

COLORADO DEPARTMENT OF REGULATORY AGENCIES
OFFICE OF POLICY AND RESEARCH

COLORADO STATE BOARD OF PHARMACY

2002 SUNSET REVIEW



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STATE OF COLORADO

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Bill Owens
Governor

October 15, 2002

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed the evaluation of the State Board of Pharmacy. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2003 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

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

The department of regulatory agencies shall submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination....

The report discusses the question of whether there is a need for the regulation provided under Article 22 of Title 12, C.R.S. The report also discusses the effectiveness of the State Board of Pharmacy and staff in carrying out the intent of the statutes and makes recommendations for statutory changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

A handwritten signature in cursive script that reads "M. Michael Cooke".

M. Michael Cooke
Executive Director

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Background

The Sunset Process

The regulatory functions of the State Board of Pharmacy (Board) in accordance with Article 22 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2003, unless continued by the General Assembly. During the year prior to this date, it is the duty of the Department of Regulatory Agencies (DORA) to conduct an analysis and evaluation of the Board pursuant to section 24-34-104(9)(b), C.R.S.

The purpose of this review is to determine whether the Board should be continued for the protection of the public and to evaluate the performance of the Board and staff of the Division of Registrations. During this review, the Board must demonstrate that there is still a need for the regulatory program and that the regulation is the least restrictive consistent with the public interest. DORA's findings and recommendations are submitted via this report to the legislative committee of reference of the Colorado General Assembly. Statutory criteria used in sunset reviews may be found in Appendix A on page 61.

Methodology

During the review of the Board, DORA staff:

- Interviewed agency staff.
- Attended Board meetings.
- Met with a representative from the Pharmacy Peer Health Assistance Diversion Program.
- Interviewed staff from the State Board of Medical Examiners and the State Veterinarian's Office.
- Conducted interviews and solicited written comments from state and local interest groups.
- Met with educators from the University of Colorado Health Sciences Center, School of Pharmacy.

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- Met with representatives from pharmacy associations, including the Colorado Society of Health-System Pharmacists, Pharmacy Sunset Review Task Force, Rx Plus Pharmacies, and the Colorado Retail Council.
 - Reviewed reports by the National Association of Chain Drug Stores, American Pharmaceutical Association, and the National Community Pharmaceutical Association.
 - Researched the functions of, and spoke with representatives from pharmacy regulatory agencies in other states.
 - Reviewed Board documents and reports, state statutes, legislative reports, previous legislation, literature on pharmacy issues, and performed background and comparative research using the Internet.

Profiles of the Professions

Pharmacists

According to the U.S. Department of Labor's *Occupational Outlook Handbook 2002-2003* edition, pharmacists dispense drugs prescribed by physicians and other health practitioners and provide information to patients about medications and their use. They advise physicians and other health practitioners on the selection, dosages, interactions, and side effects of medications. Pharmacists must understand the use, composition, and clinical effects of drugs. Compounding, the actual mixing of ingredients to form powders, tablets, capsules, ointments, and solutions, is only a small part of a pharmacist's practice, because most medicines are produced by pharmaceutical companies in a standard dosage and drug delivery form.

Pharmacists in hospitals and clinics dispense medications and advise the medical staff on the selection and effects of drugs. They may make sterile solutions and buy medical supplies. They also assess, plan, and monitor drug regimens. They counsel patients on the use of drugs while in the hospital, and on their use at home when they are discharged. Pharmacists may also evaluate drug use.

Pharmacists who work in home health care monitor drug therapy and prepare medications and solutions for use in the home. Some pharmacists specialize in specific drug therapy areas, such as psychiatric disorders, intravenous nutrition support, oncology, nuclear pharmacy, and pharmacotherapy. Approximately three out of five pharmacists work in community pharmacies, either independently owned or part of a drug store chain, grocery store, department store, or mass merchandiser.

A license to practice pharmacy is required in all states, the District of Columbia, and U.S. territories. To obtain a license, one must serve an internship under a licensed pharmacist, graduate from an accredited college of pharmacy, and pass a state examination.

The American Council on Pharmaceutical Education is the accrediting organization that sets standards for pharmacy schools. The University of Colorado, Health Sciences Center operates the only accredited pharmacy school in Colorado. In 1998, the American Council on Pharmaceutical Education accredited 81 colleges of pharmacy to confer degrees. Nearly all pharmacy programs, including the University of Colorado's, grant the degree of Doctor of Pharmacy (Pharm.D.) that requires at least six years of postsecondary study. A limited number of pharmacy schools continue to award the five-year Bachelor of Science (B.S.) in pharmacy degree. However, all accredited pharmacy schools are expected to graduate their last B.S. class by the year 2005. To be eligible for the licensure examination, state boards of pharmacy require either a Pharm.D. or a B.S. degree.

Pharmacy Technicians

Pharmacy technicians assist licensed pharmacists by providing medication and other health care products to patients. Pharmacy technicians who work in retail pharmacies have varying responsibilities, depending on state rules and regulations. In Colorado, the pharmacist responsible for the prescription or chart order may delegate certain tasks as defined in statute to a pharmacy technician. The technician is required to be under the supervision of the licensed pharmacist.

Pharmacy technicians regularly perform routine tasks to help prepare prescribed medication for patients, such as counting and labeling, weighing, measuring, and sometimes mixing the medication. Technicians may establish and maintain patient profiles, prepare insurance claim forms, and stock and take inventory of prescription and over-the-counter medications. A pharmacist must check every prescription before it can be given to a patient. Technicians refer any questions regarding prescriptions, drug information, or health matters to a pharmacist.

History of Regulation

The practice of pharmacy has been regulated in Colorado since 1887, when the General Assembly created the State Board of Pharmacy comprised of pharmacists who had ten years of experience. At that time, it was unlawful for anyone other than a licensed pharmacist to retail or dispense drugs or operate a pharmacy. Original licensing requirements included graduation from a school of pharmacy and two years of experience, or two years of experience and a passing score on a Board administered examination. Five years experience was required to operate a pharmacy.

The statute was amended in 1893 to require four years experience for licensure and to regulate specific potent drugs and metals. Between 1913 and 1917, changes were made to reflect the growing concern with the misuse of dangerous drugs. Restrictions were placed on the sale of opium, coca leaves and cocaine, and the sale of peyote was forbidden. In addition, a prescription was required and record keeping standards were implemented.

The 1921 repeal and reenactment of the pharmacy statute authorized the Colorado Pharmacy Association to select the board members. The statute also listed narcotics and prohibited their sale by any person other than a pharmacist. In 1945, the statute was further amended to provide for three types of pharmacist licenses: pharmacists, associate pharmacists, and assistant pharmacists.

Rule making authority was given to the Board in 1957, as well as the authority to suspend, revoke, or deny a license. The Board was transferred as a Type 1 policy autonomous board to the Department of Regulatory Agencies, Division of Registrations by the Administrative Organization Act of 1968.

The statute was repealed and reenacted in 1979, to require registration of prescription drug outlets, non-prescription drug outlets, wholesalers, manufacturers, and nuclear pharmacies. The Board was authorized to approve new drugs, embargo adulterated or misbranded drugs, and to approve schools of pharmacy. It was not until 1979 that persons without a degree in pharmacy were excluded from obtaining a pharmacist license.

In 1981, the definition of prescription drug outlets was expanded to include nursing homes, rural health clinics, and family planning clinics. In 1984, the Board's authority over non-prescription outlets was removed from the statute. The Board underwent sunset review in 1985 and legislation to continue the Board passed the 1986 General Assembly. The legislation required persons to pass a jurisprudence examination and amended the process for removing board members by authorizing the Governor to remove members. The legislation also clarified that a prescription drug outlet may buy controlled substances from another prescription drug outlet. The legislation also added the provision that the Board may take disciplinary action against a licensee for actions in another state that are grounds for discipline in Colorado.

Changes in 1996 were a result of recommendations made in the 1995 Sunset Review. The amended law consolidated the four classes of pharmacist licensees into one and added a definition of "pharmaceutical care" and "supervision." In addition, the bill amended the law by creating a provision that required the registration of outlets that provide pharmaceutical care and services. It also revised the section addressing pharmacist's supervision of unlicensed personnel. Lastly, it granted the Board authority to issue a confidential letter of concern when an investigation reveals practices that are not violations, but could lead to violations of the statute or Board rules and regulations.

Legal Framework

The Colorado Drugs and Druggists Act (Act) is contained in section 12-22-101, et seq, Colorado Revised Statutes (C.R.S.). The Act defines the scope of the practice of pharmacists, creates the State Board of Pharmacy (Board), and establishes the framework for the promulgation of rules and regulations by the Board. The Board licenses and regulates not only pharmacists and pharmacies, but also the distribution system where there is sale, delivery, or distribution of prescription drugs.

The Board consists of five licensed pharmacists and two public members, all appointed by the Governor. The Act specifies geographical diversity and practice diversity. The Board is required to meet at least three times a year and elect its own officers.

Definitions are contained in section 12-22-102, C.R.S. The Act defines outlet as “any prescription drug outlet, hospital, institution, nursing home, rural health clinic, convalescent home, extended care facility, family planning clinic, wholesaler, manufacturer, or mail order vendor, other than a pharmacist, that has facilities in this state registered pursuant to this article and that engages in the dispensing, delivery, distribution, manufacturing, wholesaling, or sale of drugs or devices.”

Powers and Duties of the Board

The Act empowers the Board to promulgate rules and regulations. In addition, the Board is empowered to perform a variety of general regulatory functions including granting licenses and registrations, conducting investigations and inspections, administering examinations, controlling and regulating drugs, and impounding and destroying adulterated or misbranded drugs and devices at a prescription drug outlet.

Requirements for Licensing/Registration

The Act outlines the application procedures for licensure as a pharmacist and registration as an outlet, manufacturer, or wholesaler. The Act provides exemption from licensure for hospital residency programs. The Board may issue a license by transfer to a person licensed by examination and in good standing in another state.

The Board is authorized to register various types of facilities including prescription drug outlets; wholesale drug outlets; manufacturing drug outlets; and any other outlets defined that may include rural health clinics, convalescent homes, extended care facilities, animal shelters, jails or prisons, and family planning clinics. Although prescription drug outlets operated by the State of Colorado or any political subdivision are not required to register, they are required to apply for a certificate of compliance.

Scope of Practice

The practice of pharmacy consists of initial interpretation, selection of ingredients, and final evaluation of each prescription order or chart order. Furthermore, it includes participation in drug selection and utilization of drugs and devices in the treatment of an injury, treatment and prevention of disease, and the counseling of patients and prospective drug review.

In addition, the practice includes the responsibility for the compounding, dispensing, labeling (except nonprescription drugs), delivery, storage, and distribution of drugs and devices and maintenance of proper records.

Discipline

The Board is authorized to deny, refuse to renew, restrict, suspend or revoke any license or registration. The Board is also empowered to issue letters of admonition, letters of concern, and impose probation.

The Act establishes over 20 grounds of unprofessional conduct or grounds for discipline that include such activities as fraud, misrepresentation, or deceit in procuring a license or registration; dependence on, or excessive use of, alcohol or any habit-forming drug; obtaining, dispensing, or procuring a drug by fraud, deceit, misrepresentation, or subterfuge; or affixing a false or forged label to a package containing drugs.

In addition, the Board may take disciplinary action against a licensee who has dispensed any drug without complying with the labeling, drug identification, and container requirements imposed by law; falsely represented a drug in the manufacturing, processing, packing, distributing, selling or dispensing of such drug; or utilized nonpharmacist personnel in the practice of pharmacy in violation of the delegatory restrictions of the Act.

Continuing Education

To renew or reactivate a license, pharmacists are required to complete 24 hours of approved continuing education within the preceding two years. Failure to obtain the 24 hours of approved continuing pharmaceutical education will result in the license becoming inactive.

Delegation of Duties to Unlicensed Personnel

Pharmacists are authorized to supervise up to two unlicensed personnel for duties described in the Act. This supervision ratio does not include other ancillary personnel who may be employed in the prescription drug outlet such as clerks and those working the cash register.

Labeling

Labeling requirements for medications dispensed pursuant to a prescription order must include the name and address of the outlet; the name and address of the patient; identification of the drug; and when applicable, control number, expiration dates, warnings, and precautionary statements.

Licensing of Controlled Substances

Part 3 of the Colorado Licensing of Controlled Substances Act authorizes the Board to regulate persons manufacturing and distributing controlled substances. In addition, the Board issues licenses to humane societies or animal control agencies, which have been in existence for more than five years and who euthanize injured, sick, homeless, or unwanted pets and animals.

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

Pharmacy Peer Health Assistance Diversion Program

The Pharmacy Peer Health Assistance Diversion Program is utilized by the Board to provide assistance and referral to pharmacists experiencing impaired practice due to psychiatric, psychological, or emotional problems or excessive alcohol or drug use. The program is primarily funded through the pharmacist licensure renewal process. Fourteen dollars a year of this fee is appropriated for the program.

Summary of Rules and Regulations

The general authority for the promulgation of rules and regulations pertaining to the licensing of pharmacists and registration of facilities, manufacturers, and distributors is set forth in section 12-22-108, C.R.S. A listing of these rules may be found in Appendix E on page 92.

Controlled Substances Act

The regulation of prescription drugs is a shared responsibility of the federal and state governments. While the federal government has extensive control and record keeping requirements over what may be dispensed, individual states have broad latitude over who may administer, dispense, and prescribe controlled substances.

The federal Controlled Substances Act, which is Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 provides a comprehensive approach to the regulation, manufacture, and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the production of controlled substances.

The Controlled Substances Act is administered by the U.S. Department of Justice, Drug Enforcement Administration (DEA), Diversion Control Program. The DEA's Office of Diversion Control is responsible for two distinct problems: the diversion of controlled pharmaceuticals and the diversion of controlled chemicals. Many of the narcotics, depressants, and stimulants manufactured for legitimate medical uses are subject to abuse and have been brought under legal control.

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

Food, Drug and Cosmetic Act

Section 809 of the federal Food, Drug and Cosmetic Act relates to the practice of drug compounding by a pharmacist. State licensure laws include compounding as a core component of the profession of pharmacy. While the Food, Drug and Cosmetic Act specifically exempts pharmacies from inspection and registration provisions of this legislation, it has been the contention of the U.S. Food and Drug Administration that compounded products are not exempt from the act's new drug provisions.

Medicare Beneficiary Prescription Drug Assistance and Stop-Loss Protection Act of 2000

The Medicare Beneficiary Prescription Drug Assistance and Stop-Loss Protection Act of 2000 provides prescription drug coverage and certain drug therapy management services. It addresses the inclusion of a drug therapy management program as an outpatient prescription-drug benefit, explicitly recognizing that pharmacists may provide a range of patient-care services that require different commitments of time and resources.

Program Description and Administration

Licensing/Registration

The State Board of Pharmacy (Board) in the Division of Registrations within the Department of Regulatory Agencies (DORA) is responsible for the licensing and regulation of pharmacists and pharmacy interns. The Board is also responsible for the registration and regulation of all pharmacies, wholesalers, packagers, and manufacturers that do business in Colorado.

The Board has the power and duty to inspect all places handling drugs, medicines, and chemicals. The Board is charged with the enforcement of federal and state prescription drug and controlled substance laws.

There are 7.5 full-time equivalent (FTE) employees allocated to the program that include a program administrator, 2.5 administrative assistants, and four full-time licensed pharmacists to conduct inspections and investigate complaints. The administrative assistants process license and registration applications and renewal applications, and provide administrative support to the Board. Fees are established annually to cash fund administrative expenses and for the Pharmacy Peer Health Assistance Diversion Program. Table 1 details the Board's expenditures for the past six fiscal years.

**Table 1
State Board of Pharmacy Budget**

Fiscal Year	Total Expenditures
FY 96-97	\$720,193
FY 97-98	\$713,463
FY 98-99	\$774,865
FY 99-00	\$788,680
FY 00-01	\$781,941
FY 01-02	\$776,115

Colorado currently has 982 registered pharmacies, 419 licensed pharmacy interns, and 5,353 licensed pharmacists. The Board has also issued registrations to 131 distributors, manufacturers, and wholesalers. Additionally, the Board issues licenses each year to animal shelters, hospitals, community and rural health clinics, family planning clinics, schools, and jails. Under the provisions of section 12-22-603 (3)(b), Colorado Revised Statutes (C.R.S.), the Board is required to establish fees for each pharmacist, not to exceed \$28 biennially, for the administration of

the Pharmacy Peer Health Assistance Diversion Program. Currently, the fee for a pharmacist license is \$233 biennially and the fee for a pharmacist intern license is \$41 annually. The tables below illustrate the categories and numbers of licenses and registrations granted by the Board.

**Table 2
Number of Licenses and Registrations**

Fiscal Year	Licensed Pharmacists		Pharmacy Intern		Registered Outlets	
	New	Total	New	Total	New	Total
FY 96-97	246	4,195	3	343	8	1,357
FY 97-98	269	4,374	20	342	10	1,421
FY 98-99	300	4,557	96	349	11	1,489
FY 99-00	275	4,896	78	365	21	1,575
FY 00-01	293	5,084	152	363	9	1,712
FY 01-02	234	5,353	169	419	215	1,605

**Table 3
Classification of Registered Outlets**

Type of Business	Fees	FY 97	FY 98	FY 99	FY 00	FY 01
Pharmacies	\$250	862	890	918	940	982
Out of State Pharmacies	\$100	213	214	226	257	319
Other Outlets						
1 Hospitals	\$100	14	14	14	15	15
2 Community and Rural Health Clinics	\$100	57	61	64	73	74
3 Family Planning Clinics	\$100	36	36	36	40	41
4 Universities and Schools	\$100	19	20	21	21	22
5 Jail	\$100	30	35	39	45	51
6 County Health Departments.	\$100	25	25	28	29	29
OTHER OUTLET TOTALS		181	191	202	223	232
Wholesalers, Manufacturers and Distributors	\$250	69	84	101	112	131
Limited Licenses – Animal Shelters	\$25	32	42	42	43	48
Total Number of Registered/Licensed Facilities		1,357	1,421	1,489	1,575	1,712

The Board issues licenses to new applicants by examination or by license transfer. Individuals requesting licensure by examination must submit evidence of completion of an internship, graduation from an educational institution of pharmacy approved by the Board, and successful completion of a Board administered written jurisprudence examination in addition to the national examination. Persons who produce satisfactory evidence that they have graduated from a school of pharmacy outside of the United States and have passed a foreign graduate equivalency test are eligible to take the national examination. Applicants for licensure by transfer are required to submit their documentation to a Board designated clearinghouse for review.

Table 4
Number of Licenses Issued to Pharmacists Through Examination or License Transfer

Fiscal Year	Issued by Exam	Issued by License Transfer	Total
FY 96-97	154	92	246
FY 97-98	140	129	269
FY 98-99	164	136	300
FY 99-00	155	120	275
FY 00-01	158	135	293
FY 01-02	104	130	234

Examination

The North American Pharmacist Licensure Examination (NAPLEX) developed by the National Association of Boards of Pharmacy (NABP) is utilized by the Board as part of the assessment of competence to practice pharmacy.

The NAPLEX is a computer-adaptive examination that consists of 185 multiple-choice test questions. Of these, 150 questions are used to calculate the test score. A majority of the questions on the NAPLEX are asked in a scenario-based format (i.e, patient profiles with accompanying test questions).

In addition, the computer-based Multistate Pharmacy Jurisprudence Examination (MPJE) combines national and state-specific legal questions to serve as the state law examination in participating jurisdictions. The MPJE is based on a national blueprint of pharmacy jurisprudence competencies; however, the questions are tailored to the specific law in Colorado.

The Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification program is accepted by more than 40 state boards of pharmacy, including Colorado, as a means of documenting whether an applicant has fulfilled educational equivalency criteria for licensure.

The table below illustrates examination results for fiscal year 96-97 through fiscal year 01-02. As of fiscal year 98-99, NABPLEX was no longer used and was replaced by NAPLEX. As of fiscal year 00-01, the Colorado jurisprudence examination was no longer used and was replaced by MPJE.

**Table 5
Examination Results**

	FY 96-97	FY 97-98	FY 98-99	FY 99-00	FY 00-01	FY 01-02	Totals
NABPLEX							
Pass	116	19	N/A	N/A	N/A	N/A	135
Fail	14	2	N/A	N/A	N/A	N/A	16
Total	130	21	N/A	N/A	N/A	N/A	151
NAPLEX							
Pass	N/A	76	147	128	156	100	607
Fail	N/A	3	18	19	16	15	71
Total	N/A	79	165	147	172	115	678
COLORADO JURISPRUDENCE							
Pass	140	240	281	113	N/A	N/A	774
Fail	27	45	32	15	N/A	N/A	119
Total	167	285	313	128	N/A	N/A	893
MPJE							
Pass	N/A	N/A	N/A	135	293	255	683
Fail	N/A	N/A	N/A	11	18	18	47
Total	N/A	N/A	N/A	146	311	273	730
TOTALS							
Pass	256	335	428	376	449	355	2,199
Fail	41	50	50	45	34	33	253
Total	297	385	478	421	483	388	2,452

Inspections

To successfully implement the pharmacy program, the Board employs four inspectors who are licensed pharmacists to perform routine inspections, and to enforce compliance with the provisions of the Drugs and Druggists Act (Act) and the rules and regulations.

During an inspection of a prescription drug outlet, an inspector examines packaging and labeling; dispensing; distribution; and records and record keeping. An inspection also includes an evaluation of the physical outlet that includes the environment, equipment, security, expired drugs, refrigeration, and employee list. When inspectors assess a wholesale drug outlet they assess the sanitation, storage, security, records and record keeping, controlled substances records, policy and procedure manual, and drug recalls. Other drug outlets such as hospitals, community health clinics, schools, and jails are inspected for records of controlled substances, records of dispensing, packaging and labeling of pharmaceuticals, physical premises, and established protocols.

Depending on the severity of the violation(s), inspectors may require immediate correction or give the facility a specified period of time to comply.

Facility inspection is a major part of the program. Inspectors are responsible for all field inspections whether initiated by a complaint, an application for registration, or a routine inspection. To determine the most frequent violations cited during inspections, a random survey of five percent of the inspections for fiscal year 01-02 was performed (see Appendix B on page 62). The most frequent violations cited addressed controlled substances and such issues as the lack of identification of prescriber, lack of Drug Enforcement Administration (DEA) number, lack of dates of receipt of prescriptions, and deficiencies in DEA inventories. Inadequate record keeping is another deficiency that is often noted during an inspection. For example, quantities dispensed were not recorded, prescriptions lacked required patient information that the pharmacist did not secure, and the daily printout lacked critical required information.

As illustrated in Table 6 on the following page, the number of new deficiencies significantly increased from fiscal year 99-00 to fiscal year 00-01. The number of new deficiencies is significantly greater than the previous year because of vacancies in inspector personnel positions for four months in fiscal year 99-00. During fiscal year 99-00, modified inspections were performed. When staff allocations were filled in fiscal year 00-01, inspections were resumed.

**Table 6
Inspections Performed by the Board**

Fiscal Year	Number of Inspections	Number of Deficiencies Found	
		New	Repeated
FY 96-97	1,022	N/A	N/A
FY 97-98	1,044	N/A	N/A
FY 98-99	1,129	N/A	N/A
FY 99-00	1,075	1,073	77
FY 00-01	1,052	1,795	93
FY 01-02	763	1,583	135

Complaints/Disciplinary Actions

The Board is charged with handling all complaints against licensees and registrants. Violations of the Act and of rules and regulations are discovered through a variety of channels such as self-reporting, inspections, consumer complaints, professional complaints, other agency referrals, and malpractice insurance reports. A majority of the complaints are received from consumers. The program staff screens complaints to make sure that the Board has jurisdiction to respond and that the complaint rises to the level of being a violation of the Act. At this point, the licensee is contacted stating the terms of the complaint and a response is requested in writing within 20 days. Once an inspector has had an opportunity to gather the facts, a report of the complaint and findings of the inspector is sent to the Board for review. The Board may request further study of the complaint by an inspector or make a recommendation for dismissal or disciplinary action. The Board may dismiss, impose discipline, or refer the case to the Attorney General's Office.

The data in the table below illustrates the number of complaints received during the past six fiscal years.

**Table 7
Complaints Received by the Board of Pharmacy**

	FY 96-97	FY 97-98	FY 98-99	FY99-00	FY 00-01	FY 01-02	Total
Pharmacists	93	104	106	85	71	102	561
Prescription Drug Outlets	6	4	5	3	2	10	30
Interns	4	1	2	2	1	4	14
Unlicensed Activity	0	5	1	4	0	6	16

The Board has a variety of enforcement mechanisms available created by statute. The Board may take disciplinary action by denying, suspending, refusing to renew or reinstate, or revoking a license. The Board may also issue a letter of admonition when an investigation discloses an instance of misconduct that does not warrant more severe disciplinary action by the Board. The Board also issues confidential letters of concern that are not considered formal disciplinary action. Table 8 depicts disciplinary actions taken by the Board from fiscal year 96-97 through fiscal year 01-02.

**Table 8
Disciplinary Statistics**

Fiscal Year	Letter of Admonition	Stipulation	Revocation	Dismissed with Letter of Concern	Dismissed	Total
FY 96-97	42	14	2	8	24	90
FY 97-98	40	14	2	14	18	88
FY 98-99	45	16	2	14	32	109
FY 99-00	11	14	4	16	24	69
FY 00-01	13	15	5	8	12	53
FY 01-02	8	20	3	22	18	71
TOTAL	159	93	18	82	128	480

Pharmacy Peer Health Assistance Diversion Program

The Pharmacy Peer Health Assistance Diversion Program (Program) was created through legislation in 1990, and is used by the Board to provide assistance and referral to treatment for pharmacists who are chemically dependent, or who may need psychological/psychiatric assistance or assistance with physical problems. The Program's role is to assess, educate, intervene, identify and diagnose the practitioner's problems, and then refer the practitioner for appropriate treatment. Pursuant to statute and Board rules, the vendor providing the services is selected by a formal bid process. Peer Assistance Services, Inc., a nonprofit corporation, has contracted with the Board since 1993 to provide this service.

A review of the literature demonstrates that such assistance programs are being used with increasing frequency throughout private industry and in regulation of a number of health care professionals. The underlying rationale for such programs is that addictions, substance abuse, and mental health problems are conditions that impair people's abilities to be effective at home and at work; drain health care systems in treatment costs; and negatively impact business systems in productivity. Thus, long-term investment in rehabilitation should benefit many aspects of society.

The two primary philosophies of the Program are public protection and licensee rehabilitation for those who acknowledge that they suffer from a condition that is treatable. The Program offers a possible disciplinary option to chemically dependent pharmacists rather than the revocation or suspension of their license to practice pharmacy, and the possible end of their professional careers.

All pharmacists are assessed a \$28 fee that is included in their biennial license renewal. Services offered to pharmacists by the Program include assessment and referral, short-term problem resolution, intervention, case management/monitoring, facilitated peer support groups, prevention/education programs, and 24-hour, seven-day-a-week, toll-free telephone assistance.

Pharmacists are personally responsible for fees associated with mental health or substance abuse treatment and drug screenings.

The contractual agreement between Peer Assistance Services, Inc. and the Board requires the submittal of quarterly reports to the Board. Monthly reports to the Program regarding participants include treatment and therapy reports, manager or practice monitor reports, self-help group attendance verification, drug screen reports, and self-status reports. Because voluntary participants' names are not a matter of public record, their names do not appear on the reports and their identities are kept confidential unless there is noncompliance or the pharmacists are unable to practice with reasonable skill and safety.

Licensees enter the Program either voluntarily or as agreed upon in a Board disciplinary stipulation. All licensees who enter the Program participate in a five-year rehabilitation program. Records of voluntary participants are kept confidential and are identified by case number only. However, the identity of the licensee who has agreed to participate in the Program through a Board disciplinary stipulation is public knowledge. All participants in the Program enter into contracts with Peer Assistance Services, Inc. that provide terms to be fulfilled designed to rehabilitate the licensee.

The licensee agrees to comply with the Program by signing the Rehabilitation Contract that sets up compliance requirements. The Return to Practice Agreement is another component that provides terms so that pharmacists may demonstrate compliance.

An integral component of the Program is the practice monitor (another professional pharmacist) who monitors whether or not the licensee is practicing accepted standards of practice. The monitor agrees to be a party to the Rehabilitation Contract and the Return to Practice Agreement. Under the provisions of the agreement, the practice monitor must provide competency reviews that are based on interviews with staff, review DEA order forms, and perform site visits. Any indication of noncompliance is reported to the Program that then reports to the Board within 24 hours.

A question arises concerning the protection of the public while the licensee is monitored. There is the possibility that the licensee may relapse and resume previous behavior of chemical dependency and may be a danger to the public. The Rehabilitation Contract, Return to Practice Agreement, practice monitoring, quarterly reports, frequent urinalysis and blood tests, and notifications of noncompliance within 24 hours keep the risks to a minimum.

From fiscal year 96-97 through fiscal year 01-02, there were a total of 28 pharmacists who entered the Program voluntarily and 29 pharmacists mandated to the Program by the Board through stipulation. For this same time period, 14 pharmacists were successfully discharged after contract completion and 15 were terminated because of the inability to practice with reasonable skill and safety. During this time period, an additional 18 pharmacists or immediate family members (non-diversion clients)

were provided with a variety of early intervention services that include relationship issues, health/emotional welfare, health and physical welfare, professional career issues, and answers to regulatory questions. These short-term problem resolution sessions may consist of a telephone call, or two to three meetings with a staff member of Peer Assistance Services, Inc. The Rehabilitation Evaluation Committee (REC) is a statutorily created liaison between the Board and the Program. The Program reports to the REC. The table below, provided by Peer Assistance Services, Inc., illustrates the activity of the Program.

Table 9
Pharmacy Peer Health Assistance Diversion Statistics

Criteria	FY96-97	FY97-98	FY98-99	FY99-00	FY00-01	FY01-02	Totals
New pharmacists entering on a voluntary basis	4	4	4	2	5	9	28
New pharmacists entering because mandated through stipulation	6	12	2	6	1	2	29
Total # new participants	10	16	6	8	6	12	58
Reason for entry							
Alcohol only	2	2	1	1	2	0	8
Chemical dependency	6	11	3	4	4	5	33
Dual diagnosis*	1	1	2	2	0	4	10
Mental health only	1	2	0	0	0	2	5
Physical disability	0	0	0	0	0	0	0
Other	0	0	0	1	0	0	1
# Successfully completed	2	2	1	3	3	3	14
# Terminated	1	1	4	3	4	2	15
# Non diversion contacts	2	1	3	1	2	9	18
Money awarded to PAS	\$58,880	\$72,287	\$75,897	\$76,000	\$84,000	\$88,236	\$455,264

Source: Peer Assistance Services, Inc. (PAS)

*Dual Diagnosis (mental health and chemical dependency)

Analysis and Recommendations

Recommendation 1 - Continue the State Board of Pharmacy and the Drugs and Druggist Act until 2012.

The regulation and licensing of qualified pharmacists and pharmaceutical facilities benefits the public's health, safety, and welfare. The State Board of Pharmacy (Board) provides this service by establishing minimum educational and experience requirements that provide reasonable assurance that persons licensed are qualified and that businesses providing pharmaceutical services are in compliance with applicable state and federal laws and rules and regulations. Assurance that licensed professionals act in a competent manner is provided by active investigation of complaints, facility inspections, and revocation or suspension of licenses when appropriate.

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 objectives. The first is to ensure that the public receives the quality and strength of medications prescribed by medical practitioners. The public has an expectation that when prescription drugs are dispensed by a licensed pharmacist, they are the correct drugs and the proper dosages. 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. The second objective of state regulation is to reduce the abuse of drugs by limiting access to controlled substances.

Drug therapy is the most frequently used form of medical intervention in any practice setting. Its use has grown dramatically as the population has aged, the prevalence of chronic disease has increased, and the range of effective medications has broadened. There is no question that the personal and economic consequences of inappropriate drug therapy are enormous.

Diagnostic technology emerging from the biotechnology industry has created demand for cost-effective management of treatment and increasingly complicated and expensive drugs, drug regimens, and information. For these reasons, the Board and the Drugs and Druggists Act (Act) should be continued until 2012.

Recommendation 2 – Enhance the public protection function of the Board by implementing the following three amendments.

Replace a pharmacist on the Board with a public member. Amend section 12-22-104, C.R.S., to read as follows:

12-22-104 Membership. (1) The board shall be composed of ~~five~~ FOUR 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~~ THREE nonpharmacists who have no financial interest in the practice of pharmacy.

Delete the confidentiality provision in the letter of concern. Amend section 12-22-125(7), C.R.S., to read as follows:

12-22-125(7) When a complaint or an investigation discloses an instance of conduct that does not warrant formal action by the board but the board determines that continuation of such conduct could warrant action if continued, a ~~confidential~~ letter of concern may be sent by certified mail to the pharmacist against whom the complaint was made or who was the subject of investigation. If a complaint precipitated the investigation, a response shall be sent to the person making the complaint.

Define continuous quality improvement and develop rules and regulations for a continuous quality improvement program that addresses medication errors and interventions.

12-22-102(6.5) “CONTINUOUS QUALITY IMPROVEMENT” MEANS A SYSTEM OF STANDARDS AND PROCEDURES TO IDENTIFY, EVALUATE AND IMPROVE THE QUALITY OF PHARMACY SERVICES AND PHARMACEUTICAL CARE, INCLUDING MEDICATION ERRORS.

Evaluation criteria direct the sunset review process to examine “Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final disposition of complaints are in the public interest or self-serving to the profession.” Appendix B on page 62 lists complaint charges

received by the Board from fiscal year 97-98 through fiscal year 01-02 and the percentage of those charges resulting in the issuance of a letter of concern by the Board. As the Appendix shows, 82 percent of dispensing errors resulted in a letter of concern. The next highest percentage of letters of concern issued (26 percent) was for security violations.

An analysis of the complaint data indicates that the Board disciplines pharmacists who abuse drugs themselves or sell or give away controlled substances. Discipline for these violations generally involves revocation, suspension or probation (sometimes by stipulation and referral to the Pharmacy Peer Assistance Diversion Program). However, a review of the Board's disciplinary actions against licensees reveals that a high percentage of dispensing error complaints result in dismissal or in a confidential letter of concern. Table 10 depicts final actions taken on complaints received by the Board. It should be noted that there is a clear line of demarcation from fiscal year 99-00 to fiscal year 00-01 regarding the issuance of letter(s) of admonition (LOA) versus letter(s) of concern (LOC) for dispensing errors. An increase in the use of an LOC for dispensing errors instead of an LOA may be attributed to a change in Board policy. Disciplinary actions that include letters of admonition are listed in the Board newsletter and are submitted to a national databank maintained by the National Association of Boards of Pharmacy. Letters of concern are not submitted to the national databank or noted in the newsletter because they are confidential and not formal disciplinary actions.

**Table 10
Closure Actions for Dispensing Errors**

Fiscal Year	Dismissed with Confidential Letter of Concern	Suspension	Dismissed – No Jurisdiction	Dismissed – Insufficient Evidence	Dismissed – No Violation	Letter of Admonition	No Further Action	Probation	Total
FY 97-98	5	0	0	4	2	8	0	0	19
FY 98-99	6	1	0	4	2	26	0	0	39
FY 99-00	5	0	0	5	3	15	0	1	29
FY 00-01	17	1	1	2	16	3	1	2	43
FY 01-02	19	0	0	6	3	4	0	0	32
Total	52	2	1	21	26	56	1	3	162

When the Board reviews a complaint regarding a dispensing error, especially if it is the first offense, a confidential letter of concern is issued. Article 22 of Title 12 defines the “practice of pharmacy” as an initial interpretation, selection of ingredients and final evaluation of each prescription order or chart order. Furthermore, the responsibility for the compounding, dispensing, labeling, delivery, storage and distribution of drugs and devices is the responsibility of the pharmacist. This practice is the foundation of the licensing scheme. Therefore, the Board’s reticence to discipline for dispensing errors is contrary to the purpose of the regulatory authority.

During this sunset review, staff attended Board meetings and observed complaint discussions and recommendations for final dispositions regarding dispensing errors. The Board has stated that it does not consider outcomes as part of its deliberation in regards to sanctions imposed. Other states do take outcomes into consideration. Examples of dispensing errors that were dismissed with a letter of concern are described below.

Case #1 – The prescription called for Prednisone 10 mg tablets but the drug dispensed was Methotrexate 2.5 mg tablets with a label identifying it as Prednisone 10 mg. The customer who was issued the incorrect drug suffered from Crohn’s Disease and was subsequently hospitalized. Upon investigation, it was determined that the pharmacist had made the final evaluation of the prescription. Additionally, a tablet from the bottle was identified as Methotrexate. The pharmacist denied that he dispensed the incorrect drug.

Case #2 – A prescription for Humalog (insulin) for injection was dispensed on an order for Humalog Mix 75/25 for injection. The instructions for Humalog 75/25 directed the patient to use 30 units every morning and 16 units every evening. The customer recognized the difference in the appearance of the drug and immediately returned it to the pharmacy. If she had injected the 16 units of Humalog it could have been fatal. The pharmacist admitted that she was unaware of the Humalog Mix 75/25 product availability.

Case #3 – A prescription was dispensed for a nine-week old infant. The prescription drug intended for the infant was Zantac Syrup. The infant took the medication for one month. Upon refilling the prescription, it was determined that something other than Zantac Syrup had been dispensed. Upon investigation, it was determined that the pharmacist made the final evaluation on the order dispensed but could not remember dispensing the prescription. The pharmacy manager reported that Zantac and Zyrtec Syrup are close to each other on the shelf. It was never determined what drug the infant actually consumed.

Case #4 – Prozac 10 mg was dispensed on an order for Prozac Weekly Capsules. The 16-year old customer consumed one capsule weekly as ordered. The family went on vacation and the daughter suffered from crying spells, sleeping difficulties, and overall depression. A television commercial for Prozac Weekly alerted the mother to the potential problem. The pharmacist admitted dispensing the incorrect drug and stated that he was unaware that Prozac Weekly was available.

Case #5 – It was alleged that Diazepam tablets (a Schedule IV Controlled Substance) was dispensed to the customer instead of her refill prescription for Claritin 10 mg tablets. Upon investigation, it was determined that the pharmacist had initialed the refill log but the pharmacist could not remember dispensing the prescription. Investigation further indicated that the bottle returned to the pharmacy by the customer contained Diazepam 5 mg tablets.

Case #6 – A pharmacist dispensed the generic form of Prozac 20 mg without notifying the customer both orally and in writing that she had received a generic product pursuant to section 12-22-124(3), C.R.S. The pharmacist responded that she was unaware that both written and oral notice to the customer is required.

Case #7 – A pharmacist dispensed Methotrexate tablets on an order for Medroxyprogesterone tablets. Customer reported that she received three months of the incorrect medication. Pharmacist admitted that he was responsible for the dispensing error.

Case #8 – The customer had an allergy to peppermint which is often used to mask the odor of Spironolacatone tablets. Mylan is the only company that manufacturers this drug without peppermint. A customer received a refill of her prescription with two different types of tablets in the bottle. She questioned the pharmacist who responded that the tablets were both from Mylan and that there was no new formulation listed on the bottle. When the customer consumed a tablet she subsequently had an allergic reaction. One hour later, the customer’s husband telephoned the pharmacist to further inquire about the medication that his wife had taken. He was then informed that the pharmacist had located a stock bottle and noticed that it was marked with “New Formulation and Product Appearance. The pharmacist read the package insert that reported that the tablets now contained a peppermint flavoring.

Case #9 – It was determined that patient B received patient A’s prescription and vice versa. Patient B’s prescription for Sulfamethoxazole/trimethoprim DS, a sulfa drug, was given to patient A who is allergic to sulfa drugs. She developed gastrointestinal upset and severe headache, but no anaphylactic response. The pharmacist admitted that she performed the final evaluation of patient A’s prescription order. The pharmacist stated that she is not responsible for the unlicensed assistant’s misdelivery. Rule 3.00.70(b) states that a pharmacist is responsible for unlicensed assistants.

The U.S. Pharmacopeia National Coordinating Council for Medication Error Reporting and Prevention (Council) defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. Medication errors may occur at any time, from the medication order to consumption by the patient.

The reasons for dispensing errors made by pharmacists and pharmacies are often questioned. According to a synthesis of recent research into dispensing errors, the most common causes are thought to be the following: fewer clerical employees than are needed for business operation, longer shifts for pharmacists, greater numbers of prescriptions to fill and insufficient filling time, failure to properly train or supervise pharmacy employees, confusing or poorly written prescriptions, similar drug names, lack of knowledge about medication use, and a nonsupportive system with no provision for one person to check the work of another. None of these causes justify the harm that can be caused by a misfilled prescription.

The consequences of a prescription being misfilled with a totally incorrect and unintended drug, at the very least, result in the patient not taking the drug that was prescribed for a condition or ailment. Beyond that, the patient is potentially taking another drug that may be harmful. Medications are the mainstay of treatment for most chronic conditions, and the elderly take numerous medications--an average of eight per day in the nursing facility setting. Medication errors can lead to serious patient morbidity or mortality, and because drugs are used so frequently, the number of preventable injuries is substantial.

Pharmacists-in-charge at Colorado pharmacies are responsible under Rule 3.00.50 to make a final evaluation of the drug transaction and for taking whatever action is necessary to ensure that the container, label and prescription drug dispensed, as well as all records relating to the transaction are complete, accurate and appropriate. The likelihood of discovery before the wrong medication is taken is very low because of the trust that most patients place in their pharmacy and their lack of knowledge regarding the appearance of medications or the correct dosages.

As derived from the information in Appendix B on page 62 of this review, dispensing errors accounted for 38 percent of complaints received. In reviewing and researching dispensing errors and their final disposition, this report concludes that the Board is remiss in disciplining those violations of the statute. This recommendation addresses this concern by proposing that the Board composition be changed to allow for an additional public member and one less pharmacist in addition to the development of rules and regulations addressing a continuous quality improvement (CQI) program.

Reports of medication errors and interventions should be evaluated and incorporated into a CQI program. The pharmacist must assume responsibility for developing and implementing a plan and for the prevention of medication errors through detection and evaluation. The following guidelines and recommendations from the American Society of Consultant Pharmacists offer a resource for the Board in their creation of rules and regulations regarding CQI for pharmacies:

- Establish a process for identifying and tracking medication errors.
- Define categories of medication errors, e.g., prescribing, dispensing, administration, monitoring, and compliance errors (see Appendix B on page 62).
- Simplify the process of documenting errors by developing a medication error reporting and evaluation form.
- Establish systems for detecting medication errors in the facility or pharmacy such as med pass observation, random sampling, and medication storage survey.
- Respect the confidentiality of the patient, facility, and personnel involved in the medication error.

Recommendation 3 - Grant the Board the authority to issue fines to registrants. Amend section 12-22-110, C.R.S., to read as follows:

12-22-110(1)(c) Deny, suspend, or revoke licenses or registrations AND FINE REGISTRANTS WHEN CONSISTENT WITH THE PROVISIONS OF THIS ARTICLE AND THE REGULATIONS ADOPTED THEREUNDER;

Currently, the only sanctions available to the Board for violations committed by a prescription drug outlet, manufacturer or wholesaler are revocation, suspension, or denial. When inspection reports indicate continuous violations yet those violations may not pose an immediate threat to the public welfare, there are no other sanctions available to the Board. Revoking the license of a pharmacy is a drastic measure that has severe ramifications for its clientele. By granting the Board the ability to fine registrants, the Board is given a less extreme option than revocation. Other regulatory programs such as the Office of Outfitters Registration, Office of Barber and

Cosmetologist Licensing, Board of Veterinary Medicine, Electrical Board, Examining Board of Plumbers, and the Accountancy Board, all within the Division of Registrations, have the authority to issue fines.

The following case studies are situations in which fines might have been appropriately imposed:

Case 1

In a large hospital, two pharmacists made an error on a patient's medication that resulted in the death of the patient. Subsequently, there was a hospital settlement between the patient's family and the hospital. However, the hospital did not inform the Board of the settlement as required by section 12-22-113.5, C.R.S. During an inspection of the hospital's pharmacy, a Board inspector learned of the error and subsequent settlement. It took several months from that time for the hospital to complete a malpractice settlement form and submit it to the Board. The Board disciplined the pharmacists but the Board also should have fining authority over the hospital pharmacy. Suspending the pharmacy registration is not necessarily the best possible remedy, but a lack of action implies that the statutory requirement to report malpractice settlements is not mandatory.

Case 2

A civil case was filed in which the plaintiff alleged that he was dispensed the wrong medication from a prescription drug outlet. The Board learned of the lawsuit from the plaintiff's attorney, not from the prescription drug outlet manager or owner. The claim was eventually settled. The Board learned of the disposition approximately six months after the date of settlement from the notification given to the Board by the prescription drug outlet's insurer. In addition, the insurer neglected to file a malpractice settlement form with the Board as required by section 12-22-113.5, C.R.S. The evidence indicates that a pharmacist made a dispensing error and a settlement occurred. However, the prescription drug outlet failed to notify the Board appropriately of the civil case or its disposition and the prescription drug outlet's insurer neglected to file the appropriate settlement forms with the Board.

In such situations, fining would be appropriate. The Board rules and regulations require that all pharmacists, interns, prescription drug outlet managers and owners immediately notify the Board of the filing of all legal proceedings. Additionally they shall also notify the Board, within 20 days, of the disposition of such proceedings, wherein it is alleged that a Board licensee has violated any law or regulation pertaining to the compounding, dispensing, delivery or distribution of any prescription drug or device.

Recommendation 4 - Require a two-year time period before a licensee can apply after revocation. Section 12-22-116, C.R.S., should be amended to read as follows:

12-22-116(9) NO INDIVIDUAL OR OUTLET WHOSE LICENSE OR REGISTRATION HAS BEEN REVOKED SHALL BE ALLOWED TO REAPPLY FOR LICENSURE OR REGISTRATION EARLIER THAN TWO YEARS AFTER THE EFFECTIVE DATE OF THE REVOCATION.

Language in the current Act does not preclude a licensee who has had his/her license revoked from applying for a new license immediately after the revocation occurs. The reason a license is revoked first and foremost is that the practitioner represents a significant threat to the public. Revocation cases are quite lengthy and expensive. In practice, it often takes the Board anywhere from nine to 18 months, or longer, to revoke a license, depending upon whether or not the case goes to hearing or is settled. There is a tremendous investment of staff resources and dollars to discipline the practitioner. The waiting period is intended to serve the purpose of reminding the licensees of their accountability for their behavior and the fact that it is a privilege to be licensed, not a right. Without a substantial wait, that message is lost.

Most other practice acts in the Division of Registrations require a time-out period before reinstatement of license. For example, the Board of Medical Examiners, Board of Registration of Professional Engineers and Professional Land Surveyors, Electrical Board, Examining Board of Plumbers, and the Board of Optometric Examiners require a two-year wait. On the other hand, the four Mental Health Boards and the State Grievance Board require a three-year wait before practitioners are eligible for reapplication after revocation. Because of the significant threat that pharmacists who have lost their licenses pose to the public, the two-year period is justified for public safety.

Recommendation 5 - Allow wholesalers to sell or deliver prescription medications intended for veterinary use directly to a person responsible for the animal patient if there is a written prescription by a licensed veterinarian. Amend section 12-22-121, C.R.S., to read as follows:

12-22-121(3.5) A WHOLESALER MAY SELL OR DELIVER TO A PERSON RESPONSIBLE FOR THE CONTROL OF AN ANIMAL A DRUG INTENDED FOR VETERINARY USE FOR THAT ANIMAL ONLY IF A LICENSED VETERINARIAN HAS ISSUED, PRIOR TO SUCH SALE OR DELIVERY, A WRITTEN PRESCRIPTION ORDER FOR THE DRUG IN THE COURSE OF AN EXISTING, VALID VETERINARIAN-CLIENT-PATIENT RELATIONSHIP AS DEFINED IN SECTION 12-64-103(15.5)(a), (b), AND (c), C.R.S.

Historically, livestock producers have been able to acquire prescription medications directly from wholesale distributors after a veterinarian-client-patient relationship has been established and a prescription has been filed with the pharmaceutical distributor. However, section 12-22-121(3), C.R.S., addressing the compounding, dispensing, and sale of drugs and devices has specific limitations for wholesalers. This language reads as follows:

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.

The current statutory language precludes a wholesaler from selling veterinarian drugs directly to a livestock producer even if there is a relationship with a veterinarian. When this restriction is applied to animal pharmaceutical distribution, there is an additional layer of price mark-up prior to ultimate delivery and use by Colorado's livestock producers.

The Center for Veterinary Medicine in the U.S. Public Health Service has addressed this issue by proclaiming that the sale (dispensing, shipping, or otherwise making available for use in animals) to the layperson of a veterinary prescription drug product may be made only by, or on the bona fide prescription or other order of a licensed veterinarian. Because many states do authorize persons other than pharmacists to dispense prescription drug products on a veterinarian's instructions, the term "other order" is used when instructions are for a legally authorized dispenser who is not a pharmacist, namely a wholesaler.

The labeling on veterinarian products is not much different from the labeling on many devices for people, or certain orthopedic products that are to be sold only by, or on the order of a physician. In the case of devices with such labeling, the Board has always permitted the completely unregulated sale by virtually anyone – most commonly by medial supply stores, as long as the seller obtains an order, not necessarily a prescription order as defined in section 12-22-102(22.5)(a), C.R.S., - but a simple order.

This recommendation would allow the wholesaler to legally dispense a veterinary prescription drug as long as there is an established valid veterinarian-client-patient relationship as defined in section 12-64-103(15.5), C.R.S. For quite some time, veterinarian wholesalers have sold prescription drugs directly to the rancher without any evidence of harm to the public.

The Board should adopt rules and regulations addressing this issue and consider the following requirements: 1) Orders must be issued from a licensed Colorado veterinarian; 2) The veterinarian's license number and expiration date must appear on the order; 3) Prescriptions should be valid for a period of time no longer than six months.

Recommendation 6 - Combine all statutory violations under the heading of “unprofessional conduct” and separate the listing of violations from the Board action that is authorized. Amend section 12-22-125, C.R.S., and enact section 12-22-125.2, C.R.S., to read as follows:

12-22-125. Licenses or registrations may be denied, suspended, or revoked. UNPROFESSIONAL CONDUCT – GROUNDS FOR DISCIPLINE.

(1) 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. THE TERM “UNPROFESSIONAL CONDUCT” AS USED IN THIS ARTICLE, MEANS A LICENSEE OR REGISTRANT, WHERE APPLICABLE, WHO:

(a) Is guilty of misrepresentation, fraud, or deceit in procuring or attempting to procure OR RENEW 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 OR HAS RECEIVED A DEFERRED SENTENCE FOR A FELONY. IN CONSIDERING THE CONVICTION OF A CRIME, THE BOARD SHALL BE GOVERNED BY THE PROVISIONS OF SECTION 24-5-101, C.R.S.

(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 OR ANY ACTS AS SET FORTH IN SECTION 12-22-126, C.R.S.

~~(2)(a)(i)(d)~~ Is unfit or incompetent by reason of negligence, habits, or physical or mental illness, or for any other cause, to practice as such;

~~(2)(a)(III)(e) 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); IS ADDICTED TO, DEPENDENT ON, OR ENGAGES IN THE HABITUAL USE OR ABUSE OF INTOXICATING LIQUORS, A HABIT-FORMING DRUG, OR A CONTROLLED SUBSTANCE AS DEFINED IN SECTION 18-18-102(5), C.R.S.~~

~~(2)(a)(III)(f) Knowingly permits a person not licensed as a pharmacist or pharmacy intern to engage in the practice of pharmacy;~~

~~(2)(a)(IV)(g) Has had his or her license to practice pharmacy in another state revoked or suspended OR OTHERWISE DISCIPLINED for disciplinary reasons or has committed acts in any other state that would subject him or her to disciplinary action in this state;~~

~~(2)(a)(V)(h) Has engaged in advertising which is misleading, deceptive, or false;~~

(i) HAS DISPENSED A SCHEDULE III, IV, OR V CONTROLLED SUBSTANCE ORDER MORE THAN SIX MONTHS AFTER THE DATE OF ISSUE OF THE ORDER;

(j) HAS ENGAGED IN THE PRACTICE OF PHARMACY WHILE ON INACTIVE STATUS;

(k) HAS FAILED TO MEET GENERALLY ACCEPTED STANDARDS OF PHARMACY PRACTICE;

(l) FAILS OR HAS FAILED TO PERMIT THE BOARD OR ITS AGENTS TO CONDUCT A LAWFUL INSPECTION;

(m) HAS VIOLATED ANY LAWFUL BOARD ORDER;

(n) HAS COMMITTED ANY FRAUDULENT INSURANCE ACT AS DEFINED IN SECTION 10-1-127, C.R.S.;

(o) HAS WILLFULLY DECEIVED OR ATTEMPTED TO DECEIVE THE BOARD OR ITS AGENTS WITH REGARD TO ANY MATTER UNDER INVESTIGATION BY THE BOARD;

(p) HAS FAILED TO NOTIFY THE BOARD OF ANY CRIMINAL CONVICTION OR DEFERRED JUDGMENT WITHIN 30 DAYS OF SUCH CONVICTION OR JUDGMENT;

(q) HAS FAILED TO NOTIFY THE BOARD OF ANY DISCIPLINE AGAINST HIS LICENSE IN ANOTHER STATE WITHIN 30 DAYS OF SUCH DISCIPLINE;

~~(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.~~

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

12-22-125.2 DISCIPLINARY ACTION. (1) THE BOARD MAY DISCIPLINE LICENSEES OR REGISTRANTS WHEN IT DETERMINES THAT SUCH LICENSEE OR REGISTRANT HAS ENGAGED IN UNPROFESSIONAL CONDUCT.

~~{previously 12-22-125(3)}~~**(a) THE BOARD SHALL DENY A LICENSE IN ACCORDANCE WITH SECTION 24-4-104, C.R.S. 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.**

~~{previously 12-22-125(4)}~~**(b) 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 SECTION 12-22-125, C.R.S., this part 1, the board may impose one or more of the following penalties:**

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

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

~~(e)~~(III) 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)~~(IV) Refusal to renew the offender's license or registration;

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

~~(f)~~(VI) 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.

~~{previously 12-22-125(5)(a)}~~(2) The board may also include in any disciplinary order that 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)~~(a) Submission by the respondent to such examinations as the board may order to determine the respondent's physical or mental condition or professional qualifications;

~~(II)~~(b) The taking by the respondent 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)~~(c) The review or supervision of the respondent's practice as may be necessary to determine the quality of his or her practice and to correct deficiencies therein; and

~~(IV)~~(d) The imposition of restrictions upon the nature of the respondent's practice to assure that he or she does not practice beyond the limits of his or her capabilities.

{previously 12-22-125(5)(a)(IV)(b)}(3) Upon failure of the licensee or registrant to comply with any conditions imposed by the board pursuant to paragraph **(1)(b)(7), (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.

(4) IN ADDITION TO ANY OTHER PENALTY WHICH MAY BE IMPOSED PURSUANT TO THIS SECTION, ANY REGISTRANT VIOLATING ANY PROVISION OF THIS ARTICLE OR ANY RULES OR REGULATIONS PROMULGATED PURSUANT TO THIS ARTICLE MAY BE FINED NOT LESS THAN FIVE HUNDRED DOLLARS NOR MORE THAN FIVE THOUSAND DOLLARS FOR EACH SUCH VIOLATION.

{previously 12-22-125(6)(a)}(5)(a) 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.

{previously 12-22-125(6)(b)} (b) 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 or she has the right to request in writing, within ~~twenty~~ THIRTY days after ~~proven receipt of~~ the DATE ON WHICH the letter WAS MAILED, that formal disciplinary proceedings be initiated to adjudicate the propriety of the conduct upon which the letter of admonition is based.

(c) If the request is timely made, the letter of admonition shall be deemed vacated, and the matter shall be processed by means of formal disciplinary proceedings.

{previously 12-22-125(7)}(6) When a complaint or an investigation discloses an instance of conduct that does not warrant formal action by the board but the board determines that continuation of such conduct could warrant action if continued, a confidential letter of concern may be sent by certified mail to the pharmacist against whom the complaint was made or who was the subject of investigation. If a complaint precipitated the investigation, a response shall be sent to the person making the complaint.

The Board's disciplinary powers and the grounds for discipline are currently scattered throughout various places in the statute. Grounds for discipline can be found in sections 12-22-125, C.R.S., 12-22-126, C.R.S., 18-18-304, C.R.S., and 18-18-414, C.R.S. This makes enforcement of Board actions difficult and haphazard at best. There are potential legal challenges that could be made to Board actions pursuant to some of these sections. In order to organize and clarify what is prohibited, it is recommended that all administrative infractions be in one place in the Act. This would grant the Assistant Attorney General to the Board the ability to charge all infractions administratively whether or not the District Attorney decided to charge some of the infractions criminally. Other Boards in the Department of Regulatory Agencies have consolidated infractions under the heading of "unprofessional conduct."

The revised section 12-22-125, C.R.S., contains all administrative infractions for which the Board could discipline. Some of these are broad and would take the interpretation of the Board. Most of the items listed were already in statute in one of the locations cited above. A few of the items are new, based upon lists of infractions used by other professional licensing boards in the Division of Registrations.

Proposed section 12-22-125.2, C.R.S., Disciplinary Action, addresses the Board's power to take various types of actions against licensees and registrants when they violate the unprofessional conduct section 12-22-125, C.R.S. These two sections separate the listing of the infractions from the Board action that is authorized when such infractions occur.

Recommendation 7 - Change the timelines for appealing a letter of admonition to 30 days from the date of mailing, rather than 20 days from the date of proven receipt. Amend section 12-22-125(6)(b) C.R.S., which is being renumbered as 12-22-125.2(5)(a), C.R.S., to read as follows:

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 or she has the right to request in writing, within ~~twenty~~ THIRTY days after ~~proven receipt~~ of the DATE ON WHICH the letter WAS MAILED, that formal disciplinary proceedings be initiated to adjudicate the propriety of the conduct upon which the letter of admonition is based.

In practice, the current statutory provision requires a letter of admonition to be mailed via certified mail, return receipt requested. This is the only verifiable way to prove the date on which such letter is received.

However, it is not uncommon for letters of admonition to be returned to the Board as undeliverable or unclaimed. One reason is that pharmacists relocate and do not always notify the Board of their new addresses as required. An additional consideration here is that State mail is not forwarded, it is returned to the Board as undeliverable.

A more pessimistic explanation is that the pharmacist simply refuses to sign for the letter, thus preventing the tolling period from beginning.

The Colorado Court of Appeals recently addressed this issue in *Colorado State Board of Medical Examiners v. Roberts*, 42 P.3d 70 (Colo. App. 2001). In *Roberts*, the court reviewed a provision in the Medical Practice Act that is substantially similar to the statute under discussion here. The Board of Medical Examiners issued a letter of admonition to Dr. Roberts and mailed it to him at his place of business via certified mail, return receipt requested. However, Dr. Roberts and his staff refused to sign for the letter on two separate occasions. Three months later, Dr. Roberts requested that the Board of Medical Examiners vacate the letter of admonition and institute formal disciplinary

proceedings against him. The Board of Medical Examiners refused, stating that two notices of attempted delivery by the U.S. Postal Service was sufficient to constitute receipt and begin the 20-day tolling period for requesting formal disciplinary proceedings.

Dr. Roberts and the Court of Appeals disagreed. In focusing on the plain language of the statute, the court held that “receipt” in the statute requires actual receipt.

Since the Act contains language that is substantially similar to the statutory provision reviewed in *Roberts*, it is not unreasonable to believe that at some point, the Board could encounter a similar problem.

The recommended language attempts to expedite the disciplinary process while protecting the rights of the pharmacist. By requiring the letter of admonition to be mailed by certified mail, the Board will be able to establish the date on which it is mailed. To allow for delivery time, and to be consistent with other appeals timelines, the time in which a pharmacist may request formal disciplinary proceedings is extended from 20 days to 30 days.

This recommendation neither restricts nor expands the powers of the Board or the rights of the pharmacist. Rather, it attempts to correct a procedural problem that may be exacerbated by the *Roberts* decision.

Recommendation 8 – Conform the definition of “controlled substance” in the Drugs and Druggists Act to the section in the Colorado Criminal Code that defines “controlled substance”. Amend section 12-22-303(7), C.R.S., to read as follows:

12-22-303(7) “Controlled substance” SHALL HAVE THE SAME MEANING AS THAT DEFINED IN SECTION 18-18-102(5), C.R.S. ~~means a drug, substance, or immediate precursor included in schedules I to V of part 2 of article 18 of title 18, C.R.S.~~

Section 12-22-303(7), C.R.S., defines a controlled substance as “a drug, substance, or immediate precursor included in schedules I to IV of Part 2 of Article 18 of Title 18, C.R.S.”

Section 18-18-102(5), C.R.S., a section of the Colorado Criminal Code (Criminal Code) defines a controlled substance in an identical manner except that it goes on to state, “including cocaine, marihuana, and marihuana concentrate.”

Tetrahydrocannabinols, commonly referred to as “THC”, is listed as a Schedule I Controlled Substance at section 18-18-203(2)(c)(XXIII), C.R.S. Section 12-22-303(32)(a), C.R.S., defines “THC” as,

synthetic equivalents or the substances contained in the plant, or in the resinous extractives of, cannabis, sp., or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity . . .

Thus, THC is a part of the marihuana plant, but an individual could potentially test positive for marihuana and not THC, which is the controlled substance under the Act.

In 2001, the Board of Nursing sought to take disciplinary action against a certified nurse aide (CNA) who reported to work in an intoxicated state and tested positive for cocaine, alcohol and marihuana. Because the Nurse Aide Practice Act references the Drugs and Druggists Act, which includes THC as a controlled substance, but not marihuana specifically, the administrative law judge (ALJ) requested the Board of Nursing’s Assistant Attorney General, to establish the relationship between THC and marihuana in order to proceed to hearing whether the marihuana in the CNA’s system was grounds for disciplinary action. This involved research, legal analysis of the relevant statutes, and obtaining an affidavit from a pharmacist.

Since THC is listed as a Schedule I Controlled Substance, and the Criminal Code specifically includes marihuana in its definition of a controlled substance, it is clear that the General Assembly intended that a practitioner who is found to have abused or excessively or habitually used marihuana be subject to disciplinary action. The recommended amendment will more clearly state the General Assembly’s intention.

Two other points are worth noting in relation to this issue. First, most, if not all, of Colorado’s professional practice acts contain language similar to that at issue here – they reference the Drugs and Druggists Act.

Finally, in 2000, the Colorado Constitution was amended to legalize the use of marihuana for people suffering from debilitating medical conditions. Colo.Const. art. XVIII, §14. This recommendation will not infringe upon an individual's opportunity to exercise the rights granted under this constitutional provision so long as the practitioner does not report to work while under the influence of marihuana, just as a practitioner could receive discipline for reporting to work while under the influence of alcohol. For an individual who as obtained the necessary approvals and permissions to use marihuana for medicinal purposes, a showing of abuse, or habitual or excessive use would be similar to such a showing for alcohol.

Recommendation 9 - Update the Pharmacy Peer Health Assistance Diversion Program. Amend sections 12-22-601(2), 12-22-603(3)(b), and 12-22-606, C.R.S., to read as follows:

12-22-601(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 IN CONJUNCTION WITH OR 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.

The Board should be able to use the Peer Health Assistance Diversion Program not only as an alternative to discipline, but also in conjunction with discipline.

12-22-603(3)(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 PER YEAR, 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

In Subsection (3)(b), the money allotted for this program should be increased. Currently, the program has nearly twice as many participants as the dental program, but licensees pay only one-half of what the dentists pay.

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 PHARMACIST member of the committee shall serve UP TO A MAXIMUM OF TWO TERMS for a term of four years; MEMBER’S TERMS SHALL BE STAGGERED 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 terms. 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. A PSYCHIATRIST OR A LICENSED MENTAL HEALTH PROVIDER. 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.

The terms of the members of the Rehabilitation Evaluation Committee should be extended to two four-year terms, as it requires significant time to educate new persons to participate fully. In addition, it is recommended that a psychiatrist or licensed mental health professional replace the director of the program provided by the pharmacy peer health assistance organization.

Technical Changes to the Pharmacy Law

The current Act has provisions that are ambiguous, unclear and outdated and has been amended several times since its enactment. Technical changes are necessary to improve and update the Act.

In recognition of the many recent changes in the practice of pharmacy, the National Association of Boards of Pharmacy has developed a Model Act for Boards of Pharmacy (Model Act). Though the statute has been amended slightly over the years, it has not kept pace with changes in the practice of pharmacy. The Model Act is designed to address changes in the practice of pharmacy. The public should have the benefit of statutes that are current with professional practices. Many of the recommendations that follow are premised on the Model Act while others are statutory changes to enhance and clarify the responsibility of the Board.

Due to the large number of additions and statutory clean-up recommendations, the following recommendations have been made in the order of the current statute for easier identification.

Recommendation 10 - Amend specific definitions in section 12-22-102, C.R.S., and make conforming amendments throughout the Drugs and Druggists Act to read as follow:

~~12-22-102(1) "Administration" means the giving of medication to a patient by a pharmacist qualified to administer drugs by authorization of a physician.~~
"ADMINISTER" MEANS THE DIRECT APPLICATION OF A DRUG TO THE BODY OF A PATIENT OR RESEARCH SUBJECT BY INJECTION, INHALATION, INGESTION, OR ANY OTHER MEANS.

Subsection one is deleted and language from the Model Act was inserted. The definition currently in law does not specifically define what is meant by administration. This recommended language adds needed specificity to the definition.

12-22-102(5) "Casual sale" means a sale TRANSFER, DELIVERY OR DISTRIBUTION to a corporation, individual, or other entity, other than a consumer, entitled to possess prescription drugs; except that the amount of drugs TRANSFERRED, DELIVERED OR DISTRIBUTED sold in such manner by any registered prescription drug outlet or hospital other outlet shall not exceed five percent of the total amount of drugs sold annually NUMBER OF DOSAGE UNITS OF DRUGS DISPENSED AND DISTRIBUTED ON AN ANNUAL BASIS by such outlet.

The recommended changes in this section alter the definition of a casual sale to encompass not only sales but also transfers of any nature. As the section now reads, entities would be able to transfer large quantities of drugs without compliance with regulatory standards if no money was exchanged. This is not in the best interest of the public. In general, in order to track the distribution of drugs and the providers that exchange them, normal regulatory constraints should apply. The intent of casual sale is to allow for small transfers without extensive restriction. Once a transfer becomes a certain size it should meet compliance standards. In addition, current statutory language is ambiguous regarding the amounts of drugs that can be transferred in a casual sale. It is difficult for inspectors to clearly advise facilities due to this ambiguity.

~~12-22-102(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.~~
"COMPOUNDING" MEANS THE PREPARATION, MIXING, ASSEMBLING, PACKAGING, OR LABELING OF A DRUG OR DEVICE (i) AS THE RESULT OF A PRACTITIONER'S PRESCRIPTION DRUG ORDER OR CHART ORDER OR INITIATIVE BASED ON THE PRACTITIONER / PATIENT / PHARMACIST RELATIONSHIP IN THE COURSE OF PROFESSIONAL PRACTICE, OR (ii) FOR THE PURPOSE OF, OR AS AN INCIDENT TO, RESEARCH, TEACHING, OR CHEMICAL ANALYSIS AND NOT FOR SALE OR DISPENSING. COMPOUNDING ALSO INCLUDES THE

PREPARATION OF DRUGS OR DEVICES IN ANTICIPATION OF PRESCRIPTION DRUG ORDERS BASED ON ROUTINE, REGULARLY, OBSERVED PRESCRIBING PATTERNS.

The language defining “compound” should be deleted and more specific language from the Model Act defining “compounding” inserted for further clarification.

12-22-102(7) "Delivery" means the actual, constructive, or attempted transfer OF A DRUG OR DEVICE from one person to another of a drug or device, whether or not there is an agency relationship FOR A CONSIDERATION.

The language defining “delivery” should be amended and language from the Model Act inserted for further clarification.

12-22-102(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: IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, OR OTHER SIMILAR OR RELATED ARTICLE, INCLUDING ANY COMPONENT PART OR ACCESSORY, WHICH IS REQUIRED UNDER FEDERAL LAW TO BEAR THE LABEL, “CAUTION: FEDERAL LAW REQUIRES DISPENSING BY OR ON THE ORDER OF A PHYSICIAN.”

- ~~(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~~

The language defining “device” should be deleted, and language from the Model Act inserted for further clarification

~~12-22-102(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. THE INTERPRETATION, EVALUATION, AND IMPLEMENTATION OF A PRESCRIPTION DRUG ORDER OR CHART ORDER, INCLUDING THE PREPARATION OF A DRUG OR DEVICE TO A PATIENT OR PATIENT'S AGENT IN A SUITABLE CONTAINER APPROPRIATELY LABELED FOR SUBSEQUENT ADMINISTRATION TO OR USE BY A PATIENT.~~

12-22-102(10) "Distribution" means the delivery TRANSFER of a drug or device other than by administering or dispensing.

The language defining "dispense" should be deleted, and language from the Model Act inserted for further clarification.

The use of the word delivery in this section confuses the definition of "distribution," as the word "delivery" is already specifically defined in statute. Transfer is not currently defined and has a generally accepted meaning.

12-22-102(11.5) "FILL" MEANS TO PREPARE A DRUG OR DEVICE PURSUANT TO A LAWFUL 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 ORDER.

The word "fill" is used regularly throughout the profession by laypersons and pharmacists. This new definition of "fill" is the same as the current definition of dispense.

~~12-22-102(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.~~

This language from the federal Food, Drug and Cosmetic Act is antiquated and no longer necessary. The addictive properties of drugs are addressed in the Uniform Controlled Substances Act pursuant to section 18-18-101, et seq, C.R.S.

12-22-102(16.5) "Location" means the physical confines of an individual building ~~or at the same address.~~

Pharmacies are registered according to their locations. As the Act currently exists, a complex could have several pharmacies in several buildings and register only one of those entities as a pharmacy if all the buildings in the complex had the same address. This situation places the public at risk, as the other buildings would not be inspected nor monitored for compliance with pharmacy regulations.

For example, without notifying the Board, a registered outlet (pharmacy) opened a satellite facility in a different building on its campus. During an inspection of the primary facility, the inspector was informed that one of the pharmacists was working in the "satellite" outlet. The registrant had one address but more than one facility on the campus. The registrant operated an outlet for years without the Board knowing of its existence and, consequently, it was never inspected.

12-22-102(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 COMPOUNDING AND dispensing of a prescription drug pursuant to a prescription order.

This section is incomplete without the language concerning compounding. The responsibility for compounding lies with the licensed pharmacist, not the manufacturer, and is currently included in the definition of the "practice of pharmacy."

12-22-102(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). A DRUG WHICH MAYBE SOLD WITHOUT A PRESCRIPTION AND WHICH IS LABELED FOR USE BY THE CONSUMER IN ACCORDANCE WITH THE REQUIREMENTS OF THE LAWS AND RULES OF THIS STATE AND THE FEDERAL GOVERNMENT.

The Model Act definition of "nonprescription drug" is concise and adds clarity to the current statutory definition. The current definition is so complex that it takes an inordinate amount of time to establish that the definition had been met at an administrative law hearing.

12-22-102(22) "Official compendia" means the official United States Pharmacopeia, NATIONAL FORMULARY, HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES or any supplements thereto.

This recommendation conforms the definition of "official compendia" to the definition of "drug" found in section 12-22-102(11)(a)(I),C.R.S.

12-22-102(22.5) "Order" means:

(a) A prescription order which is any order, other than a chart order, authorizing the dispensing of a single drug or device that is written, mechanically produced, computer generated and signed by the practitioner, transmitted electronically or by facsimile, or by other means of communication by a practitioner TO A LICENSED PHARMACY and which includes the name or identification of the patient, the date, and sufficient information for compounding, dispensing, and labeling; or

The word "single" as used here is not comprehensive, as sometimes physicians write more than one order on each prescription.

12-22-102(23) "OTHER Outlet" means any ~~prescription drug outlet, hospital~~ THAT DOES NOT OPERATE A REGISTERED PHARMACY, ~~institution, nursing home, rural health clinic, convalescent home, extended care facility, family planning clinic, wholesaler, manufacturer, or mail order vendor, other than a pharmacist,~~ SCHOOL, JAIL, COUNTY HEALTH DEPARTMENT, COMMUNITY HEALTH CLINIC, UNIVERSITY AND/OR COLLEGE that has facilities in this state registered pursuant to this article and that engages in the COMPOUNDING, dispensing, AND delivery, ~~distribution, manufacturing, wholesaling, or sale of drugs or devices.~~

This section as currently written has caused numerous problems for the Board. The meaning of the word "institutions" has been unclear. The definition encompasses a number of facilities that are not similar, have little in common in the regulatory scheme for pharmacies, and cannot be generalized. This recommendation suggests using the term "other outlets" and redefining it to include only those types of facilities referred to in this Subsection (23). Manufacture is defined in Subsection (17), wholesaler in Subsection (34), and prescription drug outlets are defined in Subsection (30.2). The Board has no jurisdiction over nursing homes; therefore, references to them should be deleted, as should references to similar facilities over which the Board has no jurisdiction. Defining "other outlets" separately would clarify those entities that must meet the regulatory criteria for "other outlets."

12-22-102(24.2) "PHARMACY TECHNICIAN" MEANS AN UNLICENSED PERSON WHO PERFORMS THOSE FUNCTIONS SET FORTH IN PARAGRAPH (b) OF SUBSECTION (26) OF THIS SECTION UNDER THE SUPERVISION OF A PHARMACIST.

Amend the remainder of Article 22 to conform with this recommendation by deleting all references to "unlicensed assistant" and replacing it with "pharmacy technician."

Effective July 1, 2002, the term “unlicensed assistant” pursuant to section 12-22-102(33.5), C.R.S., was repealed along with other responsibilities of the pharmacy manager. Previously, section 12-22-102(33.5)(a), C.R.S., stated "Unlicensed assistant means an unlicensed person who performs those functions set forth in paragraph (b) of subsection (26) of this section under the supervision of a pharmacist. A pharmacist manager of a prescription drug outlet employing an unlicensed assistant shall file with the board the name and date of birth of each unlicensed assistant who is employed by the outlet."

However, the term “unlicensed assistant” still exists in other parts of the statute and should be defined. The term “pharmacy technician” is generally used in this industry and more aptly describes the position of unlicensed assistant.

12-22-102(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 provision of pharmaceutical care including patient counseling and prospective drug review, drug and drug-related research not including prescriptive authority, 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 these health services, operations, or transactions necessary in the conduct, operation, and control of a prescription drug outlet by a pharmacist~~ THE INTERPRETATION, EVALUATION, IMPLEMENTATION AND THE DISPENSING OF ORDERS; PARTICIPATION IN DRUG AND DEVICE SELECTION, DRUG ADMINISTRATION, DRUG REGIMEN REVIEWS, AND DRUG OR DRUG-RELATED RESEARCH; PROVISION OF PATIENT COUNSELING AND THE PROVISION OF THOSE ACTS OR SERVICES NECESSARY TO PROVIDE PHARMACEUTICAL CARE IN ALL AREAS OF PATIENT CARE; AND

(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;~~ THE PREPARATION, MIXING, ASSEMBLING, PACKAGING, OR LABELING OR DELIVERY OF A DRUG OR DEVICE, PROPER AND SAFE STORAGE OF DRUGS AND DEVICES, AND MAINTENANCE OF PROPER RECORDS FOR THEM.

The language defining "dispense" should be deleted, and language from the Model Act inserted for further clarification.

12-22-102(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 "Rx ONLY" OR "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

"Rx Only" language should be added to comply with federal law.

12-22-102(30.2) "Prescription drug outlet" means any PHARMACY outlet registered pursuant to this article where prescriptions are filled or compounded, and are sold, dispensed, offered, or displayed.

The word "pharmacy" should be added to this definition since it is the most generally accepted term used in the profession and by laypersons. There is confusion concerning the use of the term "prescription drug outlet." The other recommended changes in this subsection are for greater specificity and to delete unnecessary terms.

12-22-102(30.3) "Refill" means the COMPOUNDING AND dispensing of any drug by a practitioner pursuant to a previously executed order.

The amended definition clarifies the process of refilling a prescription.

12-22-102(32.6) "Supervision" means that a licensed pharmacist is on the location and immediately and readily available to consult with and assist unlicensed personnel performing tasks described in subsection (26) (b) of this section.

"Immediately" was deleted because the reality of practice is that the supervising pharmacist is "readily available," not necessarily immediately, but within a reasonable time.

12-22-102(34) "Wholesaler" means a corporation, individual, or other entity with facilities in this state which buys drugs or devices for resale and OR ~~distribution~~ DISTRIBUTES to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers.

The definition of wholesaler should include any type of transfer of drugs or devices. Therefore, "and" is replaced by "or."

Recommendation 11 - Amend the powers and duties of the Board for greater clarification. Amend section 12-22-110, C.R.S., to read as follows:

Several changes are recommended for this section of the Act referencing the powers and duties of the Board. The Board's powers have not been clearly and concisely defined throughout, therefore, the following recommendations add greater clarification to the Act.

12-22-110(1)(e) Administer examinations AND DETERMINE THE QUALIFICATIONS AND FITNESS OF ~~to~~ applicants for licensure;

12-22-110(1)(f) Keep a record of all licenses, and registrations, AND RENEWALS FOR A REASONABLE PERIOD OF TIME, AND ~~of all license and registration renewals,~~ A RECORD OF ALL suspensions, and revocations, AND ANY OTHER DISCIPLINE and A RECORD of its own proceedings;

12-22-110(1)(h) MAKE INVESTIGATIONS, HOLD HEARINGS, AND TAKE EVIDENCE IN ALL MATTERS RELATING TO THE EXERCISE AND PERFORMANCE OF THE POWERS AND DUTIES VESTED IN THE BOARD AND, IN CONNECTION WITH ANY INVESTIGATION, SUBPOENA WITNESSES, ADMINISTER OATHS, AND COMPEL THE TESTIMONY OF WITNESSES AND THE PRODUCTION OF BOOKS, PAPERS, AND RECORDS RELEVANT TO ANY SUCH INVESTIGATION OR HEARING. ANY SUBPOENA ISSUED PURSUANT TO THIS ARTICLE SHALL BE ENFORCEABLE BY THE DISTRICT COURT.

The recommended language in sections 12-22-110(1)(e) - (h), C.R.S., is modeled from language existing in other board statutes. Although these powers are probably implied, they are not guaranteed without specific language.

12-22-110(4)(a) Whenever a duly authorized agent of the board finds or has probable cause to believe that in any REGISTERED OUTLET ~~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.

This recommendation expands the Board's embargo power to other facilities beyond prescription drug outlets.

The editor's note that was added to this section relates to the legalities applicable to statutory adoption. This information is unnecessary in this Act.

Recommendation 12 - Allow research companies to be exempt from the Act. Amend section 12-22-116.5, C.R.S., to read as follows:

12-22-116.5. Exemption from licensure - hospital residency programs – home renal dialysis – RESEARCH COMPANIES. (1) 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.

12-22-116.5(3) A MANUFACTURER WHICH MUST OBTAIN A PRESCRIPTION DRUG OR DEVICE SOLELY FOR USE IN ITS RESEARCH, DEVELOPMENT AND/OR TESTING PROCEDURES AND WHICH DOES NOT FURTHER DISTRIBUTE THE DRUG OR DEVICE MAY APPLY TO THE BOARD FOR A WAIVER OF REGISTRATION UNDER THIS ARTICLE. THE BOARD MAY GRANT SUCH A WAIVER PROVIDED THAT THE MANUFACTURER SUBMITS TO THE BOARD THE NAME OF THE DRUG OR DEVICE IT REQUIRES AND A SWORN AFFIDAVIT CERTIFYING THAT THE DRUG OR DEVICE WILL ONLY BE USED FOR NECESSARY RESEARCH, DEVELOPMENT AND/OR TESTING PROCEDURES AND WILL NOT BE FURTHER DISTRIBUTED. THIS WAIVER SHALL NOT APPLY TO ANY CONTROLLED SUBSTANCE AS DEFINED IN STATE OR FEDERAL LAW.

Occasionally a manufacturer needs a prescription drug for internal use in research, development, manufacturing and/or testing of a product. A typical example might be the need for sterile water for cleaning or calibration of equipment. The manufacturer does not qualify for registration in any category listed in section 12-22 120, C.R.S., because it does not produce or sell prescription drugs. Without a registration, wholesale suppliers of prescription drugs are prohibited from distributing to the manufacturer. This recommendation would create an avenue for the Board to grant an exemption for such situation, so the manufacturer would be permitted to obtain the needed product.

Recommendation 13 - Update and revise responsibilities of pharmacy managers of prescription drug outlets. Amend section 12-22-119(1)(b), C.R.S., to read as follows:

12-22-119(1)(b) 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 owner shall close the prescription drug outlet unless such owner has employed a pharmacist, and, within FOURTEEN (14) ~~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.

Currently, an owner of a prescription drug outlet has only seven days in which to make an application to transfer the registration to a new manager when the previous one has left that position. This time period is unduly short and an increase to a 14-day period is recommended.

Recommendation 14 - Amend the frequency of registration for outlets. Amend section 12-22-120(1) to read as follows:

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

It is an administrative burden for the agency to be required to renew businesses every year. All other licensees and registrants are on a biennial schedule. For administrative efficiency, the agency would like to renew pharmacists one year and businesses the next year.

Recommendation 15 - Clarify language to allow the transfer of facility registrations. Amend section 12-22-120(4), C.R.S., to read as follows:

12-22-120(4) Registrations issued by the board pursuant to this section are ~~not~~ transferable or assignable ONLY PURSUANT TO THIS ARTICLE AND BOARD REGULATIONS.

There are several provisions in the statute that address the transfer of ownership of a pharmacy. The provisions of section 12-22-114(1)(g),(h) & (m), C.R.S., regarding fees for transferring a prescription drug outlet and section 12-22-119(2), C.R.S., regarding application for the transfer of ownership of a prescription drug outlet conflict with the provisions of section 12-22-124, C.R.S. As currently written, this section precludes any transfer of facility registrations. This is not the current practice of the Board or the intent of the Act.

Recommendation 16 - Clarify the authority to transfer products between affiliated other outlets. Amend sections 12-22-121(2), (3) and (5), C.R.S., to read as follows:

12-22-121(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 OTHER OUTLET, or he may give or sell any drug to any practitioner authorized by law to prescribe the same.

12-22-121(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 OTHER OUTLET, or to any practitioner authorized by law to prescribe the same.

12-22-121(5)(b) IN THE CASE OF A COUNTY HEALTH DEPARTMENT WHICH OPERATES REGISTERED OTHER OUTLETS, ONE REGISTERED OTHER OUTLET MAY MAKE A CASUAL SALE OF A DRUG TO ANOTHER REGISTERED OUTLET PROVIDED THAT (I) THE DRUG IS SOLD IN THE ORIGINAL SEALED CONTAINER IN WHICH IT WAS ORIGINALLY RECEIVED FROM THE WHOLESALER; (II) NO SUCH CASUAL SALE IS MADE TO ANY REGISTERED OUTLET THAT IS NOT OWNED AND/OR OPERATED BY THAT COUNTY HEALTH DEPARTMENT; AND (III) THE AMOUNT SOLD DOES NOT EXCEED THE FIVE PERCENT LIMIT ESTABLISHED BY SECTION 12-22-102(5), C.R.S.

During an Other Outlet Task Force meeting, it was proposed that such transfers would be helpful when one outlet has an excess of drugs and another outlet needs additional drugs. Rather than wasting the excess drugs, they could be transferred to where they are needed. There is still the five percent limitation on total amount as expressed in section 12-22-102(5), C.R.S., that defines “casual sale.”

Currently, some of the larger county health departments already register as wholesalers if they wish to purchase drugs in bulk and distribute them to their satellite “other outlets.” Re-packaging, however is not allowed, unless they comply with federal regulations. The recommended change is proposed to reduce the red tape involved for government entities when carrying out their public responsibilities.

Subsections (2) and (3) are revised to incorporate “other outlets” into their language.

Recommendation 17 - Clarify the pharmacist’s authority to refill a prescription order. Amend section 12-22-122(2), C.R.S., to read as follows:

12-22-122(2) A pharmacist may refill a prescription order for any prescription drug EXCLUDING CONTROLLED SUBSTANCES 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).

Subsection (2) needs to be clarified to conform to federal law. The pharmacist's authority to refill a prescription when the prescriber cannot be reached is limited to prescriptions for non-controlled substances only.

Recommendation 18 – Replace the word “pharmacist” with the word “prescription drug.” Amend section 12-22-130(1)(b), C.R.S., to read as follows:

12-22-130(1)(b) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident prescription drug outlet shall maintain at all times a valid, unexpired license, permit, or registration to conduct the pharmacist PRESCRIPTION DRUG outlet in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident prescription drug outlet shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

This recommendation conforms to Recommendation 2 on page 53 that revises the definition of “prescription drug outlet” in section 12-22-102(30.2), C.R.S.

Appendix A - Sunset Statutory Evaluation Criteria

- (I) Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- (II) If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- (III) Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- (IV) Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- (V) Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- (VI) The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- (VII) Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- (VIII) Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action; and
- (IX) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Appendix B - Complaint Charges

Complaint Charge	Number of Complaints	Letter of Concern Percentage of Complaints Issued
Advertising	5	2 (40%)
Audit	6	
Beyond Scope of Training	3	1 (33%)
Controlled Substance Diversion	22	
Controlled Substance by Fraud	1	
Confidentiality	1	
Controlled Substance Possession	9	
Dispensing Error	198	162 (82%)
Denied License	8	
Dispensed w/o Orders	31	5 (16%)
Excess Refills	3	
Failure to Comply	50	1 (.02%)
Failure to Notify if New Manager	3	1 (33%)
Failure to Renew	2	
Intern Problem	1	
Legend Drug Diversion	2	
Licensee Identification	2	
Miscellaneous	39	5 (13%)
Malpractice Insurance Claim	12	2 (17%)
Manager's Responsibilities	14	1 (.07%)
Misdemeanor Conviction	1	
Other State Action	8	
Preceptor Problem	1	1 (100%)
Psychologically Impaired	1	
Records	8	
Restricted License	2	
RX Transfer	1	
Substance Abuse	19	2 (10%)
Substitution	5	
Security Violation	39	10 (26%)
Supervision Ratio	1	
Theft	3	
Unprofessional Conduct	4	
Unreported Discipline/Renewal	6	
Unlicensed Activity	4	

Appendix C - Categories of Medication Errors

Medication Administration Errors Source: American Society Of Consultant Pharmacists

Compliance Error. Inappropriate Resident Behavior Regarding Adherence To A Prescribed Medication Regimen.

Deteriorated Drug Error. Administration of a medication when the physical or chemical integrity of the dosage form has been compromised, such as expired medications, medications not properly stored, or medications requiring refrigeration that are left out at room temperature.

Dispensing Error. The failure to dispense a medication upon physician order (omission error) or within a specified period of time from receipt of the medication order or reorder (time error); dispensing the incorrect drug, dose, dosage form; failure to dispense correct amount of medication; inappropriate, incorrect, or inadequate labeling of medication; incorrect or inappropriate preparation, packaging, or storage of medication prior to dispensing; dispensing of expired, improperly stored, or physically or chemically compromised medications.

Extra Dose Error. The administration of duplicate doses to a resident or administration of one or more dosage units in addition to those that were ordered. May include administration of a medication dose after the order was discontinued (which could also be considered an Unauthorized Drug Error).

Monitoring Error. Failure to review a prescribed regimen for appropriateness, or failure to use appropriate clinical or laboratory data for adequate assessment of resident response to prescribed therapy.

Omission Error. The failure to administer an ordered dose to a resident by the time the next dose is due, assuming there has been no prescribing error. Exceptions would include a resident's refusal to take the medication and failure to administer the dose because of recognized contraindications.

Other Medication Error. Any medication error that does not fall into a predefined category.

Potential Error. A mistake in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention before actual medication administration.

Prescribing Error. The inappropriate selection of a drug (based on indication, contraindications, known allergies, existing drug therapy, and other factors); dose; dosage form; quantity; route of administration; concentration; rate of administration; or inappropriate or inadequate instructions for use of a medication ordered by a physician or other authorized prescriber.

Unauthorized Drug Error. The administration of a medication to a resident for which the physician did not write an order. This category includes a dose given to the wrong resident, dose given that was not ordered, administration of the wrong drug or a discontinued drug, and doses given outside a stated set of clinical parameters or protocols.

Wrong Administration Technique Error. Use of an inappropriate procedure or improper technique in the administration of a drug. Examples of wrong technique errors include incorrect manipulation of inhalers, failure to maintain sanitary technique with medications, not wiping an injection site with alcohol, failure to use proper technique when crushing medications, failure to check nasogastric tube placement or flushing NG tube before and after administration of medication, failure to wash hands or improper hand washing technique used.

Wrong Dosage Form Error. The administration of a medication in a dosage form different from the one that was ordered by the prescriber. This could include crushing a tablet prior to administration without an order from the prescriber.

Wrong Dose Error. When the resident receives an amount of medication that is greater than or less than the amount ordered by the prescriber.

Wrong Drug Preparation Error. A medication incorrectly formulated or manipulated before administration, such as incorrect or inaccurate dilution or reconstitution, failure to shake suspensions, crushing medications that should not be crushed, mixing drugs that are physically or chemically incompatible, and inadequate product packaging.

Wrong Rate Error. The incorrect rate of administration of a medication to a resident. May occur with intravenous fluids or liquid enteral products.

Wrong Route Error. The administration of a medication to a resident by a route other than that ordered by the physician or doses administered via the correct route but at the wrong site (e.g., left eye instead of right eye).

Wrong Time Error. The failure to administer a medication to a resident within a predefined interval from its scheduled administration time. This interval should be established by each facility and clearly stated in the facility's policies. Different intervals may be established for different drugs or drug classes, based on the therapeutic importance of dosing.

Appendix D - Pharmacy Related Statutes

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.

(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 or hospital other 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.

(16.5) "Location" means the physical confines of an individual building or at the same address.

(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) Repealed.

(19) Repealed.

(20) "Nonprescription drug" means a medicine or drug which may be sold without a prescription which is repackaged 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 a single drug or device that is written, mechanically produced, computer generated and signed by the practitioner, transmitted electronically or by facsimile, or 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, or mail order vendor, other than a pharmacist, that has facilities in this state registered pursuant to this article and that engages in the dispensing, delivery, distribution, manufacturing, wholesaling, or sale of drugs or devices.

(23.5) "Patient counseling" means the oral communication by a pharmacist or intern of information to the patient or caregiver in order to improve therapy by ensuring proper use of drugs and devices.

(23.6) "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. In addition to the preparation, dispensing, and distribution of medications, "pharmaceutical care" may include assessment and evaluation of the patient's medication related needs and development and communication of a therapeutic plan with defined outcomes in consultation with the patient and the patient's other health care professionals to attain the desired outcome. This function includes efforts to prevent, detect, and resolve medication related problems for individual patients. "Pharmaceutical care" does not include prescriptive authority.

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

(24.1) "Pharmacist manager" means an individual, licensed in this state as a pharmacist, who has direct control of the pharmaceutical affairs of a prescription drug outlet, and who is not the manager of any other prescription drug outlet.

(24.5) "Prospective drug review" means a review of the patient's drug therapy and prescription drug order prior to dispensing the drug as part of a drug regimen review.

(25) Repealed.

(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 provision of pharmaceutical care including patient counseling and prospective drug review, drug and drug-related research not including prescriptive authority, 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 these 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, effective July 1, 1981.)

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

(28) Repealed.

(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 registered pursuant to this article 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.

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

(32.5) "Satellite" means an area outside the prescription drug outlet where pharmaceutical care and services are provided and that is in the same location.

(32.6) "Supervision" means that a licensed pharmacist is on the location and immediately and readily available to consult with and assist unlicensed personnel performing tasks described in subsection (26) (b) of this section.

(33) "Therapeutically equivalent" or "equivalent" means those compounds containing the identical active chemical ingredients of identical strength, quantity, and dosage form 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.

(33.5) Repealed.

(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, 2003.

12-22-104. Membership.

(1) 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.

(2) All appointments shall be made by the governor in accordance with this section.

(3) For purposes of achieving a balance in the membership on the board, the governor shall consider:

(a) Whether the appointee's home is in:

(I) An urban or rural location; and

(II) An area already represented geographically by another appointee on the board; and

(b) The type of practice of the appointee so that various types of practices are represented on the board.

(4) (a) The term of office of each member shall be four years.

(b) In the case of any appointment to fill a vacancy, the appointee shall complete the unexpired term of the former board member.

(c) No member of the board may serve more than two consecutive full terms.

(5) No more than four members of the board shall be members of the same major political party.

(6) The pharmacist members shall be appointed so that the term of one member shall expire July 1 each year.

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)

12-22-110. Powers and duties.

(1) The board shall:

(a) Inspect, or direct inspectors who are licensed 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 and registrations, of all license and registration 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) (a) 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.

(b) (I) For purposes of this section, "practice of pharmacy", as defined in section 12-22-102 (26), may include up to thirty percent of the required hours of practical experience with a drug manufacturer under the supervision of such manufacturer or with a school of pharmacy in drug or drug related research activities.

(II) The board shall promulgate rules to implement this paragraph (b).

(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.

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. Publications.

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 and each pharmacist or pharmacy that self-insures 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 or self-insured pharmacist or pharmacy shall provide information relating to each malpractice claim as is deemed necessary by the board to conduct a further investigation and hearing.

(3) Information relating to each malpractice claim provided by insurance companies or self-insured pharmacists or pharmacies 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, C.R.S., for the following licenses and registrations:

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

(b) Repealed.

(c) For the initial licensure, upon examination, as a pharmacist, as provided in section 12-22-116 (3.3);

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- (d) For the initial licensure, without examination and upon presentation of evidence of licensure in another state, as a pharmacist, as provided in section 12-22-116 (7);
 - (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.
 - (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 pharmacists;
 - (q) For the initial and renewal registration of all other outlets under section 12-22-120 not covered in this section;
 - (r) For the initial and renewal registration of all nonresident prescription drug outlets under section 12-22-130.
- (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 - licensure requirements.

- (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 the applicant's name and address, the applicant's 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, such applicant shall appear for examination at the time and place fixed by the board.
- (3.3) (a) (I) An applicant who has graduated from a school or college of pharmacy approved by the board may take an examination before the board.
- (II) The examination shall be fairly designed to test the applicant's knowledge of pharmacy and other related subjects and shall be in a form approved by the board; except that the examination shall not be administered orally.
 - (III) An applicant for licensure by examination shall have completed an internship as prescribed by the board.
- (b) A person who produces evidence satisfactory to the board that such person has graduated and obtained a degree from a school of pharmacy outside the United States and has passed a foreign graduate equivalency test given or approved by the board may apply to take the examination set forth in paragraph (a) of this subsection (3.3).
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(3.5) Every applicant for licensure as a pharmacist, whether by examination, transfer of license, or reinstatement, shall take a jurisprudence examination approved by the board that tests such applicant's knowledge of the laws of this state.

(4) Repealed.

(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 for license transfer. The board shall designate a clearinghouse for license transfer applicants, and such individuals shall apply for license transfer through the clearinghouse designated by the board.

(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. Exemptions from licensure - hospital residency programs - home renal dialysis.

(1) 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.

(2) This article shall not apply to the sale or delivery of a dialysis solution if all of the following conditions are met:

(a) The sale or delivery is made directly by the manufacturer to a person with chronic kidney failure or to the designee of such a person;

(b) Such sale or delivery is for the purpose of self-administration by the person pursuant to an order by a physician lawfully practicing in this state; and

(c) The solution is sold or delivered in original packages, properly labeled, and unadulterated in accordance with the requirements of the "Colorado Food and Drug Act", part 4 of article 5 of title 25, C.R.S., and the "Federal Food, Drug, and Cosmetic Act".

12-22-117. Classes of pharmacists. (Repealed)

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) (a) Every licensee who desires to retain a license shall pay a renewal fee on or before the expiration date of such license.

(b) In case any licensee or registrant defaults in the payment of the renewal fee, the 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.

(c) Any pharmacist failing to renew such pharmacist's 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 such pharmacist 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.

12-22-118.5. Continuing education.

(1) Except as permitted in subsections (2) and (3) of this section, the board may not renew or reactivate the license of any pharmacist until the pharmacist presents evidence of having completed twenty-four hours of approved continuing pharmaceutical education within the preceding two years. Subject to subsection (9) of this section, such evidence may be provided by checking a sign-off box on the license renewal application.

(2) (a) The board may renew the license of a pharmacist who presents acceptable evidence that the pharmacist was unable to comply with subsection (1) of this section.

(b) The board may grant a six-month compliance extension to pharmacists who are unable to comply with subsection (1) of this section.

(c) With regard to license renewals occurring prior to July 1, 2002, the board shall require pharmacists to present evidence of having completed only twelve hours of approved continuing pharmaceutical education.

(3) The board may renew the license for the first renewal period following the issuance of the original license without requiring a pharmacist to complete any continuing pharmaceutical education if the pharmacist obtains a license within one year after the completion of the pharmacist's pharmaceutical education.

(4) To qualify for continuing education credit, a program of continuing pharmaceutical education must be currently approved by the American council on pharmaceutical education or an equivalent accrediting body as determined by the board.

(5) Each program of continuing pharmaceutical education shall consist of at least one continuing education unit, which is one hour of participation in an organized continuing educational experience, including postgraduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, cassette programs, programmed learning courses, audiovisual programs, internet programs, and any other form of presentation that is accredited.

(6) Any aspect of the practice of pharmacy may be the subject of a program of continuing pharmaceutical education, including, but not limited to, pharmaceuticals, compounding, pharmacology, pharmaceutical chemistry, biochemistry, physiology, microbiology, pharmacy administration, and professional practice management.

(7) A program of continuing pharmaceutical education may include, but is not limited to, the following:

(a) A definite stated objective;

(b) Presentation in an organized manner; and

(c) A method of program evaluation that is suitable to the type of program being presented.

(8) A program of continuing pharmaceutical education shall meet the requirements as established by the accrediting body.

(9) The board may annually audit up to five percent of the pharmacists licensed and residing in Colorado to determine compliance with this section.

(10) Failure to obtain the twenty-four hours of approved continuing pharmaceutical education shall result in the license becoming inactive. Inactive licensees shall not be required to comply with any continuing pharmaceutical education requirement so long as such licensees remain inactive, but shall continue to be required to pay applicable fees, including renewal fees. Inactive status shall be noted on the face of any license issued while the licensee remains inactive. Should an inactive pharmacist wish to resume the practice of pharmacy after being placed on an inactive list, the pharmacist shall file an application therefor, pay the registration renewal fee, and, subject to subsections (2) and (3) of this section, meet the twenty-four-hour continuing education requirement. Engaging in the practice of pharmacy while on inactive status pursuant to this article may be grounds for license revocation.

12-22-119. Prescription drug outlet under charge of pharmacist.

(1) (a) A prescription drug outlet shall be under the direct charge of a pharmacist manager. A proprietor who is not a pharmacist shall comply with this requirement and shall provide a manager who is a pharmacist.

(b) 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 owner shall close the prescription drug outlet unless such owner 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.

(c) The pharmacist manager in whose name the registration was obtained, at the time such pharmacist manager ceases to be employed as such, shall immediately report to the board the fact that he or she is no longer manager of the prescription drug outlet. Such pharmacist manager shall be held responsible as the manager until the cessation of employment is reported. The proprietor of the prescription drug outlet shall also notify the board of the termination of managership.

(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) (a) Repealed.

(b) (I) 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 pharmacy intern but who is an unlicensed assistant under such pharmacist's supervision if, in the pharmacist's 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).

(II) This paragraph (b) is effective February 1, 1999.

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.

(e) Any other outlet, as may be authorized by this article or that meets the definition of outlet as set forth in section 12-22-102 (23).

(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.

(7) A separate registration shall be required under this section for any area outside the outlet that is not a satellite where pharmaceutical care and services are provided and for any such area that is under different ownership from the outlet.

(8) No hospital outlet filling inpatient chart orders shall sell or otherwise transfer any portion of its prescription drug inventory to another registered outlet for sale or dispensing at retail. This subsection (8) shall not be construed to limit any transfer of prescription drugs for the hospital's own use or to limit the ability of a hospital outlet to engage in a casual sale as defined in section 12-22-102 (5).

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 or licensed hospital other outlet may make a casual sale or loan of or may give a drug to another registered 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 any facility approved by the board for receipt of an emergency kit, any home health agency certified by the department of public health and environment and approved by the board for receipt of an emergency kit, and any licensed hospice approved by the board for receipt of an emergency kit 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) (Deleted by amendment, L. 96, p. 1424, § 12, effective July 1, 1996.)

(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) Any facility approved by the board, any home health agency certified by the department of public health and environment and approved by the board, and any licensed hospice approved by the board may maintain emergency drugs provided and owned by a prescription drug outlet, consisting of drugs and quantities as established by the board.

(14) Repealed.

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

(16) 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 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.

12-22-121.7. Limited authority to delegate activities constituting practice of pharmacy to unlicensed personnel.

(1) Repealed.

(2) (a) A pharmacist may supervise up to two persons who are either pharmacy interns or unlicensed assistants. This supervision ratio does not include other ancillary personnel that may be in the prescription drug outlet, but are not performing duties described in section 12-22-102 (26) (b) that are delegated to such interns or unlicensed assistants.

(b) This subsection (2) is effective February 1, 1999.

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.

(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 or her license to practice pharmacy in another state revoked or suspended for disciplinary reasons or has committed acts in any other state that would subject him or her 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:

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- (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 that 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 the respondent's physical or mental condition or professional qualifications;

(II) The taking by the respondent 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 the respondent's practice as may be necessary to determine the quality of his or her practice and to correct deficiencies therein; and

(IV) The imposition of restrictions upon the nature of the respondent's practice to assure that he or she does not practice beyond the limits of this or her 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) (a) 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.

(b) 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 or she has the right to request in writing, within twenty days after proven receipt of the letter, that formal disciplinary proceedings be initiated to adjudicate the propriety of the conduct upon which the letter of admonition is based.

(c) If the request is timely made, the letter of admonition shall be deemed vacated, and the matter shall be processed by means of formal disciplinary proceedings.

(7) When a complaint or an investigation discloses an instance of conduct that does not warrant formal action by the board but the board determines that continuation of such conduct could warrant action if continued, a confidential letter of concern may be sent by certified mail to the pharmacist against whom the complaint was made or who was the subject of investigation. If a complaint precipitated the investigation, a response shall be sent to the person making the complaint.

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;

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- (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.
 - (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 18-1.3-501, 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 18-1.3-401, 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.

12-22-130. Nonresident prescription drug outlet - registration.

(1) Any prescription drug outlet located outside this state that ships, mails, or delivers, in any manner, drugs or devices into this state shall be considered a nonresident prescription drug outlet, shall be registered with the board, and shall disclose to the board the following:

(a) The location, names, and titles of all principal entity officers and all pharmacists who are dispensing drugs or devices to the residents of this state. A report containing this information shall be made on an annual basis and within thirty days after any change of office, officer, or pharmacist.

(b) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident prescription drug outlet shall maintain at all times a valid, unexpired license, permit, or registration to conduct the pharmacist outlet in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident prescription drug outlet shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(2) The registration requirements of this section shall apply only to a nonresident prescription drug outlet which only ships, mails, or delivers drugs, in any manner, and devices into this state pursuant to a prescription order.

(3) A nonresident prescription drug outlet doing business in this state that has not obtained a registration shall not conduct the business of selling or distributing drugs in this state without first registering as a nonresident prescription drug outlet. Applications for nonresident prescription drug outlet registration shall be made on a form furnished by the board. The board may require such information as it deems necessary to carry out the purpose of this section.

(4) (a) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration for failure to comply with any provision of this section or with any reasonable rule promulgated by the board.

(b) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration if such prescription drug outlet's license or registration has been revoked or not renewed for noncompliance with the laws of the state in which it is a resident.

12-22-201 to 12-22-204. (Repealed)

12-22-301. Short title.

This part 3 shall be known and may be cited as the "Colorado Licensing of Controlled Substances Act".

12-22-302. Legislative declaration.

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

12-22-303. Definitions.

As used in this part 3, unless the context otherwise requires:

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

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

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

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

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

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

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

(7) "Controlled substance" means a drug, substance, or immediate precursor included in schedules I to V of part 2 of article 18 of title 18, C.R.S.

(7.5) (a) "Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II and:

(I) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in schedule I or II; or

(II) With respect to a particular individual, which that individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in schedule I or II.

(b) "Controlled substance analog" does not include:

(I) A controlled substance;

(II) Any substance for which there is an approved new drug application;

(III) With respect to a particular person, any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the "Federal Food, Drug, and Cosmetic Act", 21 U.S.C. 355, as amended, to the extent that conduct with respect to the substance is pursuant to the exemption; or

(IV) Any substance to the extent not intended for human consumption before such an exemption takes effect with respect to the substance.

(8) "Deliver" or "delivery" means actual, constructive, or attempted transfer of a controlled substance whether or not there is an agency relationship.

(9) "Department" means the department of human services.

(10) "Detoxification treatment" means a program for a short term of not more than three weeks for the administering or dispensing, in decreasing doses, of a controlled substance to an addict while he is receiving appropriate supportive medical treatment, with the immediate goal being to render the addict no longer dependent on the intake of any amount of a controlled substance.

(11) "Dispense" shall have the same meaning as set forth in section 12-22-102 (9).

(12) "Distribute" means to deliver a controlled substance other than by administering or dispensing.

(12.5) "Distributor" has the same meaning as that set forth in section 18-18-102 (12), C.R.S.

(13) (a) "Drug" means any of the substances:

(I) Recognized as drugs in the official United States pharmacopoeia, national formulary, or the official homeopathic pharmacopoeia of the United States, or a supplement thereof;

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

(III) Other than food, intended to affect the structure or any function of the body of individuals or animals; or

(IV) Intended for use as a component of any substance specified in subparagraph (I), (II), or (III) of this paragraph (a).

(b) "Drug" does not include devices or their components, parts, or accessories.

(13.5) Repealed.

(14) "Immediate precursor" means a substance which is a principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used, in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

(15) "Maintenance treatment" means a program of more than six months' duration for the administering or dispensing of a controlled substance, approved for such use by federal law or regulation, to an addict for the purpose of continuing his dependence upon a controlled substance in the course of conducting an authorized rehabilitation program for addicts, with a long-term goal of decreasing the addict's controlled substance dependency and leading to his possible withdrawal.

(16) "Manufacturer" means a person who is licensed by this part 3 and who, by compounding, mixing, cultivating, planting, growing, or other process, produces or prepares a controlled substance, but the term does not include a pharmacist who compounds controlled substances to be dispensed pursuant to a prescription, a practitioner who compounds controlled substances for dispensing in the course of his professional practice, or a researcher acting within the provisions of this part 3.

(17) "Marihuana" or "marijuana" means all parts of the plant *cannabis sativa* L., whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin. It does not include fiber produced from the stalks, oil or cake made from the seeds of the plant, or sterilized seed of the plant which is incapable of germination, if these items exist apart from any other item defined as "marihuana" in this subsection (17). "Marihuana" does not include marihuana concentrate as defined in subsection (18) of this section.

(18) "Marihuana concentrate" means hashish, tetrahydrocannabinols, or any alkaloid, salt, derivative, preparation, compound, or mixture, whether natural or synthesized, of tetrahydrocannabinols.

(19) "Narcotic controlled substance" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

- (a) Opium or any opiate or any salt, compound, derivative, or preparation of opium or any opiate;
- (b) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent to or identical with any of the substances referred to in paragraph (a) of this subsection (19) but not including the isoquinoline alkaloids of opium;
- (c) Any opium poppy or poppy straw.

(20) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having an addiction-forming or addiction-sustaining liability. "Opiate" does not include, unless specifically designated as controlled under this part 3, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts (dextromethorphan). The term does include its racemic and levorotatory forms.

(21) "Opium poppy" means the plant of the species *papaver somniferum* L., except its seeds.

(22) "Peace officer" shall have the same meaning as set forth in section 18-1-901 (3) (I), C.R.S.

(23) "Person" means any individual, government, governmental subdivision, agency, business trust, estate, trust, partnership, corporation, association, institution, or other legal entity.

(24) "Peyote" means all parts of the plant presently classified botanically as *lophophora williamsii* lemaire, whether growing or not, the seeds thereof, any extraction from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or extracts.

(25) "Pharmacist" means an individual licensed pursuant to part 1 of this article to engage in the practice of pharmacy, as defined in section 12-22-102 (26).

(26) "Pharmacy" or "prescription drug outlet" shall have the same meaning as set forth in section 12-22-102 (30.2).

(27) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(28) "Practitioner" shall have the same meaning as set forth in section 12-22-102 (27).

(29) "Production" or "produces" means the manufacturing, planting, cultivating, growing, or harvesting of a controlled substance.

(30) "Remuneration" means anything of value, including money, real property, tangible and intangible personal property, contract rights, choses in action, services, and any rights of use or employment or promises or agreements connected therewith.

(31) "Researcher" means any person licensed by the department pursuant to this part 3 to experiment with, study, or test any controlled substance within this state and includes analytical laboratories.

(32) (a) "Tetrahydrocannabinols" means synthetic equivalents of the substances contained in the plant, or in the resinous extractives of, *cannabis*, sp., or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity, such as the following:

- (I) 1cis or trans tetrahydrocannabinol, and their optical isomers;
- (II) 6cis or trans tetrahydrocannabinol, and their optical isomers;
- (III) 3,4cis or trans tetrahydrocannabinol, and their optical isomers.

(b) Since the nomenclature of the substances listed in paragraph (a) of this subsection (32) is not internationally standardized, compounds of these structures, regardless of the numerical designation of atomic positions, are included in this definition.

(33) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use, for the use of a member of his household, or for use in administering to an animal owned by him or a member of his household.

(34) (Deleted by amendment, L. 92, p. 386, § 5, effective July 1, 1992.)

(35) "Withdrawal treatment" means a program for an intermediate term, of more than three weeks but less than six months, for the administering or dispensing, in decreasing doses, of a controlled substance, approved for such use by federal law or regulation, to an addict while receiving rehabilitative measures as indicated, with the immediate goal being to render the addict no longer dependent on the intake of any amount of a controlled substance.

12-22-304. License required - controlled substances - drug precursors - fund created - repeal.

(1) In accordance with part 3 of article 18 of title 18, C.R.S., a license issued by the department shall be obtained annually for each place of business or professional practice located in this state by:

(a) Repealed.

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

(II) (A) This paragraph (b) is repealed, effective July 1, 2007.

(B) Prior to such repeal, the licensing functions of the department shall be reviewed as provided in section 24-34-104, C.R.S.

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

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

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

(2.5) Repealed.

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

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

(4) Persons licensed as required under this part 3, or otherwise licensed as required by federal law, may possess, manufacture, distribute, dispense, administer, or conduct or do research with controlled substances only to the extent authorized by their licenses and in conformity with the provisions of this part 3 and with article 18 of title 18, C.R.S.

(5) The following persons need not be licensed by the department or by the board to lawfully possess controlled substances under this part 3:

(a) to (d) (Deleted by amendment, L. 92, p. 387, § 6, effective July 1, 1992.)

(e) (I) Employees of facilities who are administering and monitoring medications to persons under the care or jurisdiction thereof pursuant to the provisions of section 25-1-107 (1) (ee), C.R.S.

(II) This paragraph (e) is repealed, effective July 1, 2009. Prior to such repeal, the exception to the licensure requirement set forth in this paragraph (e) shall be subject to review by a legislative committee of reference designated pursuant to section 2-3-1201, C.R.S., to conduct the review pursuant to section 24-34-104, C.R.S., and the provisions of section 24-34-104 (5) to (12), C.R.S., concerning a wind-up period, an analysis and evaluation, public hearings, and claims by or against an agency shall apply to the operation of the program specified in this paragraph (e).

(5.5) and (5.6) Repealed.

(6) Any person who is required to be licensed and who is not so licensed may apply for a license at any time. No person required to be licensed shall engage in any activity for which a license is required until his application is granted and a license is issued to him by the department or the board.

(7) No license shall be issued under this part 3 to a researcher, manufacturer, or distributor of marijuana or marijuana concentrate.

12-22-305. Issuance of license - fees - repeal.

(1) The department or the board as provided in section 12-22-304 (1) or (2) shall issue the appropriate license to each manufacturer, distributor, researcher, and addiction program meeting all the requirements of this part 3 unless it determines that the issuance of the license would be inconsistent with the public interest. In determining the public interest, the department or the board shall consider the following factors:

- (a) Maintenance of effective controls against diversion of controlled substances into illegitimate medical, scientific, or industrial channels;
- (b) Compliance with applicable state and local laws;
- (c) Any conviction of the applicant under any federal or state law relating to a controlled substance;
- (d) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;
- (e) Any false or fraudulent information in an application filed under this part 3;
- (f) Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense a controlled substance as authorized by federal law; and
- (g) Any other factors relevant to and consistent with the public peace, health, and safety.

(1.5) Repealed.

(2) Issuance of a license under subsection (1) of this section does not entitle a licensee to wholesale, manufacture, distribute, or professionally use controlled substances beyond the scope of his federal registration.

(3) (a) The initial and annual license fees are as follows:

(I) Addiction program \$ 25.00

(II) Researchers \$ 25.00

(b) Notwithstanding the provisions of paragraph (a) of this subsection (3), the fees collected by the board under this article shall be determined, collected, and appropriated pursuant to section 24-34-105, C.R.S.

(4) Any person who is licensed may apply for license renewal not more than sixty days before the expiration date of his license.

(5) Neither the United States nor the state of Colorado or any of its political subdivisions shall pay any license fee required by this part 3.

12-22-306. Controlled substances program fund - disposition of fees.

There is hereby created in the state treasury the controlled substances program fund. All moneys collected by the department shall be transmitted to the state treasurer, who shall credit the same to the controlled substances program fund. The general assembly shall make annual appropriations from the controlled substances program fund to the department for the purposes authorized by this part 3. All moneys credited to the controlled substances program fund and any interest earned on such fund shall remain in the fund and shall not revert to the general fund or any other fund at the end of any fiscal year.

12-22-306.1. Fees - drug precursors - refund.

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

12-22-307. Qualifications for license.

(1) An applicant for a license under this part 3 must have adequate and proper facilities for the handling and storage of controlled substances and maintain proper control over such controlled substances to insure against their being illegally dispensed or distributed.

(2) Any person registered as a researcher by the federal government shall be presumed to possess the qualifications described in this section, so long as his federal registration is valid.

(3) No license shall be granted to any person who has been convicted within the last two years of a willful violation of this part 3 or any other state or federal law regulating controlled substances.

(4) Except for fees, compliance by a registrant with the provisions of the federal law respecting registration entitles the registrant to be licensed under this part 3.

12-22-308. Denial, revocation, or suspension of license.

(1) A license issued under this part 3 may be denied, suspended, or revoked by the department or by the board pursuant to article 4 of title 24, C.R.S., upon a finding that the licensee:

- (a) Has furnished false or fraudulent information in an application filed under this part 3;
- (b) Has been convicted of, or has had accepted by a court a plea of guilty or nolo contendere to, a felony under any state or federal law relating to a controlled substance;
- (c) Has had his or her federal registration to manufacture, conduct research on, distribute, or dispense a controlled substance suspended or revoked; or
- (d) Has violated any provision of this part 3 or the rules or regulations of the department or of the board.

(2) The department or the board may limit revocation or suspension of a license to the particular controlled substance which was the basis for revocation or suspension.

(3) If the department or the board suspends or revokes a license, all controlled substances owned or possessed by the licensee at the time of the suspension or on the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for making an appeal has elapsed or until all appeals have been concluded unless a court orders otherwise or orders the sale of any perishable controlled substances and the deposit of the proceeds with the court. Upon a revocation order's becoming final, all controlled substances may be forfeited to the state.

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

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

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

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

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

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

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

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

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

12-22-317. Exemptions.

(1) The provisions of section 18-18-414, C.R.S., shall not apply to:

- (a) Agents of persons licensed under this part 3 or under part 3 of article 18 of title 18, C.R.S., acting within the provisions of their licenses; or
- (b) Officers or employees of appropriate agencies of federal, state, or local governments acting pursuant to their official duties.

(2) All combination drugs that are exempted by regulation of the attorney general of the United States department of justice, pursuant to section 1006 (b) of Public Law 91-513 (84 Stat. 1236), known as the "Comprehensive Drug Abuse Prevention and Control Act of 1970", on or after July 1, 1981, are exempted from the provisions of this part 3 and from the provisions of part 3 of article 18 of title 18, C.R.S.

(3) The provisions of this part 3 do not apply to peyote if said controlled substance is used in religious ceremonies of any bona fide religious organization.

(4) The provisions of section 12-22-318 shall not apply to a practitioner authorized to prescribe with respect to any controlled substance which is listed in schedules III, IV, or V of part 2 of article 18 of title 18, C.R.S., and which is manufactured, received, or dispensed by him in the course of his professional practice unless he dispenses, other than by direct administration, any such controlled substance to his patients and they are charged therefor either separately or together with charges for other professional services or unless he regularly engages in dispensing any such controlled substance to his patients.

(5) The exemptions set forth in this section shall be available as a defense to any person accused of violating the provisions of section 18-18-414, C.R.S.

(6) It shall not be necessary for the state to negate any exemption or exception in this part 3 or in part 3 or 4 of article 18 of title 18, C.R.S., in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this part 3 or under part 4 of article 18 of title 18, C.R.S. The burden of proof of any such exemption or exception is upon the person claiming it.

12-22-318. Records to be kept - order forms - repeal.

(1) (a) Each person licensed or otherwise authorized under this part 3 or other laws of this state to manufacture, purchase, distribute, dispense, administer, store, or otherwise handle controlled substances shall keep and maintain separate detailed and accurate records and inventories relating to controlled substances and retain all such records and inventories for a period of two years after the respective dates of such transactions as shown on such records and inventories.

(b) Repealed.

(2) The record of any controlled substance distributed, administered, dispensed, or otherwise used shall show the date, the name and address of person to whom, for whose use, the controlled substance was distributed, administered, dispensed, used, or otherwise disposed of, and the kind and quantity of such controlled substance.

(3) Manufacturing records of controlled substances shall include the kind and quantity of controlled substances produced or removed from process of manufacture and the dates of such production or removal from process of manufacture.

(4) The keeping of a record required by federal law, containing substantially the same information as set forth in subsections (1) to (3) of this section, shall constitute compliance with the record-keeping requirements of this part 3.

(5) A record shall also be kept of any controlled substance lost, destroyed, or stolen, the kind and quantity of such controlled substance, and the date of such loss, destruction, or theft.

(5.5) Prescription drug outlets shall report thefts of controlled substances to the proper law enforcement agencies and to the board within thirty days after the occurrence of such thefts.

(6) Controlled substances listed in schedule I or II of part 2 of article 18 of title 18, C.R.S., shall be distributed by persons licensed or otherwise authorized under this part 3 or other laws of this state only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

(7) to (11) Repealed.

12-22-319. Enforcement and cooperation.

(1) Each peace officer and district attorney in this state shall enforce all the provisions of this part 3 and shall cooperate with all agencies charged with the enforcement of the laws of this state, all other states, and the United States relating to controlled substances.

(2) The board shall make any inspections, investigations, and reports that may be necessary to determine compliance with the provisions of this part 3 as they pertain to pharmacies, pharmacists, and manufacturers and distributors of controlled substances. The department shall cooperate with all agencies charged with the enforcement of the laws of this state, all other states, and the United States relating to controlled substances.

(3) The department of human services shall cooperate with all agencies charged with the enforcement of the laws of this state, all other states, and the United States relating to controlled substances. To this end, the department shall:

(a) Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances;

(b) Cooperate with the bureau and with local, state, and other federal agencies by maintaining a centralized unit to accept, catalogue, file, and collect statistics, including records of dependent and other controlled substance law offenders within the state, and make the information available for federal, state, and local law enforcement or regulatory purposes. It shall not furnish the name or identity of a patient or research subject whose identity could not be obtained under section 12-22-320.

(c) Respond to referrals, complaints, or other information received regarding possible violations and, upon notification of the appropriate licensing authority, if applicable, and upon a written finding by the executive director of the department that probable cause exists to believe that there is illegal distribution or dispensing of controlled substances, to make any inspections, investigations, and reports that may be necessary to determine compliance with the provisions of this part 3 by all licensed or otherwise authorized individuals who handle controlled substances;

(d) Cooperate with and make information available to appropriate state licensing and registration boards regarding any violations of this part 3 by persons licensed or registered by such boards;

(e) Enter into contracts and encourage and conduct educational and research activities designed to prevent and determine misuse and abuse of controlled substances.

12-22-320. Records confidential.

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

12-22-321. Rules and regulations.

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

(2) (a) Repealed.

(b) (Deleted by amendment, L. 93, p. 1121, § 35, effective July 1, 1994.)

12-22-322. Department to promulgate rules and regulations.

The department of human services shall promulgate rules and regulations for research programs and for the conduct of detoxification treatment, maintenance treatment, and withdrawal treatment programs for controlled substance addiction. Such rules and regulations shall be promulgated in accordance with the provisions of article 4 of title 24, C.R.S.

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

12-22-324. Defenses.

The common law defense known as the "procuring agent defense" is not a defense to any crime in this article or in title 18, C.R.S.

12-22-401 to 12-22-415. (Repealed)

12-22-501 to 12-22-506. (Repealed)

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.

Appendix E - State Board of Pharmacy Rules and Regulations

1. Rules of Professional Conduct
2. Orders
3. Dispensing
4. Licensing
5. Outlets
6. Emergency Services
7. Prescription Drug Outlet Manager
8. Advertising
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14. Records and Recordkeeping
15. Wholesalers
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17. Electronic Transfer Orders (ETO)
18. Pharmacy Peer Health Assistance Diversion Program

Tracked changes were deleted or accepted and did not appear in the statutory language of the recommendations as intended.

Differences between original and republished version are in **bold**.

Beginning on page 33 through page 60.

Recommendation 6 - Combine all statutory violations under the heading of “unprofessional conduct” and separate the listing of violations from the Board action that is authorized. Amend section 12-22-125, C.R.S., and enact section 12-22-125.2, C.R.S., to read as follows:

12-22-125. Licenses or registrations may be denied, suspended, or revoked. UNPROFESSIONAL CONDUCT – GROUNDS FOR DISCIPLINE.

(1) 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. THE TERM “UNPROFESSIONAL CONDUCT” AS USED IN THIS ARTICLE, MEANS A LICENSEE OR REGISTRANT, WHERE APPLICABLE, **WHO:**

(a) Is guilty of misrepresentation, fraud, or deceit in procuring or attempting to procure **OR RENEW** 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 **OR HAS RECEIVED A DEFERRED SENTENCE FOR A FELONY. IN CONSIDERING THE CONVICTION OF A CRIME, THE BOARD SHALL BE GOVERNED BY THE PROVISIONS OF SECTION 24-5-101, C.R.S.**

(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 **OR ANY ACTS AS SET FORTH IN SECTION 12-22-126, C.R.S.**

~~(2)(a)(I)(d)~~ Is unfit or incompetent by reason of negligence, habits, or physical or mental illness, or for any other cause, to practice as such;

~~(2)(a)(II)(e)~~ **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);** IS ADDICTED TO, DEPENDENT ON, OR ENGAGES IN THE HABITUAL USE OR ABUSE OF INTOXICATING LIQUORS, A HABIT-FORMING DRUG, OR A CONTROLLED SUBSTANCE AS DEFINED IN SECTION 18-18-102(5), C.R.S.

~~(2)(a)(III)(f)~~ Knowingly permits a person not licensed as a pharmacist or pharmacy intern to engage in the practice of pharmacy;

~~(2)(a)(IV)(g)~~ Has had his or her license to practice pharmacy in another state revoked or suspended **OR OTHERWISE DISCIPLINED for disciplinary reasons** or has committed acts in any other state that would subject him or her to disciplinary action in this state;

~~(2)(a)(V)(h)~~ Has engaged in advertising which is misleading, deceptive, or false;

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- (i) HAS DISPENSED A SCHEDULE III, IV, OR V CONTROLLED SUBSTANCE ORDER MORE THAN SIX MONTHS AFTER THE DATE OF ISSUE OF THE ORDER;
 - (j) HAS ENGAGED IN THE PRACTICE OF PHARMACY WHILE ON INACTIVE STATUS;
 - (k) HAS FAILED TO MEET GENERALLY ACCEPTED STANDARDS OF PHARMACY PRACTICE;
 - (l) FAILS OR HAS FAILED TO PERMIT THE BOARD OR ITS AGENTS TO CONDUCT A LAWFUL INSPECTION;
 - (m) HAS VIOLATED ANY LAWFUL BOARD ORDER;
 - (n) HAS COMMITTED ANY FRAUDULENT INSURANCE ACT AS DEFINED IN SECTION 10-1-127, C.R.S.;
 - (o) HAS WILLFULLY DECEIVED OR ATTEMPTED TO DECEIVE THE BOARD OR ITS AGENTS WITH REGARD TO ANY MATTER UNDER INVESTIGATION BY THE BOARD;
 - (p) HAS FAILED TO NOTIFY THE BOARD OF ANY CRIMINAL CONVICTION OR DEFERRED JUDGMENT WITHIN 30 DAYS OF SUCH CONVICTION OR JUDGMENT;
 - (q) HAS FAILED TO NOTIFY THE BOARD OF ANY DISCIPLINE AGAINST HIS LICENSE IN ANOTHER STATE WITHIN 30 DAYS OF SUCH DISCIPLINE;
 - ~~(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. (MOVED FROM BEFORE 12-22-125(1)(a))~~
 - (2)(b) In considering the conviction of a crime, the board shall be governed by the provisions of section 24-5-101, C.R.S.
- 12-22-125.2 DISCIPLINARY ACTION. (1) THE BOARD MAY DISCIPLINE LICENSEES OR REGISTRANTS WHEN IT DETERMINES THAT SUCH LICENSEE OR REGISTRANT HAS ENGAGED IN UNPROFESSIONAL CONDUCT.
- {previously 12-22-125(3)}(a) THE BOARD SHALL DENY A LICENSE IN ACCORDANCE WITH SECTION 24-4-104, C.R.S. 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.
- {previously 12-22-125(4)}(b) 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 SECTION 12-22-125, C.R.S., **this part 1**, the board may impose one or more of the following penalties:
- (a)(l) Suspension of the offender's license or registration for a period to be determined by the board;

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

~~(c)~~(III) 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)~~(IV) Refusal to renew the offender's license or registration;

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

~~(f)~~(VI) 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.

{previously 12-22-125(5)(a)}~~(2)~~ The board may also include in any disciplinary order that 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)~~(a) Submission by the respondent to such examinations as the board may order to determine the respondent's physical or mental condition or professional qualifications;

~~(II)~~(b) The taking by the respondent 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)~~(c) The review or supervision of the respondent's practice as may be necessary to determine the quality of his or her practice and to correct deficiencies therein; and

~~(IV)~~(d) The imposition of restrictions upon the nature of the respondent's practice to assure that he or she does not practice beyond the limits of his or her capabilities.

{previously 12-22-125(5)(a)(IV)(b)}~~(3)~~ Upon failure of the licensee or registrant to comply with any conditions imposed by the board pursuant to paragraph ~~(1)(b)(7), (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.

~~(4)~~ IN ADDITION TO ANY OTHER PENALTY WHICH MAY BE IMPOSED PURSUANT TO THIS SECTION, ANY REGISTRANT VIOLATING ANY PROVISION OF THIS ARTICLE OR ANY RULES OR REGULATIONS PROMULGATED PURSUANT TO THIS ARTICLE MAY BE FINED NOT LESS THAN FIVE HUNDRED DOLLARS NOR MORE THAN FIVE THOUSAND DOLLARS FOR EACH SUCH VIOLATION.

{previously 12-22-125(6)(a)}~~(5)~~(a) 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.

{previously 12-22-125(6)(b)} (b) 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 or she has the right to request in writing, within ~~twenty~~ THIRTY days after ~~proven receipt~~ of the DATE ON WHICH the letter WAS MAILED, that formal disciplinary proceedings be initiated to adjudicate the propriety of the conduct upon which the letter of admonition is based.

(c) If the request is timely made, the letter of admonition shall be deemed vacated, and the matter shall be processed by means of formal disciplinary proceedings.

{previously 12-22-125(7)}(6) When a complaint or an investigation discloses an instance of conduct that does not warrant formal action by the board but the board determines that continuation of such conduct could warrant action if continued, a confidential letter of concern may be sent by certified mail to the pharmacist against whom the complaint was made or who was the subject of investigation. If a complaint precipitated the investigation, a response shall be sent to the person making the complaint.

The Board's disciplinary powers and the grounds for discipline are currently scattered throughout various places in the statute. Grounds for discipline can be found in sections 12-22-125, C.R.S., 12-22-126, C.R.S., 18-18-304, C.R.S., and 18-18-414, C.R.S. This makes enforcement of Board actions difficult and haphazard at best. There are potential legal challenges that could be made to Board actions pursuant to some of these sections. In order to organize and clarify what is prohibited, it is recommended that all administrative infractions be in one place in the Act. This would grant the Assistant Attorney General to the Board the ability to charge all infractions administratively whether or not the District Attorney decided to charge some of the infractions criminally. Other Boards in the Department of Regulatory Agencies have consolidated infractions under the heading of "unprofessional conduct."

The revised section 12-22-125, C.R.S., contains all administrative infractions for which the Board could discipline. Some of these are broad and would take the interpretation of the Board. Most of the items listed were already in statute in one of the locations cited above. A few of the items are new, based upon lists of infractions used by other professional licensing boards in the Division of Registrations.

Proposed section 12-22-125.2, C.R.S., Disciplinary Action, addresses the Board's power to take various types of actions against licensees and registrants when they violate the unprofessional conduct section 12-22-125, C.R.S. These two sections separate the listing of the infractions from the Board action that is authorized when such infractions occur.

Recommendation 7 - Change the timelines for appealing a letter of admonition to 30 days from the date of mailing, rather than 20 days from the date of proven receipt. Amend section 12-22-125(6)(b) C.R.S., which is being renumbered as 12-22-125.2(5)(a), C.R.S., to read as follows:

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 or she has the right to request in writing, within ~~twenty~~ THIRTY days after ~~proven receipt~~ of the DATE ON WHICH the letter WAS MAILED, that formal disciplinary proceedings be initiated to adjudicate the propriety of the conduct upon which the letter of admonition is based.

In practice, the current statutory provision requires a letter of admonition to be mailed via certified mail, return receipt requested. This is the only verifiable way to prove the date on which such letter is received.

However, it is not uncommon for letters of admonition to be returned to the Board as undeliverable or unclaimed. One reason is that pharmacists relocate and do not always notify the Board of their new addresses as required. An additional consideration here is that State mail is not forwarded, it is returned to the Board as undeliverable.

A more pessimistic explanation is that the pharmacist simply refuses to sign for the letter, thus preventing the tolling period from beginning.

The Colorado Court of Appeals recently addressed this issue in *Colorado State Board of Medical Examiners v. Roberts*, 42 P.3d 70 (Colo. App. 2001). In *Roberts*, the court reviewed a provision in the Medical Practice Act that is substantially similar to the statute under discussion here. The Board of Medical Examiners issued a letter of admonition to Dr. Roberts and mailed it to him at his place of business via certified mail, return receipt requested. However, Dr. Roberts and his staff refused to sign for the letter on two separate occasions. Three months later, Dr. Roberts requested that the Board of Medical Examiners vacate the letter of admonition and institute formal disciplinary proceedings against him. The Board of Medical Examiners refused, stating that two notices of attempted delivery by the U.S. Postal Service was sufficient to constitute receipt and begin the 20-day tolling period for requesting formal disciplinary proceedings.

Dr. Roberts and the Court of Appeals disagreed. In focusing on the plain language of the statute, the court held that “receipt” in the statute requires actual receipt.

Since the Act contains language that is substantially similar to the statutory provision reviewed in *Roberts*, it is not unreasonable to believe that at some point, the Board could encounter a similar problem.

The recommended language attempts to expedite the disciplinary process while protecting the rights of the pharmacist. By requiring the letter of admonition to be mailed by certified mail, the Board will be able to establish the date on which it is mailed. To allow for delivery time, and to be consistent with other appeals timelines, the time in which a pharmacist may request formal disciplinary proceedings is extended from 20 days to 30 days.

This recommendation neither restricts nor expands the powers of the Board or the rights of the pharmacist. Rather, it attempts to correct a procedural problem that may be exacerbated by the *Roberts* decision.

Recommendation 8 – Conform the definition of “controlled substance” in the Drugs and Druggists Act to the section in the Colorado Criminal Code that defines “controlled substance”. Amend section 12-22-303(7), C.R.S., to read as follows:

12-22-303(7) “Controlled substance” SHALL HAVE THE SAME MEANING AS THAT DEFINED IN SECTION 18-18-102(5), C.R.S. ~~means a drug, substance, or immediate precursor included in schedules I to V of part 2 of article 18 of title 18, C.R.S.~~

Section 12-22-303(7), C.R.S., defines a controlled substance as “a drug, substance, or immediate precursor included in schedules I to IV of Part 2 of Article 18 of Title 18, C.R.S.”

Section 18-18-102(5), C.R.S., a section of the Colorado Criminal Code (Criminal Code) defines a controlled substance in an identical manner except that it goes on to state, “including cocaine, marihuana, and marihuana concentrate.”

Tetrahydrocannabinols, commonly referred to as “THC”, is listed as a Schedule I Controlled Substance at section 18-18-203(2)(c)(XXIII), C.R.S. Section 12-22-303(32)(a), C.R.S., defines “THC” as,

synthetic equivalents or the substances contained in the plant, or in the resinous extractives of, cannabis, sp., or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity . . .

Thus, THC is a part of the marihuana plant, but an individual could potentially test positive for marihuana and not THC, which is the controlled substance under the Act.

In 2001, the Board of Nursing sought to take disciplinary action against a certified nurse aide (CNA) who reported to work in an intoxicated state and tested positive for cocaine, alcohol and marihuana. Because the Nurse Aide Practice Act references the Drugs and Druggists Act, which includes THC as a controlled substance, but not marihuana specifically, the administrative law judge (ALJ) requested the Board of Nursing’s Assistant Attorney General, to establish the relationship between THC and marihuana in order to proceed to hearing whether the marihuana in the CNA’s system was grounds for disciplinary action. This involved research, legal analysis of the relevant statutes, and obtaining an affidavit from a pharmacist.

Since THC is listed as a Schedule I Controlled Substance, and the Criminal Code specifically includes marihuana in its definition of a controlled substance, it is clear that the General Assembly intended that a practitioner who is found to have abused or excessively or habitually used marihuana be subject to disciplinary action. The recommended amendment will more clearly state the General Assembly’s intention.

Two other points are worth noting in relation to this issue. First, most, if not all, of Colorado’s professional practice acts contain language similar to that at issue here – they reference the Drugs and Druggists Act.

Finally, in 2000, the Colorado Constitution was amended to legalize the use of marihuana for people suffering from debilitating medical conditions. Colo.Const. art. XVIII, §14. This recommendation will not infringe upon an individual’s opportunity to exercise the rights granted under this constitutional provision so long as the practitioner does not report to work while under the influence of marihuana, just as a practitioner could receive discipline for reporting to work while under the influence of alcohol. For an individual who as obtained the necessary approvals and permissions to use marihuana for medicinal purposes, a showing of abuse, or habitual or excessive use would be similar to such a showing for alcohol.

*Recommendation 9 - Update the Pharmacy Peer Health Assistance Diversion Program. Amend sections 12-22-601(2), **12-22-603(3)(b)**, and 12-22-606, C.R.S., to read as follows:*

12-22-601(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 IN CONJUNCTION WITH OR 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.

The Board should be able to use the Peer Health Assistance Diversion Program not only as an alternative to discipline, but also in conjunction with discipline.

(incorrect cite – moved from within changes to 12-22-606) 12-22-603(3)(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~~ PER YEAR, 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

In Subsection (3)(b), the money allotted for this program should be increased. Currently, the program has nearly twice as many participants as the dental program, but licensees pay only one-half of what the dentists pay.

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 PHARMACIST member of the committee shall serve UP TO A MAXIMUM OF TWO TERMS ~~for a term~~ of four years; MEMBER'S TERMS SHALL BE STAGGERED ~~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 terms.~~ 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.~~ A PSYCHIATRIST OR A LICENSED MENTAL HEALTH PROVIDER. 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.

The terms of the members of the Rehabilitation Evaluation Committee should be extended to two four-year terms, as it requires significant time to educate new persons to participate fully. In addition, it is recommended that a psychiatrist or licensed mental health professional replace the director of the program provided by the pharmacy peer health assistance organization.

Technical Changes to the Pharmacy Law

The current Act has provisions that are ambiguous, unclear and outdated and has been amended several times since its enactment. Technical changes are necessary to improve and update the Act.

In recognition of the many recent changes in the practice of pharmacy, the National Association of Boards of Pharmacy has developed a Model Act for Boards of Pharmacy (Model Act). Though the statute has been amended slightly over the years, it has not kept pace with changes in the practice of pharmacy. The Model Act is designed to address changes in the practice of pharmacy. The public should have the benefit of statutes that are current with professional practices. Many of the recommendations that follow are premised on the Model Act while others are statutory changes to enhance and clarify the responsibility of the Board.

Due to the large number of additions and statutory clean-up recommendations, the following recommendations have been made in the order of the current statute for easier identification.

Recommendation 10 - Amend specific definitions in section 12-22-102, C.R.S., and make conforming amendments throughout the Drugs and Druggists Act to read as follow:

12-22-102(1) ~~"Administration" means the giving of medication to a patient by a pharmacist qualified to administer drugs by authorization of a physician.~~ "ADMINISTER" MEANS THE DIRECT APPLICATION OF A DRUG TO THE BODY OF A PATIENT OR RESEARCH SUBJECT BY INJECTION, INHALATION, INGESTION, OR ANY OTHER MEANS.

Subsection one is deleted and language from the Model Act was inserted. The definition currently in law does not specifically define what is meant by administration. This recommended language adds needed specificity to the definition.

12-22-102(5) "Casual sale" means a ~~sale~~ TRANSFER, DELIVERY OR DISTRIBUTION to a corporation, individual, or other entity, other than a consumer, entitled to possess prescription drugs; except that the amount of drugs TRANSFERRED, DELIVERED OR DISTRIBUTED ~~sold~~ in such manner by any registered prescription drug outlet or hospital other outlet shall not exceed five percent of the total ~~amount of drugs sold annually~~ NUMBER OF DOSAGE UNITS OF DRUGS DISPENSED AND DISTRIBUTED ON AN ANNUAL BASIS by such outlet.

The recommended changes in this section alter the definition of a casual sale to encompass not only sales but also transfers of any nature. As the section now reads, entities would be able to transfer large quantities of drugs without compliance with regulatory standards if no money was exchanged. This is not in the best interest of the public. In general, in order to track the distribution of drugs and the providers that exchange them, normal regulatory constraints should apply. The intent of casual sale is to allow for small transfers without extensive restriction. Once a transfer becomes a certain size it should meet compliance standards. In addition, current statutory language is ambiguous regarding the amounts of drugs that can be transferred in a casual sale. It is difficult for inspectors to clearly advise facilities due to this ambiguity.

12-22-102(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.~~ "COMPOUNDING" MEANS THE PREPARATION, MIXING, ASSEMBLING, PACKAGING, OR LABELING OF A DRUG OR DEVICE (i) AS THE RESULT OF A PRACTITIONER'S PRESCRIPTION DRUG ORDER OR CHART ORDER OR INITIATIVE BASED ON THE PRACTITIONER / PATIENT / PHARMACIST RELATIONSHIP IN THE COURSE OF PROFESSIONAL PRACTICE, OR (ii) FOR THE PURPOSE OF, OR AS AN INCIDENT TO, RESEARCH, TEACHING, OR CHEMICAL ANALYSIS AND NOT FOR SALE OR DISPENSING. COMPOUNDING ALSO INCLUDES THE PREPARATION OF DRUGS OR DEVICES IN ANTICIPATION OF PRESCRIPTION DRUG ORDERS BASED ON ROUTINE, REGULARLY, OBSERVED PRESCRIBING PATTERNS.

The language defining "compound" should be deleted and more specific language from the Model Act defining "compounding" inserted for further clarification.

12-22-102(7) "Delivery" means the actual, constructive, or attempted transfer OF A DRUG OR DEVICE from one person to another ~~of a drug or device~~, whether or not ~~there is an agency relationship~~ FOR A CONSIDERATION.

The language defining "delivery" should be amended and language from the Model Act inserted for further clarification.

12-22-102(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:~~ IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, OR OTHER SIMILAR OR RELATED ARTICLE, INCLUDING ANY COMPONENT PART OR ACCESSORY, WHICH IS REQUIRED UNDER FEDERAL LAW TO BEAR THE LABEL, "CAUTION: FEDERAL LAW REQUIRES DISPENSING BY OR ON THE ORDER OF A PHYSICIAN."

- ~~(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~~

The language defining "device" should be deleted, and language from the Model Act inserted for further clarification

12-22-102(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.~~ THE INTERPRETATION, EVALUATION, AND IMPLEMENTATION OF A PRESCRIPTION DRUG ORDER OR CHART ORDER, INCLUDING THE PREPARATION OF A DRUG OR DEVICE TO A PATIENT OR PATIENT’S AGENT IN A SUITABLE CONTAINER APPROPRIATELY LABELED FOR SUBSEQUENT ADMINISTRATION TO OR USE BY A PATIENT.

12-22-102(10) "Distribution" means the ~~delivery~~ TRANSFER of a drug or device other than by administering or dispensing.

The language defining “dispense” should be deleted, and language from the Model Act inserted for further clarification.

The use of the word delivery in this section confuses the definition of “distribution,” as the word “delivery” is already specifically defined in statute. Transfer is not currently defined and has a generally accepted meaning.

12-22-102(11.5) “FILL” MEANS TO PREPARE A DRUG OR DEVICE PURSUANT TO A LAWFUL 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 ORDER.

The word “fill” is used regularly throughout the profession by laypersons and pharmacists. This new definition of “fill” is the same as the current definition of dispense.

~~12-22-102(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.~~

This language from the federal Food, Drug and Cosmetic Act is antiquated and no longer necessary. The addictive properties of drugs are addressed in the Uniform Controlled Substances Act pursuant to section 18-18-101, et seq, C.R.S.

12-22-102(16.5) "Location" means the physical confines of an individual building ~~or at the same address.~~

Pharmacies are registered according to their locations. As the Act currently exists, a complex could have several phar in several buildings and register only one of those entities as a pharmacy if all the buildings in the complex had the same address. This situation places the public at risk, as the other buildings would not be inspected nor monitored for compliance with pharmacy regulations.

For example, without notifying the Board, a registered outlet (pharmacy) opened a satellite facility in a different building on its campus. During an inspection of the primary facility, the inspector was informed that one of the pharmacists was working in the "satellite" outlet. The registrant had one address but more than one facility on the campus. The registrant operated an outlet for years without the Board knowing of its existence and, consequently, it was never inspected.

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12-22-102(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 COMPOUNDING AND dispensing of a prescription drug pursuant to a prescription order.

This section is incomplete without the language concerning compounding. The responsibility for compounding lies with the licensed pharmacist, not the manufacturer, and is currently included in the definition of the "practice of pharmacy."

12-22-102(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).~~ A DRUG WHICH MAYBE SOLD WITHOUT A PRESCRIPTION AND WHICH IS LABELED FOR USE BY THE CONSUMER IN ACCORDANCE WITH THE REQUIREMENTS OF THE LAWS AND RULES OF THIS STATE AND THE FEDERAL GOVERNMENT.

The Model Act definition of "nonprescription drug" is concise and adds clarity to the current statutory definition. The current definition is so complex that it takes an inordinate amount of time to establish that the definition had been met at an administrative law hearing.

12-22-102(22) "Official compendia" means the official United States Pharmacopeia, NATIONAL FORMULARY, HOMEOPATHIC PHARMACOPOEIA OF THE UNITED STATES or any supplements thereto.

This recommendation conforms the definition of "official compendia" to the definition of "drug" found in section 12-22-102(11)(a)(I),C.R.S.

12-22-102(22.5) "Order" means:

(a) A prescription order which is any order, other than a chart order, authorizing the dispensing of a single drug or device that is written, mechanically produced, computer generated and signed by the practitioner, transmitted electronically or by facsimile, or by other means of communication by a practitioner TO A LICENSED PHARMACY and which includes the name or identification of the patient, the date, and sufficient information for compounding, dispensing, and labeling; or

The word "single" as used here is not comprehensive, as sometimes physicians write more than one order on each prescription.

12-22-102(23) "OTHER Outlet" means any ~~prescription drug outlet,~~ hospital THAT DOES NOT OPERATE A REGISTERED PHARMACY, ~~institution, nursing home,~~ rural health clinic, ~~convalescent home, extended care facility,~~ family planning clinic, ~~wholesaler, manufacturer, or mail order vendor, other than a pharmacist,~~ SCHOOL, JAIL, COUNTY HEALTH DEPARTMENT, COMMUNITY HEALTH CLINIC, UNIVERSITY AND/OR COLLEGE that has facilities in this state registered pursuant to this article and that engages in the

COMPOUNDING, dispensing, AND delivery, ~~distribution, manufacturing, wholesaling, or sale~~ of drugs or devices.

This section as currently written has caused numerous problems for the Board. The meaning of the word “institutions” has been unclear. The definition encompasses a number of facilities that are not similar, have little in common in the regulatory scheme for pharmacies, and cannot be generalized. This recommendation suggests using the term “other outlets” and redefining it to include only those types of facilities referred to in this Subsection (23). Manufacture is defined in Subsection (17), wholesaler in Subsection (34), and prescription drug outlets are defined in Subsection (30.2). The Board has no jurisdiction over nursing homes; therefore, references to them should be deleted, as should references to similar facilities over which the Board has no jurisdiction. Defining “other outlets” separately would clarify those entities that must meet the regulatory criteria for “other outlets.”

12-22-102(24.2) “PHARMACY TECHNICIAN” MEANS AN UNLICENSED PERSON WHO PERFORMS THOSE FUNCTIONS SET FORTH IN PARAGRAPH (b) OF SUBSECTION (26) OF THIS SECTION UNDER THE SUPERVISION OF A PHARMACIST.

Amend the remainder of Article 22 to conform with this recommendation by deleting all references to “unlicensed assistant” and replacing it with “pharmacy technician.”

Effective July 1, 2002, the term “unlicensed assistant” pursuant to section 12-22-102(33.5), C.R.S., was repealed along with other responsibilities of the pharmacy manager. Previously, section 12-22-102(33.5)(a), C.R.S., stated "Unlicensed assistant means an unlicensed person who performs those functions set forth in paragraph (b) of subsection (26) of this section under the supervision of a pharmacist. A pharmacist manager of a prescription drug outlet employing an unlicensed assistant shall file with the board the name and date of birth of each unlicensed assistant who is employed by the outlet."

However, the term “unlicensed assistant” still exists in other parts of the statute and should be defined. The term “pharmacy technician” is generally used in this industry and more aptly describes the position of unlicensed assistant.

12-22-102(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 provision of pharmaceutical care including patient counseling and prospective drug review, drug and drug-related research not including prescriptive authority, 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 these health services, operations, or transactions necessary in the conduct, operation, and control of a prescription drug outlet by a pharmacist~~ THE INTERPRETATION, EVALUATION, IMPLEMENTATION AND THE DISPENSING OF ORDERS; PARTICIPATION IN DRUG AND DEVICE SELECTION, DRUG ADMINISTRATION, DRUG REGIMEN REVIEWS, AND DRUG OR DRUG-RELATED RESEARCH; PROVISION OF PATIENT COUNSELING AND THE PROVISION OF THOSE ACTS OR SERVICES NECESSARY TO PROVIDE PHARMACEUTICAL CARE IN ALL AREAS OF PATIENT CARE; AND

(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;~~ THE PREPARATION, MIXING, ASSEMBLING, PACKAGING, OR LABELING OR DELIVERY OF A DRUG OR DEVICE, PROPER AND SAFE STORAGE OF DRUGS AND DEVICES, AND MAINTENANCE OF PROPER RECORDS FOR THEM.

The language defining “dispense” should be deleted, and language from the Model Act inserted for further clarification.

12-22-102(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 “Rx ONLY” OR "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

“Rx Only” language should be added to comply with federal law.

12-22-102(30.2) "Prescription drug outlet" means any PHARMACY outlet registered pursuant to this article where prescriptions are ~~filled or~~ compounded, and ~~are sold,~~ dispensed, ~~offered, or displayed.~~

The word “pharmacy” should be added to this definition since it is the most generally accepted term used in the profession and by laypersons. There is confusion concerning the use of the term “prescription drug outlet.” The other recommended changes in this subsection are for greater specificity and to delete unnecessary terms.

12-22-102(30.3) "Refill" means the COMPOUNDING AND dispensing of any drug ~~by a practitioner~~ pursuant to a previously executed order.

The amended definition clarifies the process of refilling a prescription.

12-22-102(32.6) "Supervision" means that a licensed pharmacist is on the location and ~~immediately and~~ readily available to consult with and assist unlicensed personnel performing tasks described in subsection (26) (b) of this section.

“Immediately” was deleted because the reality of practice is that the supervising pharmacist is “readily available,” not necessarily immediately, but within a reasonable time.

12-22-102(34) "Wholesaler" means a corporation, individual, or other entity with facilities in this state which buys drugs or devices for resale ~~and OR distribution~~ DISTRIBUTES to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers.

The definition of wholesaler should include any type of transfer of drugs or devices. Therefore, “and” is replaced by “or.”

Recommendation 11 - Amend the powers and duties of the Board for greater clarification. Amend section 12-22-110, C.R.S., to read as follows:

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Several changes are recommended for this section of the Act referencing the powers and duties of the Board. The Board's powers have not been clearly and concisely defined throughout, therefore, the following recommendations add greater clarification to the Act.

12-22-110(1)(e) Administer examinations AND DETERMINE THE QUALIFICATIONS AND FITNESS OF ~~to~~ applicants for licensure;

12-22-110(1)(f) Keep a record of all licenses, ~~and~~ registrations, AND RENEWALS FOR A REASONABLE PERIOD OF TIME, AND ~~of all license and registration renewals~~, A RECORD OF ALL suspensions, ~~and~~ revocations, AND ANY OTHER DISCIPLINE and A RECORD of its own proceedings;

12-22-110(1)(h) MAKE INVESTIGATIONS, HOLD HEARINGS, AND TAKE EVIDENCE IN ALL MATTERS RELATING TO THE EXERCISE AND PERFORMANCE OF THE POWERS AND DUTIES VESTED IN THE BOARD AND, IN CONNECTION WITH ANY INVESTIGATION, SUBPOENA WITNESSES, ADMINISTER OATHS, AND COMPEL THE TESTIMONY OF WITNESSES AND THE PRODUCTION OF BOOKS, PAPERS, AND RECORDS RELEVANT TO ANY SUCH INVESTIGATION OR HEARING. ANY SUBPOENA ISSUED PURSUANT TO THIS ARTICLE SHALL BE ENFORCEABLE BY THE DISTRICT COURT.

The recommended language in sections 12-22-110(1)(e) - (h), C.R.S., is modeled from language existing in other board statutes. Although these powers are probably implied, they are not guaranteed without specific language.

12-22-110(4)(a) Whenever a duly authorized agent of the board finds or has probable cause to believe that in any REGISTERED OUTLET ~~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.

This recommendation expands the Board's embargo power to other facilities beyond prescription drug outlets.

The editor's note that was added to this section relates to the legalities applicable to statutory adoption. This information is unnecessary in this Act.

Recommendation 12 - Allow research companies to be exempt from the Act. Amend section 12-22-116.5, C.R.S., to read as follows:

12-22-116.5. Exemption from licensure - hospital residency programs – home renal dialysis – RESEARCH COMPANIES. (1) 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.

12-22-116.5(3) A MANUFACTURER WHICH MUST OBTAIN A PRESCRIPTION DRUG OR DEVICE SOLELY FOR USE IN ITS RESEARCH, DEVELOPMENT AND/OR TESTING PROCEDURES AND WHICH DOES NOT FURTHER DISTRIBUTE THE DRUG OR DEVICE MAY APPLY TO THE BOARD FOR A WAIVER OF REGISTRATION UNDER THIS ARTICLE. THE BOARD MAY GRANT SUCH A WAIVER PROVIDED THAT THE MANUFACTURER SUBMITS TO THE BOARD THE NAME OF THE DRUG OR DEVICE IT REQUIRES AND A SWORN AFFIDAVIT CERTIFYING THAT THE DRUG OR DEVICE WILL ONLY BE USED FOR NECESSARY RESEARCH, DEVELOPMENT AND/OR TESTING PROCEDURES AND WILL NOT BE FURTHER DISTRIBUTED. THIS WAIVER SHALL NOT APPLY TO ANY CONTROLLED SUBSTANCE AS DEFINED IN STATE OR FEDERAL LAW.

Occasionally a manufacturer needs a prescription drug for internal use in research, development, manufacturing and/or testing of a product. A typical example might be the need for sterile water for cleaning or calibration of equipment. The manufacturer does not qualify for registration in any category listed in section 12-22 120, C.R.S., because it does not produce or sell prescription drugs. Without a registration, wholesale suppliers of prescription drugs are prohibited from distributing to the manufacturer. This recommendation would create an avenue for the Board to grant an exemption for such situation, so the manufacturer would be permitted to obtain the needed product.

Recommendation 13 - Update and revise responsibilities of pharmacy managers of prescription drug outlets. Amend section 12-22-119(1)(b), C.R.S., to read as follows:

12-22-119(1)(b) 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 owner shall close the prescription drug outlet unless such owner has employed a pharmacist, and, within FOURTEEN (14) ~~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.

Currently, an owner of a prescription drug outlet has only seven days in which to make an application to transfer the registration to a new manager when the previous one has left that position. This time period is unduly short and an increase to a 14-day period is recommended.

Recommendation 14 - Amend the frequency of registration for outlets. Amend section 12-22-120(1) to read as follows:

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

It is an administrative burden for the agency to be required to renew businesses every year. All other licensees and registrants are on a biennial schedule. For administrative efficiency, the agency would like to renew pharmacists one year and businesses the next year.

Recommendation 15 - Clarify language to allow the transfer of facility registrations. Amend section 12-22-120(4), C.R.S., to read as follows:

12-22-120(4) Registrations issued by the board pursuant to this section are ~~not~~ transferable or assignable ONLY PURSUANT TO THIS ARTICLE AND BOARD REGULATIONS.

There are several provisions in the statute that address the transfer of ownership of a pharmacy. The provisions of section 12-22-114(1)(g),(h) & (m), C.R.S., regarding fees for transferring a prescription drug outlet and section 12-22-119(2), C.R.S., regarding application for the transfer of ownership of a prescription drug outlet conflict with the provisions of section 12-22-124, C.R.S. As currently written, this section precludes any transfer of facility registrations. This is not the current practice of the Board or the intent of the Act.

Recommendation 16 - Clarify the authority to transfer products between affiliated other outlets. Amend sections 12-22-121(2), (3) and (5), C.R.S., to read as follows:

12-22-121(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 OTHER OUTLET, or he may give or sell any drug to any practitioner authorized by law to prescribe the same.

12-22-121(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 OTHER OUTLET, or to any practitioner authorized by law to prescribe the same.

12-22-121(5)(b) IN THE CASE OF A COUNTY HEALTH DEPARTMENT WHICH OPERATES REGISTERED OTHER OUTLETS, ONE REGISTERED OTHER OUTLET MAY MAKE A CASUAL SALE OF A DRUG TO ANOTHER REGISTERED OUTLET PROVIDED THAT (I) THE DRUG IS SOLD IN THE ORIGINAL SEALED CONTAINER IN WHICH IT WAS ORIGINALLY RECEIVED FROM THE WHOLESALER; (II) NO SUCH CASUAL SALE IS MADE TO ANY REGISTERED OUTLET THAT IS NOT OWNED AND/OR OPERATED BY THAT COUNTY HEALTH DEPARTMENT; AND (III) THE AMOUNT SOLD DOES NOT EXCEED THE FIVE PERCENT LIMIT ESTABLISHED BY SECTION 12-22-102(5), C.R.S.

During an Other Outlet Task Force meeting, it was proposed that such transfers would be helpful when one outlet has an excess of drugs and another outlet needs additional drugs. Rather than wasting the excess drugs, they could be transferred to where they are needed. There is still the five percent limitation on total amount as expressed in section 12-22-102(5), C.R.S., that defines “casual sale.”

Currently, some of the larger county health departments already register as wholesalers if they wish to purchase drugs in bulk and distribute them to their satellite “other outlets.” Re-packaging, however is not allowed, unless they comply with federal regulations. The recommended change is proposed to reduce the red tape involved for government entities when carrying out their public responsibilities.

Subsections (2) and (3) are revised to incorporate “other outlets” into their language.

Recommendation 17 - Clarify the pharmacist’s authority to refill a prescription order. Amend section 12-22-122(2), C.R.S., to read as follows:

12-22-122(2) A pharmacist may refill a prescription order for any prescription drug EXCLUDING CONTROLLED SUBSTANCES 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).

Subsection (2) needs to be clarified to conform to federal law. The pharmacist's authority to refill a prescription when the prescriber cannot be reached is limited to prescriptions for non-controlled substances only.

Recommendation 18 – Replace the word “pharmacist” with the word “prescription drug.” Amend section 12-22-130(1)(b), C.R.S., to read as follows:

12-22-130(1)(b) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident prescription drug outlet shall maintain at all times a valid, unexpired license, permit, or registration to conduct the ~~pharmacist~~ PRESCRIPTION DRUG outlet in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident prescription drug outlet shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

This recommendation conforms to Recommendation 2 on page 53 that revises the definition of “prescription drug outlet” in section 12-22-102(30.2), C.R.S.