state by examination substantially equivalent to the examination given to applicants for licensure by examination in this state. The person so applying for licensure shall produce satisfactory evidence of having had the required secondary and professional education demanded of applicants for licensure as pharmacists under the provisions of this part 1. The board shall require such person to pass a jurisprudence examination which shall be administered monthly by the board or a board-approved equivalent. Such jurisprudence examination shall not be administered by the board after July 1, 1988.

(f) Repealed, L. 81, p. 706, 26, effective July 1, 1981.

(g) Class VI. Upon the payment of a fee established pursuant to section 24-34-105, C.R.S., any person who produces evidence satisfactory to the board that he has an undergraduate degree from a school of pharmacy outside the United States, who has passed a foreign graduate equivalency test given or approved by the board, who has passed an examination as required by paragraph (d) of this subsection (1), and who has completed an internship as prescribed by the board.

12-22-118. Expiration and renewal of licenses or registrations. (1) A license or registration of a pharmacist, pharmacy intern, or prescription drug outlet shall expire in accordance with the provisions of section 24-34-102 (8), C.R.S.

(2) Every licensee who desires to retain his license shall pay a renewal fee on or before the expiration date of his license. In case any licensee or registrant defaults in the payment of the renewal fee, his license or registration shall expire, and notice thereof shall be given to the licensee or registrant by first-class mail to the licensee's or registrant's last known address as shown in the records of the board. Such licensee or registrant shall not thereafter practice or carry on operations which were authorized under said license or registration. Any pharmacist failing to renew his license on or before the applicable renewal time may be reinstated for the remainder of the current renewal period by filing a proper application, satisfying the board that he is fully qualified to practice, and paying the reinstatement fee as provided in section 12-22-114 (1) (f) and all delinquent fees.

(3) Except for good cause shown, no license shall be granted to a pharmacy intern more than two years after the applicant has ceased to be an enrolled student in a college or school of pharmacy approved by the board.

12-22-119. Prescription drug outlet under charge of pharmacist. (1) A prescription drug outlet shall be under the direct charge of a manager who is a pharmacist, who is not the manager of any other prescription drug outlet, and who has direct control of the pharmaceutical affairs of said prescription drug outlet. A proprietor who is not a pharmacist shall comply with this requirement and shall provide a manager who is a pharmacist. The registration of any prescription drug outlet shall become void if the pharmacist manager in whose name the prescription drug outlet registration was issued ceases to be engaged as the manager, and the proprietor shall close the prescription drug outlet unless he has employed a pharmacist, and, within seven days after termination of the former manager's employment, has made application to transfer the registration to the new manager, and has paid the transfer fee therefor. The pharmacist manager in whose name the registration was obtained, at the time he ceases to be employed as such, shall immediately report to the board the fact that he is no longer manager of the prescription drug outlet, and he shall be held responsible as the manager until he or the proprietor does so report. The proprietor of the prescription drug outlet shall also notify the board of the termination of managership. Upon the transfer of the management of the prescription drug outlet and payment of the fee therefor, a new registration showing the name of the new manager shall be issued.

(2) No prescription drug outlet shall commence business until it has made application for a registration and has received from the board a registration showing the name of the proprietor and the name of the manager. Upon transfer of the ownership of a prescription drug outlet, an application to transfer the registration of said prescription drug outlet shall be submitted, and, upon approval of the transfer by the board, the registration shall be transferred to the new proprietor. Upon the change of name or location of a prescription drug outlet, the registrant shall submit an application to change the name or location, and, upon approval of the same and the payment of the fee therefor, a new registration showing the new name or new location shall be issued.

(3) (a) A prescription drug outlet operated by the state of Colorado, or any political subdivision thereof, is not required to be registered but, in lieu thereof, shall apply to the board, on a form approved by the board, for a certificate of compliance. The board shall determine whether said prescription drug outlet is operated in accordance with the laws of this state and the rules and regulations of the board; and, if it determines that the prescription drug outlet is so operated except for the holding of a prescription drug outlet registration, it shall issue a certificate of compliance, which shall expire and may be renewed in accordance with the provisions of section 24-34-102 (8), C.R.S.; and, thereafter, said prescription drug outlet shall have the rights and privileges of and shall be treated in all respects as a registered prescription drug outlet. The provisions of this part 1 with respect to the denial, suspension, or revocation of a prescription drug outlet registration shall apply to a certificate of compliance.

(b) An outlet as recognized in section 12-22-120 (1) (e) need not be under the direct charge of a pharmacist, but a licensed pharmacist shall either initially interpret all prescription orders compounded or dispensed from such outlet or provide written protocols for such compounding and dispensing by unlicensed persons. An outlet qualifying for registration under this paragraph (b) may also apply to the board for a waiver of such requirements concerning physical space, equipment, inventory, or business hours as may be necessary and consistent with the outlet's limited public welfare purpose. In determining the grant or denial of such waiver application, the board shall ensure that the public interest criteria set forth in section 12-22-101 are satisfied. All other provisions of this part 1, except as specifically waived by the board, shall apply to such outlet.

(4) The registration of every outlet and the license of every pharmacist and pharmacy intern regularly practicing shall be conspicuously displayed within the premises of the place of practice or outlet.

(5) The pharmacist responsible for the prescription order or chart order may delegate certain specific tasks, as provided in section 12-22-102 (26) (b), to a person who is not a pharmacist or pharmacist intern and who is under his direct and immediate supervision if in his professional judgment such delegation is appropriate; except that no such delegation may be made if the delegation jeopardizes the public health, safety, or welfare, is prohibited by rule or regulation of the board, or violates the provisions of section 12-22-126 (1).

12-22-120. Registration of facilities. (1) All outlets with facilities in this state shall register annually with the board in one of the following classifications:

(a) Prescription drug outlet;

(b) Wholesale drug outlet;

(c) Manufacturing drug outlet;

(d) Repealed, L. 84, p. 411, 3, effective February 17, 1984.

(e) Other, as may be authorized by this article.

(2) The board shall establish by rule or regulation criteria, consistent with section 12-22-116 and with the public interest as set forth in section 12-22-101, which an outlet that has employees or personnel engaged in the practice of pharmacy must meet to qualify for registration in each classification.

(3) The board shall specify by rule or regulation the registration procedures to be followed, including, but not limited to, the specification of forms for use in applying for registration and the information needed.

(4) Registrations issued by the board pursuant to this section are not transferable or assignable.

(5) It shall be lawful for a person to sell and distribute nonprescription drugs. Any person engaged in the sale and distribution of such drugs shall not be deemed to be improperly engaged in the practice of pharmacy, nor shall the board promulgate any rule or regulation pursuant to this part 1 which permits the sale of nonprescription drugs only by a licensed pharmacist or only under the supervision of a licensed pharmacist or which would otherwise apply to or interfere with the sale and distribution of nonprescription drugs.

(6) The board shall accept the licensure or certification of nursing care facilities and intermediate care facilities required by the department of public health and environment as sufficient registration under this section.

12-22-121. Compounding, dispensing, and sale of drugs and devices. (1) Except as otherwise provided in this section and part 3 of this article, no drug, controlled substance, as defined in section 12-22-303 (7), or device shall be sold, compounded, dispensed, given, received, or held in possession unless it is sold, compounded, dispensed, given, or received in accordance with this section.

(2) Except as provided in subsection (7) of this section, a manufacturer of drugs may sell or give any drug to any wholesaler of drugs or to a licensed hospital or registered prescription drug outlet, or he may give or sell any drug to any practitioner authorized by law to prescribe the same.

(3) A wholesaler may sell or give any drug or device to another wholesaler of drugs or devices, to any licensed hospital or registered prescription drug outlet, or to any practitioner authorized by law to prescribe the same.

(4) An order shall be compounded or a prescription dispensed only from a registered prescription drug outlet or other outlet registered pursuant to section 12-22-120 (1) (e).

(5) A registered prescription drug outlet may make a casual sale of or may give a drug to another registered prescription drug outlet or to a wholesaler of drugs, or it may sell or give a drug to a practitioner authorized by law to prescribe the same, or it may supply an emergency kit to a nursing care facility, an intermediate health care facility, or a residential care facility in compliance with subsection (13) of this section.

(6) A practitioner may personally compound and dispense for any patient under his care any drug which he is authorized to prescribe and which he deems desirable or necessary in the treatment of any condition being treated by him, and such practitioner shall be exempt from all provisions of this part 1 except for the provisions of section 12-22-126.

(7) Distribution of any sample shall be made only upon written receipt from a practitioner, and such receipt must be given specifically for each drug or drug strength received.

(8) It is lawful for the vendor of any drug or device to repurchase the same from the vendee to correct an error, to retire an outdated article, or for other good reason, under such rules and regulations as the board may adopt to protect consumers of drugs and devices against the possibility of obtaining unsafe or contaminated drugs or devices.

(9) A duly authorized agent or employee of an outlet registered by the board is not deemed to be in possession of a drug or device in violation of this section if he is in possession thereof for the sole purpose of carrying out the authority granted by this section to his principal or employer.

(10) Any person may apply to the board for, and the board may issue to such person, a special permit authorizing such person to dispose of any stock of drugs or devices in his possession in accordance with such permit. No disposition shall be made under any such permit to anyone other than a person to whom a wholesaler or manufacturer of drugs or devices would be authorized to sell such drug or device.

(11) Any hospital employee or agent authorized by law to administer or dispense medications may dispense a twenty-four-hour supply of drugs on the specific order of a practitioner to a registered emergency room patient.

(12) The original, duplicate, or electronic or mechanical facsimile of a chart order by the physician or lawfully designated agent shall constitute a valid authorization to a pharmacist or pharmacy intern to dispense to a hospitalized patient for administration such amounts of such drugs as will enable an authorized person to administer to such patient the drug ordered by the practitioner. It shall be the responsibility of the practitioner to verify for accuracy any chart order transmitted to anyone other than a pharmacist or pharmacist intern within forty-eight hours of such transmittal.

(13) A nursing care facility, an intermediate health care facility, and a residential care facility providing twenty-four-hour on-site nursing services may maintain emergency drugs provided and owned by a prescription drug outlet, consisting of drugs and quantities as established by the board.

(14) The board by regulation, and subject to the restrictions of section 12-22-119 (5), shall determine a uniform standard number of unlicensed persons for whom a pharmacist may have the responsibility when the pharmacist and unlicensed persons are engaged in dispensing.

(15) Interns under the direct and immediate supervision of a pharmacist may engage in the practice of pharmacy.

(16) After September 1, 1976, no manufacturer or wholesaler of prescription drugs shall sell or give any prescription drug, as provided in subsections (2) and (3) of this section, to a licensed hospital or registered prescription drug outlet or to any practitioner unless the prescription drug stock container bears a label containing the name and place of business of the manufacturer of the finished dosage form of the drug and, if different from the manufacturer, the name and place of business of the packer or distributor.

12-22-122. Prescription required - exception. (1) Except as provided in section 18-18-414, C.R.S., and subsection (2) of this section, an order is required prior to dispensing any prescription drug. Orders shall be readily retrievable within the appropriate statute of limitations.

(2) A pharmacist may refill a prescription order for any prescription drug without the prescriber's authorization when all reasonable efforts to contact the prescriber have failed and when, in the pharmacist's professional judgment, continuation of the medication is necessary for the patient's health, safety, and welfare. Such prescription refill shall only be in an amount sufficient to maintain the patient until the prescriber can be contacted, but in no event shall a refill under this subsection (2) continue medication beyond seventy-two hours. However, if the prescriber states on the prescription that there shall be no emergency filling of the prescription, then the pharmacist shall not issue any medication not authorized by the prescription. Neither a prescription drug outlet nor a pharmacist shall incur any liability as a result of refusing to refill a prescription pursuant to this subsection (2).

12-22-123. Labeling. (1) A prescription drug dispensed pursuant to an order must be labeled as follows:

(a) Repealed, L. 86, p. 622, 36, effective July 1, 1986.

(b) Drugs compounded and dispensed pursuant to a chart order for a patient in a hospital shall bear a label containing the name of the outlet, the name and location of the patient, and the identification of the drug and, when applicable, any suitable control numbers, the expiration date, any warnings, and any precautionary statements.

(c) If the prescription is for an anabolic steroid, the purpose for which the anabolic steroid is being prescribed shall appear on the label.

(2) Except as otherwise required by law, any drug dispensed pursuant to a prescription order shall bear a label prepared and placed on or securely attached to the medicine container stating at least the name and address of the prescription drug outlet, the serial number, and the date of the prescription or of its filling, the name of the drug dispensed unless otherwise requested by the practitioner, the name of the practitioner, the name of the patient, and, if stated in the prescription, the directions for use and cautionary statements, if any, contained in such prescription.

12-22-124. Substitution of prescribed drugs authorized - when - conditions. (1) A pharmacist filling a prescription order for a specific drug by brand or proprietary name may substitute an equivalent drug product if the substituted drug product is the same generic drug type as defined in section 12-22-102 (12) and, in the pharmacist's professional judgment, the substituted drug product is therapeutically equivalent as defined in section 12-22-102 (33), is interchangeable with the prescribed drug, and is permitted to be moved in interstate commerce. A pharmacist making a substitution shall assume the same responsibility for selecting the dispensed drug product as he would incur in filling a prescription for a drug product prescribed by a generic name; except that he shall be charged with notice and knowledge of the federal food and drug administration list of approved drug substances and manufacturers as may be published from time to time.

(2) If, in the opinion of the practitioner, it is in the best interest of his patient that an equivalent drug not be substituted, he may so indicate on the prescription by either writing the words "dispense as written" or by initialing in his own handwriting a preprinted box labeled "dispense as written". In no case shall a facsimile of the handwritten signature or the handwritten initials of a practitioner be preprinted to indicate "dispense as written". If the prescription is communicated orally by the practitioner to the pharmacist, the practitioner may indicate the prohibition on substitution in the same manner and at the same time.

(3) If a substitution is made, the substitution shall be communicated to the purchaser in writing and orally, the container shall be labeled with the name of the drug dispensed, and the pharmacist shall indicate on the file copy of the prescription both the name of the prescribed drug and the name of the drug dispensed in lieu thereof. Communication of such substitution to institutionalized patients shall not be required.

(4) Except as provided in subsection (5) of this section, in no case shall the pharmacist substitute a drug product as provided in this section unless the drug product substituted costs the purchaser less than the drug product prescribed. The prescription shall be priced as if it had been prescribed generically.

(5) If a prescription drug outlet does not have in stock the prescribed drug product and the only equivalent drug product in stock is higher priced, the pharmacist, with the consent of the purchaser, may substitute the higher priced drug product. This subsection (5) applies only to a prescription drug outlet located in a town, as defined in section 31-1-101 (13), C.R.S.

12-22-125. Licenses or registrations may be denied, suspended, or revoked. (1) The board may deny, suspend, or revoke any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(a) Is guilty of misrepresentation, fraud, or deceit in procuring or attempting to procure a license or registration;

(b) Is guilty of the commission of a felony or has had accepted by a court a plea of guilty or nolo contendere to a felony;

(c) Has violated any of the provisions of this part 1, the lawful rules and regulations of the board, or any state or federal law pertaining to drugs.

(2) (a) The board may deny, suspend, or revoke any license to practice as a pharmacist or pharmacy intern, after a hearing held in accordance with the provisions of this section, upon proof that the licensee:

(I) Is unfit or incompetent by reason of negligence, habits, or physical or mental illness, or for any other cause, to practice as such;

(II) Is habitually intemperate or is addicted to or uses to excess habit-forming drugs or controlled substances, as defined in section 12-22-303 (7);

(III) Knowingly permits a person not licensed as a pharmacist or pharmacy intern to engage in the practice of pharmacy;

(IV) Has had his license to practice pharmacy in another state revoked or suspended for disciplinary reasons or has committed acts in any other state which would subject him to disciplinary action in this state;

(V) Has engaged in advertising which is misleading, deceptive, or false.

(b) In considering the conviction of a crime, the board shall be governed by the provisions of section 24-5-101, C.R.S.

(3) Proceedings for the denial, suspension, or revocation of a license or registration and judicial review shall be in accordance with the provisions of article 4 of title 24, C.R.S., and the hearing and opportunity for review shall be conducted pursuant to said article by the board or an administrative law judge at the board's discretion.

(4) Upon the finding of the existence of grounds for discipline of any person holding or seeking a license or registration or the renewal thereof under the provisions of this part 1, the board may impose one or more of the following penalties:

(a) Suspension of the offender's license or registration for a period to be determined by the board;

(b) Revocation of the offender's license or registration;

(c) Restriction of the offender's license or registration to prohibit the offender from performing certain acts or from practicing pharmacy in a particular manner for a period to be determined by the board;

(d) Refusal to renew the offender's license or registration;

(e) Placement of the accused on probation and supervision by the board for a period to be determined by the board;

(f) Suspension of the registration of the outlet owned by the offender or in which the offender is employed for a period to be determined by the board.

(5) (a) The board may also include in any disciplinary order which allows the licensee or registrant to continue to practice such conditions as the board may deem appropriate to assure that the licensee is physically, mentally, morally, and otherwise qualified to practice pharmacy in accordance with the generally accepted professional standards of practice, including any or all of the following:

(I) Submission by the respondent to such examinations as the board may order to determine his physical or mental condition or his professional qualifications;

(II) The taking by him of such therapy courses of training or education as may be needed to correct deficiencies found either in the hearing or by such examinations;

(III) The review or supervision of his practice as may be necessary to determine the quality of his practice and to correct deficiencies therein; and

(IV) The imposition of restrictions upon the nature of his practice to assure that he does not practice beyond the limits of his capabilities.

(b) Upon failure of the licensee or registrant to comply with any conditions imposed by the board pursuant to paragraph (a) of this subsection (5), unless due to conditions beyond the licensee's or registrant's control, the board may order suspension of the offender's license or registration in this state until such time as the licensee or registrant complies with such conditions.

(6) When a complaint or an investigation discloses an instance of misconduct which, in the opinion of the board, does not warrant formal action by the board but which should not be dismissed as being without merit, a letter of admonition may be sent by certified mail to the pharmacist against whom a complaint was made and a copy thereof to the person making the complaint, but, when a letter of admonition is sent by certified mail by the board to a pharmacist complained against, such pharmacist shall be advised that he has the right to request in writing, within twenty days after proven receipt of the letter, that formal disciplinary proceedings be initiated against him to adjudicate the propriety of the conduct upon which the letter of admonition is based. If such request is timely made, the letter of admonition shall be deemed vacated, and the matter shall be processed by means of formal disciplinary proceedings.

12-22-125.5. Judicial review. The court of appeals shall have initial jurisdiction to review all final actions and orders that are subject to judicial review of the board. Such proceedings shall be conducted in accordance with section 24-4-106 (11), C.R.S.

12-22-126. Unlawful acts. (1) It is unlawful:

(a) To practice pharmacy without a license;

(b) To obtain or dispense or to procure the administration of a drug by fraud, deceit, misrepresentation, or subterfuge, or by the forgery or alteration of an order, or by the use of a false name or the giving of a false address;

(c) To willfully make a false statement in any order, report, application, or record required by this part 1;

(d) To falsely assume the title of or to falsely represent that one is a pharmacist, practitioner, or registered outlet;

(e) To make or utter a false or forged order;

(f) To affix a false or forged label to a package or receptacle containing drugs;

(g) Repealed, L. 86, p. 622, 36, effective July 1, 1986.

(h) To sell, compound, dispense, give, receive, or possess any drug or device unless it was sold, compounded, dispensed, given, or received in accordance with sections 12-22-121 to 12-22-124;

(i) Except as provided in section 12-22-124, to dispense a different drug or brand of drug in place of the drug or brand ordered or prescribed without the oral or written permission of the practitioner ordering or prescribing the drug;

(j) To manufacture, process, pack, distribute, sell, dispense, or give a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by such other drug manufacturer, processor, packer, or distributor;

(k) For an employer or an employer's agent or employee to coerce a pharmacist to dispense a prescription drug against the professional judgment of the pharmacist;

(l) For an employer or an employer's agent or employee or a pharmacist to use or coerce to be used a nonpharmacist personnel in any position or task which would require the nonpharmacist to practice pharmacy or to make a judgmental decision using pharmaceutical knowledge, or in violation of the delegatory restrictions enumerated in section 12-22-119 (5);

(m) To dispense any drug without complying with the labeling, drug identification, and container requirements imposed by law.

12-22-127. Penalty for violations. Any person who violates any of the provisions of this part 1 commits a class 2 misdemeanor and shall be punished as provided in section 18-1-106, C.R.S.; and any person committing a second or subsequent offense commits a class 6 felony and shall be punished as provided in section 18-1-105, C.R.S.

12-22-128. New drugs - when sales permissible. (1) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.

(2) This section shall not apply to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs if the drug is plainly labeled to be for investigational use only.

12-22-129. Advertising of prescription drug prices. A prescription drug outlet may advertise its prices for prescription drugs. If the drug is advertised by its brand or proprietary name, its generic name shall also be included in the advertisement.

PART 6

12-22-601. Legislative declaration. (1) The general assembly hereby finds, determines, and declares that the creation of a pharmacy peer health assistance diversion program for those persons subject to the jurisdiction of the state board of pharmacy will serve to safeguard the life, health, property, and public welfare of the people of this state. Such pharmacy peer health assistance diversion program will help practitioners experiencing impaired practice due to psychiatric, psychological, or emotional problems or excessive alcohol or drug use or addiction. The general assembly further declares that such pharmacy peer health assistance diversion program will protect the privacy and welfare of those persons who provide services and at the same time assist the board in carrying out its duties and responsibilities to ensure that only qualified persons are allowed to engage in providing those services which are under the jurisdiction of the board.

(2) It is the intent of the general assembly that the pharmacy peer health assistance diversion program and its related procedures shall be utilized by the state board of pharmacy as an alternative to the use of disciplinary proceedings by the board, which proceedings are by their nature time-consuming and costly to the people of this state. The pharmacy peer health assistance diversion program is hereby established to alleviate the need for such disciplinary proceedings, while at the same time providing safeguards that protect the public health, safety, and welfare. The general assembly further declares that it is its intent that the state board of pharmacy will act to implement the provisions of this article.

(3) The general assembly further finds, determines, and declares that effective July 1, 1994, the pharmacy peer health assistance fund shall be terminated, the balance of moneys in the fund shall be transferred prior to June 30, 1994, to an administering entity selected by the board, which entity shall administer the programs of board selected designated providers, and that the fiscal year beginning July 1, 1993, shall be used by the department of regulatory agencies as a transition year to plan for the transfer of responsibilities for such programs.

12-22-602. Definitions. As used in this part 6, unless the context otherwise requires:

(1) "Board" shall have the same meaning as set forth in section 12-22-102 (4).

(1.5) "Committee" means the rehabilitation evaluation committee which is appointed by the board to carry out specified duties pursuant to section 12-22-606.

(2) "Impaired practice" means a licensee's inability to meet the requirements of the laws of this state and the rules and regulations of the board governing his or her practice when the licensee's cognitive, interpersonal, or psychomotor skills are

affected by psychiatric, psychological, or emotional problems or excessive alcohol or drug use or addiction.
(3) "Licensee" means any pharmacist or intern who is licensed by the board.

(4) "Peer health assistance organization" means an organization which provides a formal, structured program that meets the requirements specified in this part 6. Such program is administered by appropriate professionals for the purpose of assisting licensees experiencing impaired practice to obtain evaluation, treatment, short-term counseling, monitoring of progress, and ongoing support for the purpose of arresting and treating the licensee's psychiatric, psychological, or emotional problems or excessive alcohol or drug use or addiction.

12-22-603. Pharmacy peer health assistance fund. (1) (a) There is hereby created in the state treasury the pharmacy peer health assistance fund. The fund shall consist of moneys collected by the board and required to be credited to the fund pursuant to subsection (3) of this section. Any interest earned on the investment of moneys in the fund shall be credited at least annually to said fund.

(b) Prior to June 30, 1994, the board shall transfer the balance in the fund, if any, to the administering entity chosen by the board pursuant to paragraphs (d) and (e) of subsection (3) of this section.

(2) Repealed.

(3) (a) Repealed.

(b) Effective July 1, 1994, as a condition of licensure and licensure renewal in this state, every applicant shall pay to the administering entity that has been selected by the board pursuant to the provisions of paragraphs (d) and (e) of this subsection (3) an amount set by the board not to exceed twenty-eight dollars biennially, which amount shall be used to support designated providers that have been selected by the board to provide assistance to pharmacists needing help in dealing with physical, emotional, psychiatric, psychological, drug abuse, or alcohol abuse problems which may be detrimental to their ability to practice.

(c) The board shall select one or more peer health assistance organizations as designated providers. To be eligible for designation by the board a peer health assistance program shall:

(I) Provide for the education of pharmacists with respect to the recognition and prevention of physical, emotional, and psychological problems and provide for intervention when necessary or under circumstances which may be established by rules promulgated by the board;

(II) Offer assistance to a pharmacist in identifying physical, emotional, or psychological problems;

(III) Evaluate the extent of physical, emotional, or psychological problems and refer the pharmacist for appropriate treatment;

(IV) Monitor the status of a pharmacist who has been referred for treatment;

(V) Provide counseling and support for the pharmacist and for the family of any pharmacist referred for treatment;

(VI) Agree to receive referrals from the board;

(VII) Agree to make their services available to all licensed Colorado pharmacists.

(d) The administering entity shall be a qualified, nonprofit, private foundation that is qualified under section 501 (c) (3) of the federal "Internal Revenue Code of 1986", as amended, and shall be dedicated to providing support for charitable, benevolent, educational, and scientific purposes that are related to pharmaceutical education, pharmaceutical research and science, and other pharmaceutical charitable purposes.
(e) The responsibilities of the administering entity shall be:
(I) To collect the required annual payments;
(II) To verify to the board, in a manner acceptable to the board, the names of all pharmacist applicants who have paid the fee set by the board;
(III) To distribute the moneys collected, less expenses, to the designated provider, as directed by the board, and to members of the rehabilitation evaluation committee, pursuant to section 12-22-606 (3);
(IV) To provide an annual accounting to the board of all amounts collected, expenses incurred, and amounts disbursed; and
(V) To post a surety performance bond in an amount specified by the board to secure performance under the requirements of this section. The administering entity may recover the actual administrative costs incurred in performing its duties under this section in an amount not to exceed ten percent of the total amount collected.

12-22-604. Eligibility for awards - pharmacy peer health assistance organization - repeal. (Repealed)

12-22-605. Eligibility - participants. (1) Any licensee who is experiencing impaired practice may apply to the board for participation in a qualified peer health assistance program.
(2) In order to be eligible for participation, a licensee shall:
(a) Acknowledge the existence of a psychiatric, psychological, or emotional problem or excessive alcohol or drug use or addiction;
(b) After a full explanation of the operation of and the requirements of the peer health assistance program, agree to voluntarily participate in such program and agree in writing to participate in the program of the peer health assistance organization designated by the board.
(3) Notwithstanding the provisions of this section, the board may summarily suspend the license of any licensee who is referred to a peer health assistance program by the board and who fails to attend or to complete such program. The board shall thereupon schedule a hearing on such suspension which shall be conducted in accordance with section 24-4-105, C.R.S.

12-22-606. Rehabilitation evaluation committee - created. (1) The board shall establish a rehabilitation evaluation committee, which shall consist of five members to be appointed by the board. Each member of the committee shall serve for a term of four years; except that, of the three voting members, one shall serve an initial term of one year, one shall serve an initial term of two years, and one shall serve an initial term of three years. Other than the staff member for the board, no member shall serve more than one full four-year term. The members shall be selected as follows: Three members who are licensed pharmacists including one who has recovered from an addiction to alcohol or drugs; one member who is the staff member for the board; and one member who is the director of a program provided by a pharmacy peer health assistance organization. The staff member for the board and the peer health assistance program director shall be nonvoting members of the committee.

(2) (a) The committee shall meet as necessary to review applications to participate in the pharmacy peer health assistance diversion program. For each application, the committee shall make a recommendation to the board that the application be approved or that it be rejected. The board shall either grant or deny applications, based upon reasonable grounds which shall be stated in writing. Such applications may also include requests by licensees to continue in practice while participating in an approved program. The committee shall make a recommendation to the board that such request to continue in practice be approved or rejected. In those cases where a committee has recommended approval of the application for participation in the program, the licensee may begin participation in the program of the designated pharmacy peer health assistance organization pending final board action on the committee's recommendation. If a committee has recommended that a request to continue in practice be approved, such licensee may continue to practice pending final board action on the committee's recommendation.

(b) The committees shall review reports from pharmacy peer health assistance organizations and from individual participants concerning each participant's progress in the program and his or her compliance with any requirements established by the board.

(3) (a) Repealed.

(b) Effective July 1, 1994, rehabilitation evaluation committee members shall be reimbursed from funds collected by the administering entity pursuant to section 12-22-603 (3) (e), for actual and necessary expenses incurred in the performance of their duties under this section and shall be paid from such fund only for time actually spent in the performance of duties under this section in the same manner and at the same rate of per diem compensation or percentage thereof as provided by law for members of boards or commissions within the division of registrations in the department of regulatory agencies as provided in section 24-34-102 (13), C.R.S.

(4) (Deleted by amendment, L. 94, p. 1264, 2, effective July 1, 1994.)

12-22-607. Liability. Nothing in this section shall be construed to create any liability of the board, members of the board, a committee, the members of a committee, or the state of Colorado for the actions of the board in making awards to pharmacy peer health assistance organizations or in designating licensees to participate in the programs of such organizations. No civil action may be brought or maintained against the board, its members, a committee, the members of a committee, or the state for an injury alleged to have been the result of an act or omission of a licensee participating in or referred to a state-funded program provided by a pharmacy peer health assistance organization. However, the state shall remain liable under the provisions of the "Colorado Governmental Immunity Act", article 10 of title 24, C.R.S., if an injury alleged to have been the result of an act or omission of a licensee participating in or referred to a state-funded peer health assistance diversion program occurred while such licensee was performing duties as an employee of the state.

12-22-608. Immunity. Any member of the board or any member of a rehabilitation evaluation committee acting pursuant to the provisions of this part 6 shall be immune from suit in any civil action if such member acted in good faith within the scope of the function of such board or committee, made a reasonable effort to obtain the facts of the matter as to which the member acted, and acted in the reasonable belief that the action taken by the member was warranted by the facts.