Department of Regulatory Agencies

Office of Policy, Research and Regulatory Reform

2011 Sunset Review:
Colorado State Board of Pharmacy

October 14, 2011

Consumer Protection

Department of Regulatory Agencies

Executive Director's Office
Barbara J. Kelley
Executive Director

John W. Hickenlooper
Governor

October 14, 2011

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 mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed the evaluation of the Colorado 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 2012 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 Division of Registrations and staff in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Barbara J. Kelley
Executive Director

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Summary

What Is Regulated?
The Pharmaceuticals and Pharmacists Act (Act) provides regulatory oversight for pharmacists, pharmacy interns and pharmacy businesses (prescription drug outlets, wholesalers, manufacturers, "other outlets" and limited licenses).

Why Is It Regulated?
The purpose of the Act is to provide for the protection of the consuming public with respect to prescription drugs, including controlled substances.

Who Is Regulated?
In fiscal year 09-10, there were 6,468 licensed pharmacists and 979 licensed pharmacy interns. There were also 1,365 prescription drug outlets, 748 wholesalers, 23 manufacturers, 211 "other outlets" and 45 limited licenses.

How Is It Regulated?
The Act is enforced by the Colorado State Board of Pharmacy (Board). The Board is a Type 1 policy autonomous board with the authority to impose discipline on licensees and registrants, promulgate rules and establish policy.

What Does It Cost?
In fiscal year 09-10, the total expenditures for the oversight of the pharmacists, pharmacy interns and pharmacy businesses were $1,011,688. There were 5.75 full-time equivalent employees associated with this regulatory oversight.

What Disciplinary Activity Is There?
In fiscal year 09-10, there were 158 disciplinary actions imposed on licensees and registrants. The types of discipline utilized by the Board varied, but included: revocations, suspensions, stipulations and letters of admonition. Also, the Board is authorized to impose fines on registrants, and in fiscal year 09-10, the Board issued 69 fines, totaling $473,822.

Where Do I Get the Full Report?
The full sunset review can be found on the internet at: www.dora.state.co.us/opr/oprpublications.htm.

Key Recommendations

Continue the Colorado State Board of Pharmacy for nine years, until 2021.
The purpose of the Act is to ensure consumer protection regarding prescription drugs, including controlled substances. This sunset review revealed that the overall regulatory oversight of pharmacists, pharmacy interns and pharmacy businesses was functioning well and provided the appropriate level of protection to consumers. Specifically, the most common complaint filed against practitioners was for dispensing errors. A dispensing error occurs when a licensed pharmacist has given the final interpretation of the prescription order, counseled the patient and the order is dispensed to the consumer and the medication received 1) is the incorrect drug, quantity or strength, 2) it is incorrectly labeled (including incorrect directions for use) or 3) dispensing a prescription without conducting a proper drug regimen review. This sunset review also revealed that the Board consistently imposed discipline on licensees for dispensing errors.

Expand the current definition of the "other outlet" registration to allow ambulatory surgery centers and medical clinics operated by hospitals as well as long-term care facilities to register as "other outlets."
Currently, both ambulatory surgery centers (ASCs) and medical clinics operated by hospitals procure prescription drugs and controlled substances by utilizing the individual medical license of a facility's medical director. Drugs procured for ASCs and medical clinics are utilized by every practitioner working in the facility, not only the practitioner who is legally responsible for them. Allowing ASCs and medical clinics to obtain an "other outlet" registration provides greater flexibility to and reduces the compliance burden on the hospital, as well as the prescribing physician. Similarly, the function and role of long-term care facilities are continually changing. More hospital patients are discharged to these facilities, often at times when there is not a pharmacist available. As such, long-term care facilities are utilizing the prescription drugs and controlled substances in emergency kits as a "first dose" for medication. Expanding the definition of "other outlet" to include long-term care facilities would provide greater latitude for facilities to have a larger variety and quantity of drug stock to administer to patients.

Major Contacts Made During This Review

Colorado Department of Regulatory Agencies, Division of Registrations
Colorado Health Care Association
Colorado Hospital Association
Colorado Medical Society
Colorado Pharmacist Society
Colorado Trial Lawyers Association
Drug Enforcement Administration
Mountain Vet Supply
National Association of Boards of Pharmacy
National Association of Chain Drug Stores
Peer Assistance Services
Regis University
University of Colorado

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are Prepared by:
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Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria[1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

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

[1] Criteria may be found at §24-34-104, C.R.S.
[2] § 12-22-116(3.3)(a)(I), C.R.S.
[3] About.com. *Prescription Drugs.* Retrieved June 28, 2011, from

Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review via DORA's website at: www.dora.state.co.us/pls/real/OPR_Review_Comments.Main.

The regulatory functions of the Colorado State Board of Pharmacy (Board) as enumerated in Article 22 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2012, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of the Board pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether Article 22 of Title 12, C.R.S., should be continued for the protection of the public and to evaluate the performance of the Division of Registrations (Division) and staff. During this review, the Division and Board must demonstrate that the regulation serves to protect the public health, safety or welfare, and that the regulation is the least restrictive regulation consistent with protecting the public. DORA's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, DORA staff attended Board meetings, interviewed Board members and Division staff, reviewed Division records and minutes including complaint and disciplinary actions, interviewed officials with state and national professional associations, interviewed pharmacy professionals, reviewed Colorado statutes and Board rules, and reviewed the laws of other states.

Profile of the Profession

The Pharmaceuticals and Pharmacists Act (Act), which is located in section 12-22-101, *et seq.,* C.R.S., provides regulatory oversight for:

- Pharmacists;
- Pharmacy interns; and
- Pharmacy businesses.

Pharmacists

In order to obtain a license to practice as a pharmacist in Colorado, an applicant is required to complete a degree in pharmacy from a school or college of pharmacy approved by the Board.[2] Board-approved schools or colleges of pharmacy are accredited by the American Council of Pharmaceutical Education. Currently, there are two accredited programs in Colorado: the University of Colorado School of Pharmacy and Regis University School of Pharmacy. Both programs offer a Pharm.D., which is a doctorate degree in pharmacy.

An applicant for licensure must also complete a minimum of 1,500 hours of internship experience.

Pharmacists play an important role in the health care community. They work in concert with health care professionals, such as physicians who prescribe medications for patients, to fill prescriptions. Pharmacists work in a variety of settings but most commonly in retail or hospital pharmacies. In this capacity, pharmacists work closely with patients to ensure they receive the proper medication(s).

More specifically, pharmacists are responsible for, among other things, dispensing prescription drugs and controlled substances to individuals. Prescription drugs are medications that can be dispensed to consumers with instructions to a pharmacist from a licensed health care provider, such as a doctor, dentist or nurse practitioner.[3] There are thousands of prescription drugs available to consumers.

Controlled substances are drugs that are subject to the U.S. Controlled Substances Act (1970), which regulates the prescribing and dispensing, as well as the manufacturing, storage, sale or distribution of substances assigned to five levels or "schedules."[4] Drugs are assigned to the five schedules according to their potential for or evidence of abuse; potential for physiologic dependence; contribution to a public health risk; harmful pharmacologic effect; or role as a precursor of other controlled substances.[5] The controlled substances schedules are discussed in further detail in the Legal Framework section of this report.

Further, pharmacists, at times, are called upon to compound ingredients in order to fill a prescription or chart order. Compounding is "the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient."[6]

[2] § 12-22-116(3.3)(a)(I), C.R.S.
[3] About.com. *Prescription Drugs.* Retrieved June 28, 2011, from http://drugs.about.com/od/pdrugandmedicalterms/g/Rx_drug_def.htm
[4] MediLexicon. *Controlled Substance -- Medical Definition.* Retrieved June 28, 2011, from http://www.medilexicon.com/medicaldictionary.php?t=86017
[5] MediLexicon. *Controlled Substance -- Medical Definition.* Retrieved June 28, 2011, from http://www.medilexicon.com/medicaldictionary.php?t=86017
[6] U.S. Food and Drug Administration. *Pharmacy Compounding.* Retrieved June 26, 2011, from http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155168.htm

Pharmacists may "advise their patients, physicians and other health practitioners on the selection, dosages, interactions and side effects of medications, as well as monitor the health and progress of patients" to ensure medications are used safely and effectively.[7]

Some pharmacists specialize in specific drug therapy areas, including, but not limited to:[8]

- Intravenous nutrition support;
- Oncology (cancer);
- Nuclear pharmacy (used for chemotherapy); and
- Psychiatric pharmacy (the use of drugs to treat mental disorders).

In addition to the duties highlighted above, pharmacists may participate in various capacities, including, but not limited to:

- Acting as a pharmacist manager;
- Providing oversight of pharmacy technicians; and
- Providing oversight and training of pharmacy interns (preceptor).

A pharmacist manager is required in prescription drug outlets (e.g., retail pharmacies and hospital pharmacies). Pharmacist managers are charged with a variety of responsibilities, including, but not limited to:[9]

- Ensuring that the operation of the prescription drug outlet is in compliance with all applicable laws;
- Maintaining records of initial interpretation and final evaluations of prescription and chart orders; and
- Ensuring that all prescription drugs and controlled substances are procured from an entity or person registered by the Board.

Pharmacists are also responsible for the oversight of pharmacy technicians. Pharmacy technicians are unlicensed persons who are authorized to perform the following functions:[10]

- The preparation, mixing, assembling, packaging, labeling or delivery of a drug or device;[11]
- Proper and safe storage of drugs or devices; and
- The maintenance of proper records for drugs and devices.

[7] U.S. Bureau of Labor Statistics. *Occupational Outlook Handbook, 2010-11 Edition - Pharmacists.* Retrieved June 13, 2011, from http://data.bls.gov/cgi-bin/print.pl/oco/ocos079.htm
[8] U.S. Bureau of Labor Statistics. *Occupational Outlook Handbook, 2010-11 Edition - Pharmacists.* Retrieved June 13, 2011, from http://data.bls.gov/cgi-bin/print.pl/oco/ocos079.htm
[9] State of Colorado Board of Pharmacy. Rule 7.00.20(l) and Rule 7.00.30(a)(c).
[10] §§ 12-22-102(26)(b)(I-III) and 12-22-102(24.2), C.R.S.
[11] A device is defined in § 12-22-102(8), C.R.S., as an instrument, apparatus, machine, contrivance, implant or similar related article that is required under federal law to bear a label, "Caution: federal law requires dispensing by or on the order of a physician."

The Act enables a pharmacist to supervise up to three unlicensed pharmacy technicians.[12]

> If three pharmacy technicians are on duty, at least one is required to be certified by a nationally recognized certification board, possess a degree from an accredited pharmacy technician program or have completed 500 hours of experiential training.[13]

Further, a pharmacist may function as a preceptor for pharmacy interns. A preceptor serves as an authorized licensee, once approved by the Board, to train pharmacy interns to practice within the pharmacy laws, rules and regulations.[14]

In order to obtain approval from the Board to function as a preceptor and ultimately supervise and train pharmacy interns, a pharmacist must meet the following requirements, including, but not limited to:[15]

- Been licensed and in the practice of pharmacy for at least two years immediately prior to his or her application to the Board for approval as a preceptor; and
- Not received any formal discipline by the Board, other than letters of admonition, or been found guilty by a court in the previous five years.

Once the documentation is approved by the Board, a pharmacist is approved to function as a preceptor and cannot train more than two pharmacy interns at the same time.[16]

The duties of pharmacists continue to evolve and, to a certain extent, expand. For example, pharmacists are now permitted, with the proper training and qualifications, to provide immunizations, such as influenza immunizations, to consumers.

Pharmacy Interns

Pharmacy interns are authorized to practice all aspects of pharmacy, including receiving and reducing to writing, oral prescription orders under the direct supervision of a pharmacist.[17]

In order to be eligible for licensure as a pharmacist, pharmacy interns are required to obtain a minimum of 1,500 hours experience practicing pharmacy. The intern hours may be obtained by participation in a rotation program conducted by an accredited school or college of pharmacy.[18] Also, pharmacy interns may obtain intern hours independently, while under the supervision of a licensed pharmacist.

[12] § 12-22-121.7(2)(a), C.R.S.
[13] § 12-22-121.7(2)(a), C.R.S.
[14] State of Colorado Board of Pharmacy. Rule 4.00.20.
[15] State of Colorado Board of Pharmacy. Rule 4.00.20(a)(b).
[16] State of Colorado Board of Pharmacy. Rule 4.00.20(e).
[17] § 12-22-121(15), C.R.S., and State of Colorado Board of Pharmacy Rule 2.00.10(a).
[18] State of Colorado Board of Pharmacy. Rule 4.00.10(a)(1).

Up to 30 percent of the 1,500 internship hours may be obtained with a drug manufacturer or with a school or college of pharmacy in drug or drug-related research activities.[19]

Preceptors are required to complete an evaluation of pharmacy interns to evaluate the areas of training and performance.[20]

Pharmacy Businesses

The Board registers and licenses pharmacy businesses, both in-state and out-of-state, including:

- Prescription drug outlets (PDOs);
- Wholesale distributors of prescription drugs;
- Manufacturers of prescription drugs;
- Other outlets; and
- Limited licenses.

In-state pharmacy businesses are required to maintain records of their inventory and receipt of drugs (including controlled substances) as well as prescription and chart orders. In other words, each time a registrant receives drugs from a registered source, and when a prescription or chart order is filled, the pharmacy must keep a record of the completed transaction(s). This requirement assists in effectively tracking drugs that are coming into a pharmacy as well as the drugs that are being dispensed through a prescription or chart order. Pharmacy businesses must retain these records for a minimum of two years.

In-State and Out-of-State Prescription Drug Outlets

PDOs are pharmacies where prescriptions are compounded and dispensed.[21] Whether the prescription drug outlet is located in a retail or hospital setting, or if it is a specialty pharmacy, such as one devoted to dispensing sterile parenteral products, these facilities are required to obtain a registration from the Board.[22]

Non-resident prescription drug outlet pharmacies (OSPs) are required to obtain a registration from the Board prior to shipping prescription drugs into Colorado. OSPs must provide to the Board official verification of the current pharmacy license or registration issued by the board of pharmacy in the state where the pharmacy is located.[23] OSPs must also provide to the Board a copy of the most recent report of inspection conducted by the state where the pharmacy is located.[24]

[19] State of Colorado Board of Pharmacy. Rule 4.00.10(a)(2).
[20] § 12-22-111(4), C.R.S.
[21] § 12-22-102(30.2), C.R.S.
[22] DORA Board of Pharmacy. *Prescription Drug Outlet – Pharmacy (PDO).* Retrieved February 2, 2011, from http://www.dora.state.co.us/pharmacy/bus/PDO.htm
[23] DORA Board of Pharmacy. *Non-Resident (Out-of-State) Prescription Drug Outlet – Pharmacy (OSP).* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/OSP.htm
[24] DORA Board of Pharmacy. *Non-Resident (Out-of-State) Prescription Drug Outlet – Pharmacy (OSP).* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/OSP.htm

In-State and Out-of-State Wholesale Distributors of Prescription Drugs

A wholesale distributor of prescription drugs (wholesaler), which can either be a person or entity, must be registered by the Board.[25] Wholesalers include, but are not limited to:

- Repackagers;
- Warehouses;
- Authorized distributers of record;
- Drug wholesalers or distributors;
- Specialty wholesale distributors;
- Pharmacy buying cooperative warehouses;
- Retail pharmacies that conduct wholesale distribution; and
- Chain company warehouses.

Out-of-state wholesalers are, obviously, located outside of Colorado and engage in the distribution of drugs. In order to engage in the distribution of drugs in Colorado, out-of-state wholesalers must provide proof that they are registered and in good standing with their resident board of pharmacy and obtain a registration from the Board.

Manufacturers of Prescription Drugs

A manufacturer that has a facility in Colorado is required to possess a registration from the Board if it manufactures any prescription drug in this state.[26] As long as a registered manufacturer only distributes to its authorized distributor of record,[27] the manufacturer is not required to register as a wholesaler as well.

Other Outlets

"Other outlet" registrations were created to provide oversight for prescription drugs that are dispensed to patients within a facility, such as a jail, but do not have the volume of prescriptions or chart orders of PDOs, as well as walk-in patients in rural health and family planning clinics and public health departments.

In order to ensure that drugs within a facility that has an "other outlet" registration are dispensed properly, the facility must have a licensed pharmacist make an initial interpretation of all prescriptions dispensed or a consultant pharmacist must provide written Board–approved protocols for the dispensing of drugs by non-pharmacists.[28]

[25] DORA Board of Pharmacy. *Wholesale Distributors of Prescription Drugs.* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/wholesalers.htm
[26] DORA Board of Pharmacy. *In-State Manufacturers of Prescription Drugs (MFR).* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/manufacturers.htm
[27] Authorized distributor of record is defined in § 12-22-801(1)(b), C.R.S., as a wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.
[28] DORA Board of Pharmacy. *Other Outlet.* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/otheroutlet.htm

Protocols must establish the following:[29]

- A system of recordkeeping to document the procurement, administration, compounding, dispensing and/or distribution of all prescription drugs and devices;
- A system to ensure that no drug or device is dispensed that will be outdated prior to utilization by the consumer, based on the practitioner's directions for use;
- A system by which drugs are dispensed in compliance with the labeling, drug identification and container requirements; and
- The duties of the consulting pharmacist.

If a consultant is utilized by a facility with an "other outlet" registration, the consultant pharmacist must also perform inspections to ensure compliance with the Board-approved protocols.[30]

Limited Licenses

Limited licenses are issued to non-profit humane societies and government-operated animal control agencies. The limited license enables these facilities to obtain a registration with the Drug Enforcement Administration to obtain sodium pentobarbital in combination with other prescription drugs for the purpose of euthanizing animals, for chemical capture, or for immobilizing animals prior to euthanasia.[31]

[29] State of Colorado Board of Pharmacy. Rule 14.00.20(a-d).
[30] DORA Board of Pharmacy. *Other Outlet.* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/otheroutlet.htm
[31] DORA Board of Pharmacy. *Limited License.* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/limitedlicense.htm

Legal Framework

History of Regulation

In Colorado, the practice of pharmacy has been regulated since 1887. In 1887, the General Assembly created the Colorado Board of Pharmacy (Board). The initial Board consisted of pharmacists who had a minimum of 10 years of experience practicing pharmacy.

In an attempt to provide enhanced protection to consumers, the regulation of the pharmacy profession has continually evolved. Beginning in the mid-1980s, the Board has gone through numerous sunset reviews. In fact, sunset reviews of the Board were completed in 1985, 1995 and 2002.

The 1985 sunset review recommended persons take and pass a jurisprudence examination prior to being eligible for licensure. Also, the 1985 sunset review recommended clarifying that registered prescription drug outlets (PDOs) were permitted to purchase controlled substances from other registered PDOs. During the 1986 legislative session, the General Assembly passed the recommendations highlighted above.

The Board again underwent a sunset review in 1995. A notable recommendation from the 1995 sunset review was to allow the Board to issue confidential letters of concern when, upon completion of an investigation of a practitioner, it was revealed that although the practices may not be violations of the statute or applicable rules, those practices could lead to future violations. The General Assembly passed the recommendation in the 1996 legislative session.

The 2002 sunset review also contained recommended changes to the Board's regulatory authority. Specifically, one of the recommendations granted the Board fining authority over registrants. In 2003, the General Assembly passed the recommendation.

Federal Laws

Federal Controlled Substances Act

The federal Controlled Substances Act (CSA), which is Title 21, Chapter 13 of the United States Code, prohibits unauthorized manufacturing, distributing or dispensing of controlled substances.[32] There are five levels or "schedules" of controlled substances – I through V. Schedules II through V are permitted to be dispensed to consumers, through a prescription or chart order, as long as the prescriber has obtained a Drug Enforcement Administration registration.

[32] DEA Get Smart About Drugs. *Federal Controlled Substances Act.* Retrieved June 26, 2011, from http://www.getsmartaboutdrugs.com/identify/federal_controlled_substances_act.html

Schedule 1

Schedule I substances have a high potential for abuse and have no currently accepted medical use for treatment.[33] Examples of schedule I controlled substances are: heroin, lysergic acid diethylamide (LSD) and peyote.[34]

Since schedule I controlled substances do not have an accepted medical use in treatment, they cannot be prescribed, administered or dispensed to consumers.

Schedule II

Schedule II controlled substances have a high potential for abuse which may lead to severe psychological or physical dependence.[35] Examples of schedule II controlled substances are: oxycodone (OxyContin), methadone and fentanyl.

Schedule III

Schedule III controlled substances have a potential for abuse, although the potential is lower than schedule II controlled substances, and abuse may lead to moderate or low physical dependence or high psychological dependence.[36] Schedule III controlled substances may include combinations of codeine with aspirin or acetaminophen.[37]

Schedule IV

Schedule IV controlled substances have a low potential for abuse, and examples of schedule IV controlled substances include: Xanax, Valium and Ativan.[38]

Schedule V

Schedule V controlled substances have the lowest potential for abuse and consist primarily of preparations containing limited quantities of certain narcotics.[39] Examples include cough preparations containing not more than 200 milligrams codeine per 100 milliliters or per 100 grams.[40]

[33] U.S. Department of Justice. *Definition of Controlled Substance Schedules.* Retrieved June 26, 2011, from http://www.deadiversion.usdoj.gov/schedules/index.html
[34] U.S. Department of Justice. *Definition of Controlled Substance Schedules.* Retrieved June 26, 2011, from http://www.deadiversion.usdoj.gov/schedules/index.html
[35] U.S. Department of Justice. *Definition of Controlled Substance Schedules.* Retrieved June 26, 2011, from http://www.deadiversion.usdoj.gov/schedules/index.html
[36] U.S. Department of Justice. *Definition of Controlled Substance Schedules.* Retrieved June 26, 2011, from http://www.deadiversion.usdoj.gov/schedules/index.html
[37] U.S.Legal.com. *Controlled Substances Law & Legal Definition.* Retrieved June 28, 2011, from http://definitions.uslegal.com/c/controlled-substances/
[38] U.S. Department of Justice. *Definition of Controlled Substance Schedules.* Retrieved June 26, 2011, from http://www.deadiversion.usdoj.gov/schedules/index.html
[39] U.S. Department of Justice. *Definition of Controlled Substance Schedules.* Retrieved June 26, 2011, from http://www.deadiversion.usdoj.gov/schedules/index.html
[40] U.S. Department of Justice. *Definition of Controlled Substance Schedules.* Retrieved June 26, 2011, from http://www.deadiversion.usdoj.gov/schedules/index.html

Food, Drug and Cosmetic Act

The Food, Drug and Cosmetic Act, among other things, clarifies that the role and responsibility regarding regulatory oversight of compounding of drugs resides with the individual states.

State Law

The Pharmaceuticals and Pharmacists Act (Act) is created in section 12-22-101, *et seq.,* Colorado Revised Statutes, and contains five parts. The Act highlights the general provisions (Part 1), including composition and responsibilities of the Board and licensing requirements as well as the regulatory oversight of controlled substances (Part 3), peer health assistance diversion program (Part 6), prescription drug monitoring program (Part 7), which is not included in this sunset review because it is reviewed as a stand-alone review, and wholesalers (Part 8).

Part 1

The Board is a policy autonomous board, with the authority to, among other duties, formally discipline licensees and registrants and promulgate rules, when necessary.

The Board is comprised of seven members – five professional members and two public members. All Board members are appointed by the Governor.[41]

Five of the Board members are required to be licensed pharmacists with a minimum of five years of experience as a practicing pharmacist in Colorado.[42]

In order to serve as a public member on the Board, an individual cannot have a financial interest in the practice of pharmacy.[43]

The Board is required to meet at least once every four months,[44] and all Board meetings and hearings must be open to the public except that the Board may conduct any portion of its meetings in executive session, which is closed to the public.[45]

[41] § 12-22-104(2), C.R.S.
[42] § 12-22-104(1), C.R.S.
[43] § 12-22-104(1), C.R.S.
[44] § 12-22-107, C.R.S.
[45] § 12-22-107, C.R.S.

The Board has a variety of powers and duties, including, but not limited to:[46]

- Investigative authority to inspect all outlets regulated by the State of Colorado related to pharmacies;
- Administer examinations to determine the qualifications and fitness of applicants for licensure;
- Fine registrants for violations of the Act or rules (a minimum of $500 and a maximum of $5,000 per violation); and
- Make investigations, hold hearings and take evidence in all matters relating to the exercise and performance of the powers and duties of the Board.

The Board is also authorized to formally discipline licensees and registrants. Specifically, the Board can suspend, revoke, refuse to renew or otherwise discipline any licensee or registrant for violations of the Act, including unprofessional conduct, as highlighted in the Act. There are several unprofessional conduct provisions outlined in the Act related to licensees and registrants, including, but not limited to:[47]

- Engaging in advertising that is misleading, deceptive or false;
- Engaging in the practice of pharmacy while on inactive status;
- Failing to permit the Board or its agents to conduct an inspection;
- Failing to notify the Board of any criminal conviction or deferred judgment within 30 days after the conviction or deferred judgment; and
- Failing to notify the Board of any discipline against his or her license or registration in another state within 30 days after the discipline.

If a licensee's license is revoked by the Board, he or she may not reapply for licensure for two years after the effective date of the revocation.[48]

The Board is also authorized to place conditions on a licensee or registrant's practice. More specifically, the Board may implement conditions on a licensee to ensure that he or she is physically, mentally, morally and otherwise qualified to practice pharmacy.[49] The Board may include any of the following conditions:[50]

- Require a licensee to submit to examinations to determine the licensee's physical or mental condition or professional qualifications;
- Require a licensee to attend training or education courses to correct deficiencies;
- Impose restrictions upon the nature of the licensee's practice to ensure that he or she does not practice beyond his or her capabilities; or
- Impose restrictions on the type(s) of drugs a registrant is authorized to sell in Colorado.

[46] §§ 12-22-110(1)(a), (c), (h), (i) and (I), C.R.S.
[47] §§ 12-22-125(1)(h), (j), (l), (p) and (q), C.R.S.
[48] § 12-22-116(9), C.R.S.
[49] § 12-22-125.2(3), C.R.S.
[50] §§ 12-12-125.2(3)(a), (b) and (d), C.R.S.

The Board may detain or embargo any drug, device or over-the-counter medication that is adulterated or misbranded.[51]

Licensure/Registration

Applicants for licensure as a pharmacist in Colorado are required to complete four tasks: graduate from a college or school of pharmacy; take and pass a written examination, which tests a candidate's knowledge of pharmacy; take and pass a jurisprudence examination, which tests a candidate's knowledge of applicable laws and rules related to the practice of pharmacy and complete the required 1,500 internship hours.

Upon completion of the requirements highlighted above, an applicant is eligible for licensure.

Once licensed, pharmacists (not pharmacy interns) are required to complete a minimum of 24 hours of continuing education every two years.[52]

Each program of continuing education, must be approved by the American Council on Pharmaceutical Education or an equivalent accrediting body as determined by the Board,[53] and consist of one continuing education unit, which is one hour of educational experience.[54] Continuing education units may include, but are not limited to:[55]

- Post-graduate studies;
- Institutes;
- Seminars;
- Lectures;
- Conferences;
- Workshops; and
- Correspondence courses.

To be eligible to obtain a pharmacy intern license, an applicant must have graduated from, be enrolled in, be in attendance at, or be in good standing with an accredited school or college of pharmacy.[56]

Once an applicant completes the required application and obtains a pharmacy intern license, he or she is required to complete a minimum of 1,500 hours of experience practicing pharmacy. The practice of pharmacy includes, but is not limited to, the interpretation, evaluation, implementation and dispensing of prescription orders.[57]

[51] § 12-22-110(4)(a), C.R.S.
[52] § 12-22-118.5(1), C.R.S.
[53] § 12-22-118.5(4), C.R.S.
[54] § 12-22-118.5(5), C.R.S.
[55] § 12-22-118.5(5), C.R.S.
[56] State of Colorado Board of Pharmacy. Rule 4.00.10(c).
[57] § 12-22-102(26)(a), C.R.S.

Additionally, PDOs, which are pharmacies where prescriptions are compounded and dispensed,[58] must obtain a registration from the Board. In order to be eligible to obtain a PDO registration from the Board, an applicant must complete an application to the Board, which includes, among other things, the name of the proprietor and the pharmacist manager.[59]

"Other outlets" are required to obtain a registration from the Board. "Other outlet" registrations were created to provide oversight for prescription drugs that are dispensed to patients within a facility, such as a jail, but do not have the volume of prescriptions or chart orders of PDOs, as well as walk-in patients in rural health and family planning clinics and public health departments.

Labeling Prescription Drugs

All drugs dispensed by pharmacists must contain a label. Prescription drugs dispensed by pharmacists pursuant to a prescription order must be labeled with the following information:[60]

- The name and address of the prescription drug outlet;
- The serial number and the date of the prescription or of its dispensing;
- The name of the patient;
- The name of the drug;
- The name of the practitioner; and
- The directions for use and cautionary statements.

Drugs dispensed pursuant to a chart order must contain the following information:[61]

- Name of the outlet (facility);
- Name and location of the patient; and
- Identification of the drug.

Also, when applicable, drugs dispensed pursuant to a chart order must contain the following:[62]

- Any suitable control numbers;
- The expiration date;
- Any warnings; and
- Any precautionary statements.

[58] § 12-22-102(30.2), C.R.S.
[59] § 12-22-119(2), C.R.S.
[60] § 12-22-123(2), C.R.S.
[61] § 12-22-123(1)(b), C.R.S.
[62] § 12-22-123(1)(b), C.R.S.

Recordkeeping

The Act requires facilities that store, dispense or distribute prescription drugs including controlled substances to maintain all records of receipt, distribution or other disposal for a minimum of two years.[63] These records are subject to inspection by the Board or its representative(s).

Additionally, the Act permits a wholesaler to maintain a portion of its records at a central location that is different from the storage facility; however, the records must be available within 48 hours after a request for inspection.[64]

Part 3: Controlled Substances

The Board licenses manufacturers who manufacture and distribute controlled substances in Colorado,[65] and distributors that distribute controlled substances in Colorado.[66]

The Board also issues licenses to humane societies and animal control agencies for the purpose of being authorized to purchase, possess and administer sodium pentobarbital or sodium pentobarbital in combination with other prescription drugs.[67] These drugs are medically recognized to euthanize animals, or immobilize animals prior to euthanasia.[68]

Licensees under Part 3 are required to maintain separate detailed records and inventories related to controlled substances, and licensees must keep these records for a minimum of two years.[69]

Part 6: Pharmacy Peer Health Assistance Diversion Program

The pharmacy peer health assistance diversion program (peer assistance program) is intended to provide assistance to pharmacists and pharmacy interns experiencing impaired practice due to psychiatric, psychological or emotional problems or excessive alcohol or drug use or addiction.[70] The Board may utilize the peer assistance program as an alternative to or in conjunction with formal discipline of licensed pharmacists.[71]

As a condition of licensure and licensure renewal, every applicant is required to pay an amount not to exceed $56, which is set by the Board, biennially, into the Pharmacy Peer Assistance Fund.[72] The funds collected support providers that have been selected by the Board to provide assistance to pharmacists and pharmacy interns who need help with physical, emotional, psychiatric, psychological, alcohol or drug abuse problems.[73]

[63] § 12-22-131(1)(a), C.R.S.
[64] § 12-22-131(1)(b), C.R.S.
[65] § 12-22-304(2)(a), C.R.S.
[66] § 12-22-304(2)(b), C.R.S.
[67] §12-22-304(3)(b), C.R.S.
[68] §12-22-304(3)(b), C.R.S.
[69] §12-22-318(1)(a), C.R.S.
[70] § 12-22-601(1), C.R.S.
[71] § 12-22-601(2), C.R.S.
[72] § 12-22-603(3)(b), C.R.S.
[73] §12-22-603(3)(b), C.R.S.

The peer assistance program utilized by the Board must:[74]

- Provide for the education of pharmacists concerning the recognition and prevention of physical, emotional and psychological problems and provide for intervention when necessary;
- Offer assistance to a pharmacist in identifying physical, emotional or psychological problems;
- Evaluate the extent of physical, emotional or psychological problems and refer the pharmacist for appropriate treatment;
- Monitor the status of a pharmacist who has been referred for treatment;
- Provide counseling and support for the pharmacist and for the family of any pharmacist referred for treatment;
- Agree to receive referrals from the Board; and
- Agree to make services available to all licensed Colorado pharmacists.

In order to be eligible to participate in the peer assistance program, a pharmacist or pharmacy intern is required to:[75]

- Acknowledge the existence of a psychiatric, psychological or emotional problem or excessive alcohol or drug use or addiction; and
- Agree, in writing, to voluntarily participate in the peer assistance program.

Additionally, the Board established a rehabilitation evaluation committee (REC), which consists of five members who are appointed by the Board. Three members must be licensed pharmacists, including one who has recovered from an addiction to alcohol or drugs; one member must be on the Board's staff and one member must be a psychiatrist or a licensed mental health provider.[76]

The purpose of the REC is to review applications from pharmacists and pharmacy interns for participation in the peer assistance program. After reviewing the applications, the REC makes recommendations to the Board concerning whether an applicant should participate in the peer assistance program.

The REC also reviews reports from the peer assistance program organization and from individual participants concerning each participant's progress in the program.[77]

Part 8: Wholesalers[78]

Part 8 requires wholesalers (in-state and out-of-state) to obtain a license from the Board prior to engaging in the wholesale distribution of prescription drugs and controlled substances.

[74] §§ 12-22-603(3)(c)(I-VII), C.R.S.
[75] §§ 12-22-605(2)(a) and (b), C.R.S.
[76] § 12-22-606(1), C.R.S.
[77] § 12-22-606(2)(b), C.R.S.
[78] Wholesalers are referred to as licensed in Part 8 and registered in Part 1 of the Act.

In order to obtain a wholesaler license from the Board, an applicant is required to provide the following information:[79]

- Name, full business address and telephone number;
- Trade and business names used;
- Addresses, telephone numbers and the names of the contact persons for all facilities used for storage, handling and distribution of prescription drugs;
- Type of ownership or operation;
- Names of the owner and operator;
- List of licenses and permits used in any other state that authorizes the wholesaler to purchase or possess prescription drugs; and
- Name of the wholesaler's designated representative for the facility.

Recordkeeping

Licensed wholesale facilities are required to maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs and controlled substances.[80] The records must include the pedigree[81] of each wholesale distribution of a drug that occurs outside the normal distribution channel.[82] The normal distribution channel is a chain of custody for a prescription drug that goes directly or by drop shipment[83] from a manufacturer of the prescription drug to:[84]

- A wholesaler to a pharmacy to a patient or, when appropriate, a person who is authorized to dispense or administer the drug to a patient; a wholesaler to a chain pharmacy warehouse to its intra-company pharmacies to a patient; a chain pharmacy warehouse to its intra-company pharmacies to a patient; or a pharmacy to a patient;
- A manufacturer's co-licensed partner, third-party logistics provider or exclusive distributor to a wholesaler to a pharmacy to a patient or, when appropriate, a person who is authorized to dispense or administer the drug to a patient;
- A manufacturer's co-licensed partner or third-party logistics provider or exclusive distributor to a wholesaler to a chain pharmacy warehouse's intra-company pharmacy to a patient or, when appropriate, a person who is authorized to dispense or administer the drug to a patient;
- A specialty wholesaler to a pharmacy, physician or hospital; or
- A wholesaler to a pharmacy buying cooperative warehouse to a pharmacy that is a member or member owner of a cooperative to a patient or, when appropriate, a person who is authorized to dispense or administer the drug to a patient.

[79] §§ 12-22-802(3)(a)(I-VII), C.R.S.
[80] § 12-22-805(1), C.R.S.
[81] Pedigree is defined in section 12-22-801(1)(j), C.R.S., as a document or electronic file containing information that records each distribution of any prescription drug that leaves the normal distribution channel.
[82] § 12-22-805(1), C.R.S.
[83] Drop shipment is defined in section 12-22-801(f), C.R.S., as the sale of the manufacturer's prescription drug.
[84] §§ 12-22-801(1)(i)(I-V), C.R.S.

Program Description and Administration

The Pharmaceuticals and Pharmacists Act (Act) in section 12-22-101, *et seq.,* Colorado Revised Statutes (C.R.S.), provides regulatory authority for:

- Pharmacists;
- Pharmacy interns; and
- Pharmacy businesses.

The regulation of pharmacists, pharmacy interns and pharmacy businesses is vested in the Colorado State Board of Pharmacy (Board). The Board is a Type 1, policy autonomous board that is responsible for issuing licenses and registrations, rulemaking and policymaking. The Board is comprised of seven members (five licensed pharmacists and two public members) who are appointed by the Governor.

The Act, in section 12-22-107, C.R.S., requires the Board to meet at least every four months. In practice, the Board generally meets on a monthly basis.

The Division of Registrations (Division), which is located within the Department of Regulatory Agencies (DORA), is responsible for the inspections of pharmacies and administrative functions related to the Board. Specifically, the Division is responsible for a variety of oversight duties including, issuing licenses, conducting investigations, preparing meeting agendas, taking meeting minutes and advising Board members on regulatory issues.

In fiscal year 10-11, the Division devoted 5.75 full-time equivalent (FTE) employees to provide inspections of pharmacies and professional support to the Board. The FTE are as follows:

- General Professional VI (Health Care Section Director) - 0.05 FTE;
- Pharmacy III (Program Director) - 0.60 FTE;
- Pharmacy II (Division Inspectors) - 4.00 FTE;
- Program Assistant II - 0.10 FTE; and
- Technician III - 1.00 FTE.

The aforementioned FTE do not include staffing in the centralized offices of the Division, which include the following:

- Director's Office;
- Office of Investigations;
- Office of Expedited Settlement;
- Office of Examination Services;
- Office of Licensing; and
- Office of Support Services.

Table 1 highlights the total expenditures for regulation of pharmacists, pharmacy interns and pharmacy businesses in fiscal years 05-06 through 09-10.

Table 1
Total Program Expenditures in Fiscal Years 05-06 through 09-10

Fiscal Year	Cash Fund Expenditures
05-06	$961,502
06-07	$1,081,353
07-08	$1,148,112
08-09	$1,141,659
09-10	$1,011,688

Licensing and Registration

The Act requires pharmacists and pharmacy interns to obtain a license from the Board prior to practicing pharmacy in Colorado. Also, pharmacy businesses are required to become registered with the Board. Specifically, the following pharmacy businesses must be registered (or licensed with limited licenses) with the Board:

- Prescription drug outlets (PDOs), in-state and out-of-state;
- Wholesalers (in-state and out-of-state);
- Manufacturers;
- "Other outlets"; and
- Limited licenses.

Tables 2 through 8 in this sunset review contain summary information concerning the aforementioned licensed professions as well as the registered businesses. For detailed information of any of the license types or registrants (including license renewals, etc.), please refer to Appendix A on page 52 of this report.

Table 2 highlights the total number of pharmacists in fiscal years 05-06 through 09-10.

Table 2
Total Number of Pharmacists in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Pharmacists
05-06	5,823
06-07	6,145
07-08	6,061
08-09	6,412
09-10	6,468

As highlighted in Table 2, the number of pharmacists has increased during fiscal years 05-06 through 09-10. In fact, from fiscal year 05-06 to 09-10, the number of pharmacists increased approximately 10 percent.

In fiscal year 09-10, the fee to obtain an initial pharmacy license from the Board was $225. Once licensed, a pharmacist is required to renew his or her license every two years, and in fiscal year 09-10, the renewal fee was $236.

A pharmacist who is licensed in another state may apply to the Board to be licensed in Colorado by a license transfer. In order to be eligible for a license transfer, an applicant must possess an active license, which was obtained through the passage of an examination, which is in good standing from another state.

In fiscal year 09-10, the licensing fee to obtain a pharmacist license by a license transfer was $225.

Table 3 delineates the total number of pharmacy interns in fiscal years 05-06 through 09-10.

Table 3
Total Number of Pharmacy Interns in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Pharmacy Interns
05-06	755
06-07	882
07-08	816
08-09	973
09-10	979

As evidenced in Table 3, the number of licensed pharmacy interns has increased approximately 23 percent from fiscal year 05-06 to 09-10.

In fiscal year 09-10, the initial licensing fee for pharmacy interns was $26, while the fee for renewal, which is every two years, was $32.

Table 4 highlights the total number of PDOs (both in-state and out-of-state) registered by the Board in fiscal years 05-06 through 09-10. PDOs are retail and hospital pharmacies where prescriptions are compounded and dispensed.

Table 4
Total Number of Prescription Drug Outlets in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Prescription Drug Outlets
05-06	1,307
06-07	1,288
07-08	1,317
08-09	1,326
09-10	1,365

During fiscal years 05-06 through 09-10, the number of registered PDOs remained fairly constant. In fact, the increase in the number of PDOs was approximately four percent from fiscal year 05-06 to 09-10.

Registration fees for in-state and out-of-state PDOs are the same. In fiscal year 09-10, the initial fee for a PDO to become registered by the Board was $450, and registrants must pay a renewal fee of $450 every two years.

Table 5 depicts the total number of registered wholesalers (in-state and out-of-state) in fiscal years 05-06 through 09-10. Wholesalers are distributors of prescription drugs.

Table 5
Total Number of Wholesalers in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Registered Wholesalers
05-06	N/A
06-07	335
07-08	465
08-09	647
09-10	748

In fiscal year 05-06, wholesalers were not registered by the board as wholesalers; instead, they were licensed as drug companies.

The large increase in the total number of registered wholesalers from 335 in fiscal year 06-07 to 748 in fiscal year 09-10 is attributable to the creation of Part 8 (wholesalers) of the Act by the General Assembly in 2006. Prior to 2006, out-of-state wholesalers of controlled substances were not required to register with the Board. After the creation of Part 8, out-of-state wholesalers of controlled substances and prescription drugs were required to register with the Board. As a result, more out-of-state wholesalers began registering with the Board.

Registration fees for in-state and out-of-state wholesalers are $450 for a new and renewal registration (every two years).

Table 6 illustrates the total number of manufacturers of prescription drugs registered by the Board in fiscal years 05-06 through 09-10. Manufacturers must be registered if they manufacture or sell prescription drugs in Colorado.

Table 6
Total Number of Manufacturers of Prescription Drugs in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Manufacturers of Prescription Drugs
05-06	N/A
06-07	15
07-08	15
08-09	19
09-10	23

Manufacturers of prescription drugs were regulated by the Board as drug companies, and in 2006, the General Assembly eliminated the drug company license and replaced it with the manufacturers of prescription drugs registration. As a result, there were no manufacturers of prescription drugs registered in fiscal year 05-06.

The fee to obtain a new and renewal (every two years) manufacturer of prescription drugs registration is $450.

Table 7 highlights the total number of “other outlet” businesses registered by the Board in fiscal years 05-06 through 09-10. Businesses such as jails possess an “other outlet” registration from the Board to dispense prescription drugs to inmates.

Table 7
Total Number of “Other Outlet” Businesses Fiscal Years 05-06 through 09-10

Fiscal Year	Number of “Other Outlet” Businesses
05-06	208
06-07	212
07-08	215
08-09	211
09-10	211

The data in Table 7 indicate that the number of registered "other outlet" businesses has remained fairly constant during the five-year period. In fact, there were only three more "other outlet" businesses registered in fiscal year 09-10 than in fiscal year 05-06.

"Other outlet" registrations, both new and renewal (every two years) are $100.

Table 8 depicts the total number of limited licenses issued by the Board in fiscal years 05-06 through 09-10. Limited licenses are issued to non-profit humane societies and government-operated animal control agencies.

Table 8
Total Number of Limited Licenses in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Limited Licenses
05-06	48
06-07	48
07-08	48
08-09	44
09-10	45

The data in Table 8 show that the number of limited licenses issued by the Board during the five-year period has been relatively constant.

Limited licenses are $25 for a new license, $50 for a renewal license (every two years).

Examinations

In order to be eligible for a pharmacist license in Colorado, an applicant is required to pass two examinations: the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE).

The minimum requirements to be eligible to take the examination are graduation from a college or school of pharmacy approved by the Board and completion of a minimum of 1,500 hours of pharmacy internship experience.

Table 9 provides an aggregate overview of the total number of examinations (NAPLEX and MPJE) and pass rates in fiscal years 05-06 through 09-10 for candidates seeking licensure in Colorado.

Table 9
Total Number of Professional and Jurisprudence Examinations in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Professional Examinations Given	Pass Rate for Professional Examinations	Number of Jurisprudence Examinations Given	Pass Rate for Jurisprudence Examinations
05-06	137	90%	243	93%
06-07	123	87%	361	91%
07-08	156	96%	393	91%
08-09	160	93%	371	92%
09-10	169	95%	422	95%

The data in Table 9 indicate that there were more jurisprudence examinations given than professional examinations in each of the five fiscal years. The greater number of jurisprudence examinations given is attributable to pharmacists who are already licensed in another state and wish to practice in Colorado. These pharmacists are required to take and pass the Colorado-specific jurisprudence examination and not the professional examination.

North American Pharmacist Licensure Examination

The NAPLEX was created to assess an applicant's knowledge (competence) to practice pharmacy.

The NAPLEX examination was developed by the National Association of Boards of Pharmacy (NABP),[85] and is administered by Pearson VUE at its Pearson Professional Centers.[86] There are three Pearson Professional Centers in Colorado: Greenwood Village, Pueblo and Westminster.

The current fee to take the NAPLEX is $450. If an applicant does not pass the NAPLEX he or she is required to wait 91 days before re-taking the examination.

"The NAPLEX is a 185-question computer-based examination that uses adaptive test technology to deliver a mixture of selected-response and constructed-response test questions,"[87] and an applicant must complete the examination in 4 hours and 15 minutes.

[85] NAPLEX North American Pharmacist Licensure Examination/MPJE Multistate Pharmacy Jurisprudence Examination Registration Bulletin. *NAPLEX/MPJE Registration Procedures.* Retrieved June 22, 2011, from http://www.nabp.net/programs/assets/NAPLEX-MPJE.pdf
[86] NAPLEX North American Pharmacist Licensure Examination/MPJE Multistate Pharmacy Jurisprudence Examination Registration Bulletin. *Testing Appointment Information.* Retrieved June 22, 2011, from http://www.nabp.net/programs/assets/NAPLEX-MPJE.pdf
[87] NAPLEX North American Pharmacist Licensure Examination/MPJE Multistate Pharmacy Jurisprudence Examination Registration Bulletin. *NAPLEX.* Retrieved June 22, 2011, from http://www.nabp.net/programs/assets/NAPLEX-MPJE.pdf

The NAPLEX contains three content areas:[88]

- Assessing pharmacotherapy to assure safe and effective therapeutic outcomes;
- Assessing safe and accurate preparation and dispensing of medications; and
- Assessing, recommending and providing health care information that promotes public health.

Multistate Pharmacy Jurisprudence Examination

The purpose of the MPJE is to test an applicant's knowledge of the applicable federal and state laws concerning the practice of pharmacy.

The MPJE was also developed by the NABP and is administered by Pearson VUE.

The current fee to take the MPJE is $200. If an applicant fails the MPJE, he or she must wait 30 days to re-take the examination.

The MPJE is a 90-question computer-based test, and an applicant must complete the test in two hours.

There are three content areas of the MPJE:[89]

- Pharmacy practice;
- Licensure, registration, certification and operational requirements; and
- Regulatory structure and terms.

Inspections and Audits

The Division utilizes three full-time pharmacy inspectors to inspect, and when necessary, audit registered and licensed facilities throughout Colorado. The Division also employs one chief pharmacy inspector who is responsible for the supervision of the pharmacy inspectors.

Division inspectors attempt to inspect each facility that is registered or licensed by the Board at least once annually. Any deficiencies found during an inspection are noted on an inspection form, which is provided to the facility. If necessary, a facility is given a specified period of time to correct the deficiencies and report to the Board once the deficiencies are corrected.

[88] NAPLEX North American Pharmacist Licensure Examination/MPJE Multistate Pharmacy Jurisprudence Examination Registration Bulletin. *NAPLEX.* Retrieved June 22, 2011, from http://www.nabp.net/programs/assets/NAPLEX-MPJE.pdf

[89] NAPLEX North American Pharmacist Licensure Examination/MPJE Multistate Pharmacy Jurisprudence Examination Registration Bulletin. *Computer-Adaptive MPJE.* Retrieved June 22, 2011, from http://www.nabp.net/programs/assets/NAPLEX-MPJE.pdf

Inspections

Table 10 highlights the total number of inspections completed in fiscal years 05-06 through 09-10.

Table 10
Total Number of Inspections Completed in Fiscal Years 05-06 through 09-10

Fiscal Year	Inspections Completed
05-06	1,474
06-07	1,198
07-08	1,428
08-09	1,277
09-10	1,051

As illustrated in Table 10, the number of inspections decreased in fiscal year 09-10 to 1,051 from fiscal year 08-09, when the Division completed 1,277 inspections. The decrease in the number of inspections is attributable to staffing; the Division was in the process of filling an inspector vacancy and operated nearly half of the fiscal year with only two inspectors, instead of the usual staffing - three inspectors.

During an inspection of a PDO, an inspector ensures that a facility is in compliance with the Act and applicable rules. Division inspectors inspect the entire pharmacy, including, but not limited to:

- Records related to the receipt/distribution/inventories of prescription drugs and controlled substances;
- Dispensing records for prescription drugs and controlled substances;
- Compounding records;
- Immunization records; and
- The physical pharmacy to ensure compliance with space, compounding equipment, security, and other requirements.

Also, an inspection of a wholesale facility reviews a variety of requirements, as highlighted in the applicable State Board of Pharmacy Rules, including, but not limited to:

- Sanitation of the facility;
- Storage of drugs, including, if applicable, controlled substances;
- Pedigree requirements; and
- Records of receipt and distribution of drugs.

When an inspector inspects an “other outlet” facility, he or she reviews a number of factors to ensure compliance with the current Act and applicable rules, including, but not limited to:

- Required protocols;
- Sanitation of the facility; and
- Records of receipt and dispensing of drugs.

Facilities that have a limited license are inspected to ensure compliance with the Act and applicable rules. Specifically, inspections include, but are not limited to:

- A review of storage practices for drugs;
- Security of drugs; and
- Records of receipt and dispensing of drugs.

Audits

If inspectors identify major issues during an inspection, such as a large disparity between drugs that were ordered and dispensed, the Division may initiate an audit, which might include, among other things, a more detailed and in-depth inspection of a facility’s records.

Table 11 illustrates the total number of audits completed by Division inspectors in fiscal years 05-06 through 09-10.

Table 11
Total Number of Audits Completed by Inspectors in Fiscal Years 05-06 through 09-10

Fiscal Year	Audits Completed
05-06	3
06-07	3
07-08	3
08-09	3
09-10	2

As highlighted above, the number of audits has remained consistent in the past five fiscal years, with the exception of fiscal year 09-10, when Division inspectors completed two audits.

Complaints/Disciplinary Actions

There have been a number of complaints to the Board associated with the regulation of pharmacists, pharmacy interns and pharmacy businesses. Table 12 highlights the total complaints to the Board, as well as the nature of the complaints, in fiscal years 05-06 through 09-10.

Table 12
Total Number of Complaints to the Board in Fiscal Years 05-06 through 09-10

Nature of Complaint	FY 05-06	FY 06-07	FY 07-08	FY 08-09	FY 09-10
Allowing Unlicensed Person to Practice	8	3	3	7	4
Change of Ownership Violation	0	1	0	0	0
Complaint Based on Discipline in Another State	4	1	1	1	2
Deceiving the Board	0	0	1	0	0
Delivery Error	3	3	1	4	4
Dispensing Errors	75	65	69	71	79
Distributing to Unregistered Entity	0	1	1	0	2
Drug Diversion	10	7	2	11	8
Failure to Change Pharmacist Manager Properly	10	2	14	3	12
Failure to Maintain Hours of Operation	1	0	0	0	0
Failure to Report Convictions or Discipline	3	22	10	24	6
False Social Security Number Given on Licensing Application	0	0	1	0	0
Felony Conviction	2	5	5	3	2
Prescription Drug Monitoring Program Failure to Submit	0	0	79	93	228
Pharmacist Manager Responsibilities	6	7	12	25	4
Practicing on Expired License	0	0	1	2	0
Receiving Drugs from Unregistered Source	0	0	5	13	2
Recordkeeping	7	4	10	10	11
Security Violation	24	23	31	18	25
Self Reports (reporting a violation, a criminal conviction or disciplinary action)	3	1	9	10	12
Stipulation Violations	5	6	12	15	11
Substance Abuse	8	5	6	2	2
Unknown	2	0	1	0	0
Unregistered/Unlicensed Practice	1	4	8	129	14
Wholesaler Issues with Designated Representatives[90]	0	1	1	4	4
Total	172	161	283	445	432

[90] Generally, in fiscal years 05-06 through 09-10, the complaints to the Board concerning wholesaler issues with designated representatives were associated with wholesalers that failed to report past convictions.

Clearly, as highlighted in Table 12, the category that received the most complaints in fiscal years 05-06 through 09-10 was "dispensing errors." A dispensing error occurs when a licensed pharmacist has given the final interpretation of the prescription order, counseled the patient and the order is dispensed to the consumer and the medication received is 1) the incorrect drug, quantity or strength, 2) it is incorrectly labeled (including incorrect directions for use) or 3) dispensing a prescription without conducting a proper drug regimen review. Regardless of whether the consumer actually consumes (takes) the drug, once it is dispensed to the consumer, and if the order is incorrect and a complaint is filed, it is considered a dispensing error.

The "unregistered/unlicensed" category experienced a dramatic increase in complaints in fiscal year 08-09. The increase is attributable to a change in the Board Rules that required all registrants to procure drugs from registered sources. In an attempt to discern whether registrants were actually adhering to the newly established rules, inspectors reviewed whether registrants where procuring drugs from registered sources. Some of the inspections identified instances where registrants were not complying with the changes in the rules. As a result, the number of complaints increased dramatically in fiscal year 08-09.

The "unknown" category represents some complaint files that are either lost or missing. Consequently, Division staff was unable to categorize these complaints into any of the other categories in Table 12.

It is important to note that the complaint data highlighted in Table 12 include complaints related to the Prescription Drug Monitoring Program (PDMP). Complaints concerning the PDMP are within the Board's jurisdiction and it is appropriate to report the complaints in this sunset review; however, PDMP has its own sunset review and is not part of this review.

Generally, when the Board receives a complaint, staff reviews it and typically sends a 30-day letter to the pharmacist, pharmacy intern or pharmacy business (respondent), informing him or her that a complaint has been filed.

After all of the information has been received by Division staff, the complaint and correspondence from the respondent and complainant are given to the Board for review.

Upon reviewing the information, the Board has several options available, including, but not limited to:

- Dismissing the complaint for lack of jurisdiction;
- Dismissing the complaint for lack of sufficient evidence of a violation;
- Dismissing the complaint with a confidential letter of concern; or
- Referring the case directly to the Attorney General's Office for legal action.

Table 13 illustrates the total number of disciplinary actions imposed on pharmacists, pharmacy interns and pharmacy businesses in fiscal years 05-06 through 09-10.

Table 13
Total Final Agency Actions in Fiscal Years 05-06 through 09-10

Type of Action	FY 05-06	FY 06-07	FY 07-08	FY 08-09	FY 09-10
Revocations/Relinquishments	8	4	3	24	14
Suspensions	8	7	20	15	21
Stipulations	39	37	42	117	92
Letter of Admonition	24	30	20	31	19
Other Actions	1	3	5	71	12
Total Disciplinary Actions	**80**	**81**	**90**	**258**	**158**
Dismissals with Letters of Concern (LOC)	5	52	83	127	167
Total Dismissals including LOCs	**93**	**115**	**149**	**193**	**243**

In fiscal years 05-06 through 09-10, there were a total of 1,493 complaints filed with the Board related to pharmacists, pharmacy interns and pharmacy businesses. During the same timeframe, there were a total of 667 disciplinary actions imposed on licensees or registrants by the Board.

The increase in the number of revocations from three in fiscal year 07-08 to 24 in fiscal year 08-09 and 14 in fiscal year 09-10 is attributable to issues related to the PDMP. Specifically, the Board registers hundreds of out-of-state PDOs, with varying degrees of business in Colorado. Some out-of-state PDOs serve a large customer base, while others serve a relatively small number of customers. Some out-of-state PDOs repeatedly violated the PDMP reporting requirements and were subsequently fined by the Board. Many of the out-of-state PDOs paid the fine(s) to the Board and others failed to do so. Out-of-state PDOs that failed to pay their fines resulted in revocations of their registrations by the Board.

The Board has a variety of options available concerning formal discipline. If the Board determines that a pharmacist or pharmacy intern has violated the Act or applicable rules, the Board may issue a letter of admonition (the lowest form of discipline) to the respondent of a complaint.

The Board may also utilize the Expedited Settlement Process (ESP) within the Division to settle a disciplinary matter. The ESP process was established to resolve disciplinary issues without a formal hearing. ESP staff obtains the parameters concerning the level of discipline that the Board believes is warranted.

As a result of the formal disciplinary process, including the ESP process, the Board may place conditions on a licensee or registrant's practice. More specifically, the Board may impose conditions on a licensee to assure that he or she is physically, mentally, morally and otherwise qualified to practice pharmacy.[91] The Board may include any of the following conditions:[92]

- Require a licensee to submit to examinations to determine the licensee's physical or mental condition or professional qualifications;
- Require a licensee to attend training or education courses to correct deficiencies;
- Require the review of supervision of the licensee's practice; or
- Impose restrictions upon the nature of the licensee's practice to ensure that he or she does not practice beyond his or her capabilities.

During fiscal years 05-06 through 09-10, the ESP process resolved 220 cases related to pharmacists, pharmacy interns and pharmacy businesses. Specifically, 14 cases were resolved in fiscal year 05-06, 15 cases were resolved in fiscal year 06-07, 30 cases were resolved in fiscal year 07-08, 67 cases were resolved in fiscal year 08-09 and 94 cases were resolved in fiscal year 09-10.

If the ESP process fails, that is, the respondent does not agree to the terms offered through the ESP process, the Board may refer the case to the Attorney General's Office for formal proceedings against a pharmacist or pharmacy intern's license or a pharmacy business's registration.

Once the Attorney General's Office receives a case, there are three options available:

- Recommend that the Board dismiss the case;
- Recommend settling the case; or
- File formal charges on behalf of the Board.

The Attorney General's Office may recommend dismissal of a case. This generally occurs when there is a lack of evidence to prove the pharmacist, pharmacy intern or pharmacy business has violated the Act or applicable rules.

The Attorney General's Office may recommend settlement of the case when new (usually mitigating) information is obtained by the attorney, there are problems with provability of the claims, or if settlement is in the best interest of justice.[93]

If the Attorney General's Office files formal charges against a pharmacist, a pharmacy intern or a pharmacy business on behalf of the Board, the case is scheduled for an administrative hearing before an administrative law judge (ALJ). During a hearing before an ALJ, both sides, the respondent (oftentimes represented by an attorney hired by the respondent) and Attorney General's Office, present evidence.

[91] § 12-22-125.2(3), C.R.S.
[92] §§ 12-12-125.2(3)(a-d), C.R.S.
[93] Jurisprudence Resource Manual: Fundamentals of Psychotherapy Practice in Colorado. p.16.

If the Board adopts the ALJ decision, a Final Agency Order is issued, which outlines the discipline imposed. The Board may also reject the ALJ decision and issue a Final Agency Order outlining an alternate form of discipline.

If, however, the respondent disagrees with the findings of the ALJ and subsequently, the Board, he or she may appeal the decision through the Court of Appeals.

Importantly, when a pharmacist or pharmacy intern is formally disciplined, the discipline is reported to the national Healthcare Integrity and Protection Data Bank (HIPDB). The HIPDB is maintained and operated by the U.S. Department of Health and Human Services.

Additionally, the Board is authorized to issue fines to registrants for violations of the Act or applicable rules. Table 14 highlights the total number of fines, including the total amount of fines collected, in fiscal years 05-06 through 09-10.

Table 14
Total Number of Fines Issues and Collected in Fiscal Years 05-06 through 09-10

Fiscal Year	Number of Fines Collected/Paid	Total Value of Fines Collected/Paid
05-06	12	$108,500
06-07	10	$19,000
07-08	15	$281,000
08-09	98	$560,350
09-10	69	$473,822

In fiscal year 08-09, there was a dramatic increase in the number of fines imposed on registrants as well as the total monetary value of fines collected/paid by registrants. The reason for the increase is twofold. First, the number of registrants that were not in compliance with the PDMP reporting requirements increased in fiscal year 08-09. Second, the implementation of the Board Rules related to the requirement that wholesalers only procure drugs from sources that were registered with the Board was slow in being adhered to by registrants.

Analysis and Recommendations

Recommendation 1 – Continue the Colorado State Board of Pharmacy for nine years, until 2021.

The first sunset review criterion asks whether regulation is necessary to protect the health, safety and welfare of the public. The Colorado State Board of Pharmacy (Board) is a seven-member, Type 1, policy autonomous board that, among other duties, is charged with imposing discipline on pharmacists, pharmacy interns and pharmacy businesses when violations of the Pharmaceuticals and Pharmacists Act (Act) or applicable rules occur.

As highlighted in Tables 12, 13 and 14 on pages 30, 32 and 34, of this sunset review, there are a variety of complaints and ultimately disciplinary actions, including fines, imposed on Board-licensed and registered entities for violations of the Act. The most common violation of the Act by licensees in fiscal years 05-06 through 09-10 was for dispensing errors of prescription drugs and controlled substances. A dispensing error occurs when a licensed pharmacist has given the final interpretation of the prescription order, counseled the patient and the order is dispensed to the consumer and the medication received is 1) the incorrect drug, quantity or strength, 2) it is incorrectly labeled (including incorrect directions for use) or 3) dispensing a prescription without conducting a proper drug regimen review.

Prescription drugs are medications that can be dispensed to consumers with instructions to a pharmacist from a licensed health care provider, such as a doctor, dentist or nurse practitioner.[94] There are thousands of prescription drugs available to consumers.

Controlled substances are drugs that are subject to the U.S. Controlled Substances Act (1970), which regulates the prescribing and dispensing, as well as the manufacturing, storage, sale or distribution of substances assigned to five levels or "schedules."[95]

One of the issues raised during the 2002 sunset review of the Act was whether the Board was consistently imposing discipline related to dispensing errors.

As a result, this sunset review attempted to discern whether the Board was, in fact, imposing discipline for dispensing errors consistently. The Department of Regulatory Agencies (DORA) staff reviewed a sample of case files (approximately 80) from fiscal years 05-06 through 09-10. The case files included formal disciplinary actions imposed on licensees as well as dismissals (including confidential letters of concern) related to dispensing errors.

[94] About .com Prescription Drugs. Retrieved June 28, 2011, from http://drugs.about.com/od/pdrugandmedicalterms/g/Rx_drug_def.htm

[95] MediLexicon. *Controlled Substances -- Medical Definition.* Retrieved June 28, 2011, from http://www.medilexicon.com/medicaldictionary.php?t=86017

A review of these case files revealed that the Board was consistently imposing discipline on licensees for dispensing errors. Further, DORA staff's review of the case files highlighted the fact that in a majority of instances where the Board determined that a dispensing error occurred, licensees were issued letters of admonition.

During the course of this sunset review, DORA staff also attended Board meetings to, among other things, observe the Board to ensure that it is functioning effectively and within the statutorily mandated processes, such as open meeting requirements and executive session. DORA staff also observed the Board to determine whether the current composition is operating effectively, such as participation in decision-making concerning discipline.

DORA staff's observation of the Board determined that it is functioning well and making informed decisions related to discipline, rulemaking and policymaking.

As a result, the General Assembly should continue the regulatory oversight of pharmacists, pharmacy interns and pharmacy businesses for nine years, until 2021. The new 2021 sunset date will enable DORA staff to conduct sunset reviews of both the Act as well as the Prescription Drug Monitoring Program (PDMP) in the same cycle. Although the Act and PDMP are currently separate sunset reviews, a concurrent review will enable DORA to evaluate the continued need and effectiveness of these related programs as a whole.

Reconciling the sunset dates for both the Act as well as the PDMP will create a more efficient and elegant use of DORA's resources concerning sunset reviews.

Recommendation 2 – Repeal the Rehabilitation Evaluation Committee.

The Rehabilitation Evaluation Committee (REC), which consists of five members appointed by the Board, was created by the General Assembly to serve as a resource for the Board in evaluating whether a licensee is eligible to participate in the peer assistance program. The REC evaluates whether a licensee is eligible to participate in the peer assistance program and issues a recommendation to the Board. The Board, in turn, can either accept the recommendation from the REC or make a determination about a licensee's participation in the peer assistance program on its own.

Currently, if a licensee voluntarily contacts the peer assistance program vendor seeking assistance with an emotional, psychiatric, physiological, drug abuse or alcohol abuse problem, an assessment is completed by the peer assistance program vendor's staff, and the licensee completes an application requesting participation in the peer assistance program. The peer assistance program vendor recommends whether a licensee should participate in the peer assistance program.

The REC, in turn, reviews the applications and recommendations from the peer assistance program vendor then makes recommendations to the Board. The Board does not review these applications (and does not know the identity of the licensee who voluntarily contacts the peer assistance program vendor). Instead, it relies on the recommendation from the peer assistance program vendor, who completes an evaluation of the licensee and then provides the recommendation from the REC. In other words, the REC essentially ratifies the recommendation from the peer assistance program vendor concerning whether a licensee should participate in the peer assistance program.

Conversely, if a licensee is ordered by the Board to participate in the peer assistance program, an assessment is completed by the peer assistance program vendor's staff, and the assessment is forwarded to the Board for review and ultimately a determination on whether a licensee is permitted to participate in the peer assistance program. The REC also reviews the assessments but does not make a recommendation to the Board. In fact, in most cases, the Board reviews the recommendations from the peer assistance program vendor prior to the REC reviewing the assessments.

Since the REC makes recommendations on whether a licensee should voluntarily participate in the peer assistance program, which is essentially a ratification of the recommendation offered by the peer assistance program vendor, the REC is not necessary, as an independent body, to make recommendations to the Board. Also, the REC does not serve a useful purpose when the Board orders an assessment of a licensee in determining whether he or she should participate in the peer assistance program. In fact, the REC often reviews the information after the Board has reviewed the assessment provided by the peer assistance program vendor. Thus, the General Assembly should repeal the REC from the Act.

Recommendation 3 – Define when the Board may raise fees for licensees to contribute to the Pharmacy Peer Health Assistance Fund.

Currently, section 12-22-603(3)(b), Colorado Revised Statutes (C.R.S.), states that every licensee must pay an amount not to exceed $56 biennially to fund the Pharmacy Peer Health Assistance Fund (Fund). The Board is responsible for establishing the amount licensees are required to pay to support the Fund. The purpose of the Fund is for a designated provider (a third-party provider) to provide assistance to pharmacists and pharmacy interns who are dealing with physical, emotional, psychiatric, psychological, drug abuse or alcohol abuse problems.[96]

[96] § 12-22-603(3)(b), C.R.S.

The Board, however, is restricted from increasing the fee for licensees beyond $56 biennially, and the current fee for licensees is at the maximum ($56 biennially). The Board should be authorized to increase the fee, if necessary. Doing so would allow the third-party provider to provide services, including preventative outreach, to pharmacists and pharmacy interns on Colorado's western slope. Currently, the third-party administrator does not allocate staff on the western slope to assist pharmacists and pharmacy interns.

Other practice acts, such as medical, dental and nursing, contain language that allows for adjustments in fees paid by licensees to their peer assistance funds. Section 12-22-603(3)(b), C.R.S., should be amended to include language that would allow the Board, when necessary, to adjust the fees to pay into the Fund. In order to facilitate consistency within the aforementioned practice acts, the following language should be included in section 12-22-603(3)(b), C.R.S.,

> …which maximum amount may be adjusted annually by the Board to reflect changes in the United States Bureau of Statistics consumer price index for the Denver-Boulder consolidated metropolitan statistical area for all urban consumers or goods or its successor index.

In order for the Board to have greater flexibility in increasing fees to cover the costs of providing program services across the state, the General Assembly should include the aforementioned language in section 12-22-603(3)(b), C.R.S.

Recommendation 4 – Expand the current definition of the "other outlet" registration to allow ambulatory surgery centers and medical clinics operated by hospitals as well as long-term care facilities to register as "other outlets."

The category of "other outlet" registrations was initially created to provide oversight for prescription drugs that are dispensed to patients within a facility, such as a jail, which does not have the volume of prescriptions or chart orders of PDOs, as well as to walk-in patients in rural health and family planning clinics and public health departments.

A facility with an "other outlet" registration is subject to inspections to ensure, among other things, proper recordkeeping practice for drugs, including inventory as well as dispensing of drugs.

Nationally, including in Colorado, there has been a rapid increase in the number of ambulatory surgery centers (ASCs), which reflects a general trend toward surgeries performed on an outpatient basis.[97] ASCs are medical facilities that specialize in same-day or outpatient surgical procedures, such as orthopedic surgeries.[98]

[97] Surgeryencyclodedia. *Ambulatory Surgery Centers.* Retrieved July 20, 2011, from http://www.surgeryencyclopedia.com/A-Ce/Ambulatory-Surgery-Centers.html
[98] Surgeryencyclodedia. *Ambulatory Surgery Centers.* Retrieved July 20, 2011, from http://www.surgeryencyclopedia.com/A-Ce/Ambulatory-Surgery-Centers.html

Similarly, the number of medical clinics operated by hospitals to provide outpatient surgeries has increased.

Both ASCs and medical clinics operated by hospitals procure prescription drugs and controlled substances by utilizing the individual medical license (and the required Drug Enforcement Administration (DEA) registration for controlled substances) of a facility's medical director. Drugs procured for ASCs and medical clinics are utilized by every practitioner working in the facility, not only by the practitioner who is legally responsible for them.

Problems could arise from the current system utilized by ASCs and medical clinics to procure prescription drugs and controlled substances. For example, Board staff has fielded inquiries from ASCs and medical clinics concerning when the practitioner who procured prescription drugs and controlled substances with his or her medical license and DEA registration leaves the practice. Since the prescription drugs and controlled substances were procured by the person who left the practice, the practice would be without appropriate prescription drugs or controlled substances.

Also, there is a certain amount of risk involved for the practitioner who procures the prescription drugs and controlled substances with his or her medical license and DEA registration. The practitioner enables other practitioners to use the prescription drugs and controlled substances, but the procuring practitioner, oftentimes, does not have direct control of the drugs. If issues arise with the drugs such as diversion, the practitioner who procured the drugs is ultimately responsible. This places a burden on the practitioner who procured the drugs.

In an attempt to address the issues highlighted above, ASCs and medical clinics should be authorized to register as "other outlets" with the Board. This is permissive in the sense that ASCs and medical clinics that do not want to amend their current practice of securing drugs with a practitioner's medical license and DEA registration will not be required to obtain an "other outlet" registration.

An "other outlet" registration shifts the responsibility from the individual practitioner to the facility concerning drug procurement as well as accountability for the drugs. Specifically, in order to obtain an "other outlet" registration, the facility is required to obtain a consultant pharmacist who is responsible for the facility and must have a consultant pharmacist to provide written Board–approved protocols for the dispensing of drugs by non-pharmacists.[99] Once an "other outlet" registration is secured, the facility must obtain a DEA registration for the possession and dispensing of controlled substances.

It is important to note that expanding the definition of "other outlet" to include ASCs and medical clinics would facilitate the procurement and administration of drugs in the facility only. The "other outlet" registration does not permit facilities to fill prescription orders for patients upon leaving the facility.

[99] DORA Board of Pharmacy. *Other Outlet.* Retrieved February 10, 2011, from http://www.dora.state.co.us/pharmacy/bus/otheroutlet.htm

With respect to long-term care facilities licensed by the Colorado Department of Public Health and Environment (CDPHE), the Act gives the Board the authority to establish, via rulemaking, the appropriate quantity of prescription drugs and controlled substances for emergency kits provided to such facilities. Emergency kits are a supply of prescription drugs and, in authorized facilities, controlled substances, which are intended to be utilized in emergency situations.

The medical director or equivalent in long-term care facilities, as well as the consulting pharmacist employed by a PDO or "other outlet" that supplies the emergency kits to long-term care facilities, determine the specific drugs to be kept in the emergency kit.[100] The number of drugs is limited to a total of 60, 12 of which can be controlled substances.[101]

Pharmacists employed by the PDO or "other outlet" providing the emergency kit to a facility or a nurse in the facility are authorized to have access to the contents within an emergency kit.

When a drug is removed from an emergency kit for administration, the PDO or "other outlet" must obtain a prescription order or long-term care facility chart order for the drug within 72 hours after being notified that the emergency kit was opened and the drug was used.[102]

The function and role of long-term care facilities are continually changing. More hospital patients, who, for example, have knee replacement surgery, are discharged to these facilities, often at times when there is not a pharmacist available. Long-term care and assisted living facilities are more often utilizing the prescription drugs and controlled substances in the emergency kits as a "first dose" for medication to recently admitted patients. The "first dose" from the emergency kit is intended to enable a patient to receive his or her required medication until a prescription order or chart order can be filled by a pharmacist. However, facilities are limited to the quantity and types of drugs in the emergency kits.

With the changing role and function of long-term care facilities, specifically concerning administering medications, the General Assembly should also expand the definition of "other outlet" to include long-term care facilities. Doing so would provide greater latitude for facilities that choose to have a larger quantity of drug stock to administer to patients. Importantly, this is a permissive change that will allow, not mandate, facilities to register as an "other outlet" with the Board.

In summary, the General Assembly should amend the current definition of "other outlet" in section 12-22-102(23), C.R.S., to include ASCs, medical clinics and long-term care facilities.

[100] State of Colorado Board of Pharmacy. Rule 10.00.20(a).
[101] State of Colorado Board of Pharmacy. Rule 10.00.20(a).
[102] State of Colorado Board of Pharmacy. Rule 10.00.71.

Recommendation 5 – Create a "hospital satellite pharmacy registration" for inpatient hospitals under common ownership or control in Colorado to provide pharmaceutical care and services at a location different than the main hospital location.

Currently, inpatient hospitals must have one designated area that is the principal compounding/dispensing area for drugs. This area is registered by the Board as a prescription drug outlet (PDO).

In addition to the principal compounding/dispensing area, or PDO, inpatient hospitals are authorized to operate satellite pharmacies, which are defined in section 12-22-102(32.5), C.R.S., as an area outside the PDO where pharmaceutical care and services are provided "in the same location." Satellite pharmacies serve as extensions of the principal compounding/dispensing area. Specifically, inpatient hospitals often utilize satellite pharmacies because doing so allows them to store and dispense drugs at various locations within an inpatient hospital, which makes the delivery of drugs to patients easier and more efficient.

In order to operate a satellite pharmacy in a hospital setting, inpatient hospital staff must complete an application and submit it to the Board for approval. Satellite pharmacies, however, are *not* required to obtain a registration from the Board. Instead, they operate under the inpatient hospital PDO. Once approved by the Board, a hospital is authorized to operate a satellite pharmacy, and drugs can be stored and dispensed from this location.

Satellite pharmacies serve as a cost-effective option for inpatient hospitals enabling the pharmacies located within the inpatient hospitals to store and dispense drugs throughout the hospital. This structure also facilitates maintenance of an appropriate level of regulation to ensure public protection.

However, there are certain instances where inpatient hospitals cannot utilize satellite pharmacies because of the requirement that the satellite pharmacy be at the same location as the primary PDO. For example, a hospital that has multiple buildings, some of which are connected by a "skywalk" or tunnel, may have different addresses for each building. In this case, the DEA requires facilities with different addresses (but part of the same inpatient hospital) to possess their own DEA registrations in order to procure and dispense controlled substances. Prior to obtaining a DEA registration, the DEA requires a facility to obtain a registration from the Board.

Recall that the Act authorizes the use of satellite pharmacies, which operate under the PDO of the principal compounding/dispensing area in the same location. Since the DEA requires a separate registration, and also a registration issued by the Board for each facility with a different address (without consideration for buildings that are connected), some hospitals are not able to utilize satellite pharmacies.

When inpatient hospitals are not able to utilize satellite pharmacies, it places an undue burden on those hospitals through increased costs associated with the additional required registrations. Specifically, the PDO registration requires a full-time pharmacist while an inpatient satellite pharmacy does not. The PDO registration is the only other option currently available for inpatient hospitals which have separate buildings.

A potential option to address the issue presented above is to expand the "other outlet" registration, which would replace inpatient hospital satellite pharmacies at inpatient hospitals that have multiple buildings with different addresses. The "other outlet" registration is less onerous than the PDO registration. Specifically, the "other outlet" registration requires a consultant pharmacist, not a full-time pharmacist, and a protocol, which among other things, details recordkeeping practices. The "other outlet" registration was intended for smaller, stand-alone facilities to possess and dispense drugs to patients.

Since an "other outlet" is a registration issued by the Board, it would fulfill the requirement of the DEA that mandates facilities acquire a Board registration prior to obtaining a DEA registration.

However, expanding the current definition of "other outlet" to replace satellite pharmacies does not adequately address the problem because the Board Rules prohibit an "other outlet" registration for facilities with more than 25 beds. While this makes sense, given that the "other outlet" registration is intended for smaller, stand-alone facilities, and inpatient hospital buildings, oftentimes, contain more than 25 beds. Since inpatient hospitals oftentimes have more than 25 beds in buildings, utilizing the "other outlet" registration is not a practical option to address the issue of providing a Board registration to buildings with inpatient hospitals.

In order to adequately address this issue, the General Assembly should create an inpatient hospital pharmacy satellite registration for inpatient hospitals where the satellite facility is located in a building, or a common group of buildings as in a campus setting, that falls under the same ownership and control as the building or site where the PDO is located. The creation of the inpatient hospital satellite pharmacy registration would address the DEA requirement that facilities with different addresses possess a separate registration from the Board in order to receive a DEA registration. Also, the creation of the inpatient hospital satellite pharmacy registration would allow inpatient hospitals to continue to operate their satellite pharmacies without registering each one as a PDO.

Additionally, inpatient hospital satellite pharmacy registration requirements should mirror the requirements currently highlighted in the Board Rules regarding satellite pharmacies. Doing so will ensure that registered inpatient hospital satellite pharmacies maintain the same standards and requirements as satellite facilities that operate under a hospital's PDO.

It is important to note that inpatient hospitals currently utilizing pharmacy satellites at the same address as the main PDO may continue to do so. The inpatient hospital satellite pharmacy registration is intended to address the issue of inpatient hospitals with multiple buildings that have different addresses.

The implementation date for the inpatient hospital satellite pharmacy registration should be January 1, 2013. The Act should direct the Board to promulgate rules related to campus limits on the distance of satellites to the main PDO.

Recommendation 6 – Exempt veterinary prescription drugs from the pedigree requirement.

Currently, the federal Prescription Drug Marketing Act (PDMA), specifically section 503(b), requires businesses to provide pedigree, which is a statement authenticating drugs for human prescription drugs if they are distributed outside the normal distribution channel. This requirement applies to human drugs regardless of whether the drugs are used by humans or, in certain instances, animals. The PDMA considers the normal distribution channel for prescription drugs to be distributed from a drug manufacturer to an authorized dealer of record.

However, the PDMA does not require businesses to provide pedigree for veterinary prescription drugs, even if they are distributed outside the normal distribution channel.

Additionally, section 12-22-801(3)(b), C.R.S., allows the Board to exempt wholesalers from providing pedigree if they distribute veterinary prescription drugs only. Further, if a wholesaler distributes both human and veterinary prescription drugs within the normal distribution channel, they are not required to provide pedigree for drugs.

If, however, wholesalers distribute human and veterinary prescription drugs outside the normal distribution channel (e.g., wholesaler to wholesaler), the Act requires them to provide pedigree for all of the drugs distributed, including veterinary prescription drugs. This requirement is both inconsistent with the federal law concerning pedigree for veterinary prescription drugs and costly for businesses.

Recall that the PDMA requires only human drugs to provide pedigree only if distributed outside the normal distribution channel. In order for the Act to be consistent with current federal law, the General Assembly should amend section 12-22-801(3)(b), C.R.S., to exempt veterinary prescription drugs from the pedigree requirement.

Recommendation 7 – Permit licensed veterinarians to call in an order of a drug intended for veterinary use.

Currently, section 12-22-121(3)(b), C.R.S., authorizes a wholesaler to sell or deliver drugs intended for animal use only if a licensed veterinarian issues a written prescription order. The Act does not permit licensed veterinarians to submit verbal prescription orders to wholesalers. This presents an unnecessary burden on licensed veterinarians.

The process veterinarians utilize in treating animals, particularly in the context of large farms or commercial operations, is different than the process utilized by licensed practitioners who treat people. For example, a veterinarian may visit a dairy farm on the eastern plains in Colorado, and upon examining the cattle, the veterinarian may notice that several of the cows have an infection. The current provision in the Act does not permit the licensed veterinarian to call a wholesaler and procure medication to treat the infected cows. Instead, the veterinarian must write a prescription order and submit the prescription order either personally or by facsimile. Oftentimes veterinarians, such as in the scenario presented above, are many miles from the wholesaler from which they procure veterinary prescription drugs or they do not have immediate access to a facsimile machine.

The current provision prohibiting veterinarians from calling a wholesaler to procure medications could delay treatment for animals, thereby potentially enabling a disease or infection to unnecessarily spread among the animals.

Also, this prohibition presents a potential increase in costs for veterinarians. Instead of verbally ordering drugs, a veterinarian must travel, in some cases long distances, to where he or she can deliver a written prescription order or to a facsimile machine where he or she can send a written prescription order.

The Act should require veterinarians who utilize verbal prescription orders to submit a written prescription order to the wholesaler within 72 hours. Doing so will provide the necessary documentation to effectively track the prescription drugs. By example, the State of Kansas uses the aforementioned 72 hour requirement, and interviews with Kansas Board of Pharmacy staff revealed that the process is effective.

As such, section 12-22-121(3)(b), C.R.S., as it is currently written, presents an unnecessary burden on practitioners, potentially compromising the health of animals and increasing costs for veterinarians. The General Assembly should, therefore, amend section 12-22-121(3)(b), C.R.S., to authorize veterinarians to verbally call in a prescription order to wholesalers in order to treat animals and provide a written prescription within 72 hours.

Recommendation 8 – Authorize the Board to issue letters of admonition to registrants.

Currently, the Act, specifically, sections 12-22-125.2(6)(a) and (b), C.R.S., authorize the Board to issue letters of admonition (LOAs) to licensees only for violations of the Act. Sections 12-22-125.2(6)(a) and (b), C.R.S., do not authorize the Board to issue LOAs to registrants, which is an inconsistent application of disciplinary authority for the Board.

To provide consistency in the levels of discipline available to the Board with respect to similar conduct, the Board's authority should include the issuance of LOAs to registrants.

Therefore, the General Assembly should amend sections 12-22-125.2(6)(a) and (b), C.R.S., to authorize the Board to issue LOAs to registrants as well as licensees. Doing so gives the Board an additional option of discipline to utilize concerning registrants.

Recommendation 9 – Revise the requirement in section 12-22-125.2(7)(a), C.R.S., that the Board send a confidential letter of concern by certified mail to a licensee or registrant to allow the Board to send via any accepted transmittal process.

Section 12-22-125.2(7)(a), C.R.S., requires the Board to send a confidential letter of concern to a licensee or registrant via certified mail.

Certified mail is a service offered by the U.S. Postal Service, and its purpose is to provide a delivery confirmation. For example, when the Board sends a confidential letter of concern to a licensee or registrant via certified mail, the Board receives confirmation that the letter was delivered. Sending a confidential letter of concern to a licensee or registrant is more costly than sending letters via first class or priority mail.

Also, a confidential letter of concern is not formal discipline; rather, it is treated as a dismissal. Therefore, it is not necessary for the Board to send a confidential letter of concern to a licensee or registrant via certified mail. This requirement is inconsistent with other practice acts that only require a letter of concern to be sent to a licensee or registrant via first class mail.

Therefore, the General Assembly should revise the requirement in section 12-22-125.2(7)(a), C.R.S., that the Board send a confidential letter of concern to a licensee or registrant via certified mail to allow the Board to send the letter via any accepted transmittal process. Doing so would remove an unnecessary requirement that is both more costly for the Board and inconsistent with other practice acts.

Recommendation 10 – Amend section 12-22-119(1)(b), C.R.S., to extend the amount of time a PDO has to inform the Board it has a new pharmacist manager (as well as pay the applicable transfer fee) from 14 to 30 days.

A pharmacist manager is required in PDOs (e.g., retail pharmacies and hospital pharmacies). Pharmacist managers are charged with a variety of responsibilities, including, but not limited to:[103]

- Ensuring that the operation of the PDO is in compliance with all applicable laws;
- Maintaining records of initial interpretation and final evaluations of prescription and chart orders; and
- Ensuring that all prescription drugs and controlled substances are procured from an entity or person registered by the Board.

[103] State of Colorado Board of Pharmacy. Rule 7.00.20(l) and State of Colorado Board of Pharmacy. Rule 7.00.30(a) and (c).

Section 12-22-119(1)(b), C.R.S., requires the owner of a PDO to transfer the registration of a pharmacist manager who leaves the PDO to a new pharmacist manager and pay the required transfer fee to the Board within 14 days of the change.

The current 14-day requirement for the transfer of a pharmacy manager as well as paying the applicable transfer fee to the Board has been difficult for the owners of PDOs to comply with. In fact, a number of complaints highlighted in the Program Description Section of this sunset review were related to owners who failed to comply with the 14-day requirement.

Extending the 14-day requirement to 30 days would allow owners of PDOs additional time to submit the required documentation, including the transfer fee, to the Board. Increasing this timeframe could reduce the number of complaints that are purely administrative in nature and that pose no additional or other risk of harm to the public.

Also, since this requirement is administrative in nature, increasing this timeframe poses a minimal threat to public safety.

As such, the General Assembly should increase the number of days an owner of a PDO has to report a transfer of pharmacist managers as well as pay the transfer fee to the Board from 14 to 30 days. Doing so will provide greater latitude for owners of PDOs to comply with this requirement, which may decrease the number of complaints to the Board, while not compromising public safety.

Recommendation 11 – Repeal the requirement that pharmacists and pharmacy interns actually experience impaired practice in order to be eligibile to participate in the peer assistance program.

Currently, section 12-22-605(1), C.R.S., states that any licensee who is experiencing impaired practice may apply to the Board for participation in the peer assistance program. Impaired practice is defined in section 12-22-602(2), C.R.S., as,

> a licensee's inability to meet the requirements of the laws of Colorado and Board rules when the licensee's cognitive, interpersonal or psychomotor skills are affected by psychiatric, psychological, emotional problems or excessive alcohol or drug use or addiction.

Additionally, section 12-22-605(2)(a), C.R.S., highlights eligibility requirements for licensee's to participate in peer assistance, including:

- A licensee must acknowledge the existence of a psychiatric, psychological or emotional problem or excessive alcohol or drug use or addiction; and
- After a full explanation of the operation of and the requirements of the peer assistance program, the licensee must agree to voluntarily participate in the program and agree, in writing, to participate in the program of the peer health assistance organization designated by the Board.

There are several concerns associated with the eligibility requirements for licensees to participate in the peer assistance program. First, the Act currently requires licensees to experience impaired practice prior to being eligible for participation in the peer assistance program. However, there are instances where a practitioner may choose to participate in the peer assistance program to prevent the escalation of a situation to the point where the practitioner may experience impaired practice. Peer assistance is a referral service that has experience in providing appropriate referrals to adequately address the unique needs of pharmacists. For example, a licensee who is going through a divorce may need assistance to proactively address psychological issues such as depression. In this example, the licensee may not be experiencing impaired practice, but instead, has chosen to seek assistance as a proactive measure to prevent impaired practice.

Additionally, in the scenario presented above, the licensee does not technically fulfill the requirements for participation in the peer assistance program. However, proactively seeking assistance could eliminate or lessen the chances of the licensee experiencing impaired practice, which could, in turn, enhance consumer protection.

The Act also, as highlighted above, requires licensees to apply to the Board prior to participation in the peer assistance program. This requirement is counter-intuitive to the process where a licensee could contact peer assistance on his or her own to address any issues he or she is experiencing. Requiring licensees to apply to the Board in order to receive assistance from peer assistance may serve as a deterrent to licensees who wish to utilize the services of peer assistance.

In order to ensure that licensees are eligible to utilize peer assistance, regardless of whether they are experiencing impaired practice, the General Assembly should repeal the requirement that pharmacists and pharmacy interns experience impaired practice in order to be eligible to participate in the peer assistance program. Doing so removes an unnecessary barrier for licensees to participate in peer assistance and proactively address psychological or substance abuse issues or potential issues. Repealing this requirement may enhance consumer protection because licensees will have more latitude to participate in peer assistance prior to experiencing impaired practice.

Also, repealing the aforementioned language would make the Act consistent with other practice acts, such as dental and nursing, related to practitioners experiencing impaired practice in order to be eligible to participate in peer assistance programs.

Recommendation 12 – Revise section 12-22-124(2), C.R.S., to allow the utilization of electronic technology when a practitioner determines that a drug cannot be substituted for a patient.

Currently, section 12-22-124(2), C.R.S., states that if, in the opinion of the prescriber,

> it is in the best interest of his patient that an equivalent drug not be substituted, he may indicate this on the prescription by either writing the words "dispense as written" (DAW) or by initialing in his own handwriting a preprinted box labeled DAW.

Also, section 12-22-124(2), C.R.S., prohibits a facsimile of the handwritten signature or the handwritten initials of a practitioner to be preprinted to indicate DAW. Further, if the prescription is communicated orally by the practitioner to the pharmacist, the practitioner may indicate DAW verbally.

Noticeably absent from section 12-22-124(2), C.R.S, is any reference to electronically generated prescription orders. With the advent of the digital age, where practitioners are increasingly utilizing electronic technology, including in generating prescription orders to pharmacies, the Act should be amended to reflect and address utilization of electronic prescription orders, particularly with regard to issues such as allowing practitioners to prohibit the substitution of drugs when they believe that it is in the best interest of the patient to not allow for substitution of drugs by a pharmacist.

As such, the General assembly should amend section 12-22-124(2), C.R.S., to authorize the utilization of electronic technology when a practitioner determines that a drug cannot be substituted for a patient. Doing so would allow for the adaptation of technology and likely improve efficiency.

Recommendation 13 – Establish that a pharmacist's or pharmacy intern's failure to properly address his or her own physical or mental condition is grounds for discipline, and authorize the Board to enter into confidential agreements with pharmacists and pharmacy interns to address their respective conditions.

One of the Board's critical responsibilities is to take disciplinary action against pharmacists and pharmacy interns who are unfit to practice pharmacy. The Board may take disciplinary action against any pharmacist or pharmacy intern who, among other things, has a physical or mental illness. [104]

[104] § 12-22-125(d), C.R.S.

Having such a condition may affect a candidate's ability to be regulated as a pharmacist or pharmacy intern. Pharmacist and pharmacy intern applications for initial regulation ask:

> Within the last five years, have you been diagnosed with or treated for a condition that significantly disturbs your cognition, behavior or motor function, and that may impair your ability to practice as a pharmacist safely and competently, such as bipolar disorder, severe major depression, schizophrenia or other major psychotic disorder, a neurological illness or sleep disorder?

Further, at each two-year renewal, pharmacists and pharmacy interns must attest that they are in compliance with the Act, so in effect they are attesting that they do not have such a physical or mental condition. If they have acquired such a condition since the last renewal, they must disclose such to the Board.

The intent of these provisions is clear: to protect the public from unsafe practitioners. But in many cases, pharmacists and pharmacy interns with such conditions could continue to practice safely, under certain defined circumstances. For example, a pharmacist with a spinal injury could continue to dispense prescription drugs and counsel customers. A pharmacist with bipolar disorder might be able to treat patients safely provided he or she takes the proper medication.

Under the current system, pharmacists and pharmacy interns with such conditions may enter into an agreement or practice limitation with the Board in order to continue practicing via probationary status, which is highlighted as follows:[105]

> The Board may include in any disciplinary order that allows pharmacists or pharmacy interns to continue to practice such conditions as the Board may deem appropriate to assure that the pharmacist or pharmacy intern is physically, mentally, morally and otherwise qualified to practice pharmacy in accordance with generally accepted professional standards.

Such conditions may include requiring a pharmacist or pharmacy intern to undergo a physical or mental examination to determine his or her physical or mental condition or professional qualifications.[106] The Board may also restrict the scope of the pharmacist's or pharmacy intern's practice to ensure that he or she does not practice beyond the limits of his or her capabilities.[107]

[105] § 12-22-125.2(3), C.R.S.
[106] § 12-22-125.2(3)(a), C.R.S.
[107] § 12-22-125.2(3)(d), C.R.S.

These orders provide a mechanism for these pharmacists and pharmacy interns to continue to practice, but are troubling philosophically. The orders are considered discipline, and become part of the pharmacist's and pharmacy intern's permanent record. Being injured in a car accident, suffering a stroke, or receiving a diagnosis of bipolar disorder is fundamentally different from committing an act that constitutes grounds for discipline under the Act. While these conditions might temporarily or permanently affect a pharmacist's or pharmacy intern's ability to practice, it seems unjust for a pharmacist or pharmacy intern who successfully manages bipolar disorder with medication to be included in the same category as a pharmacist or pharmacy intern who has stolen a car or committed insurance fraud.

Essentially, current law compels the Board to discipline pharmacists and pharmacy interns simply for having a physical or mental condition that might affect their practice.

During the 2010 legislative session, the General Assembly passed Senate Bill 10-1260 (SB 1260), which contains a provision allowing the Medical Board to enter into confidential agreements with physicians with physical or mental conditions that might affect their practice. These agreements establish the measures that physicians must adhere to in order to practice safely.

The legislation made another important change: previously, a physician would be subject to discipline simply for having a physical or mental condition that might affect his or her practice. Under SB 1260, the Medical Board may discipline a physician if he or she fails to:[108]

> Notify the board...of a physical or mental illness or condition that impacts the licensee's ability to perform a medical service with reasonable skill and with safety to patients, failing to act within the limitations created by a physical or mental illness or condition that renders the licensee unable to perform a service with reasonable skill and with safety to the patient, or failing to comply with the limitations agreed to under a confidential agreement(.)

Simply having a physical or mental condition or illness is no longer a reason to impose discipline. As long as the physician notifies the Medical Board of his or her condition or illness, enters into a confidential agreement outlining the measures he or she must take to assure safe practice, and adheres to the agreement, there is no violation of the Medical Practice Act. Consequently, these agreements do not constitute discipline and do not appear to be reportable to the National Practitioner Data Bank. If a physician fails to meet the requirements or stay within the limitations enumerated in the agreement, the Medical Board may then take disciplinary action. This assures adequate public protection.

The General Assembly should enact a similar provision for pharmacists and pharmacy interns by granting the Board the authority to enter into confidential agreements with pharmacists and pharmacy interns and promulgate rules. To assure public protection, the General Assembly should also establish failure to properly address the pharmacist's and pharmacy intern's own physical or mental condition as grounds for discipline.

[108] Senate Bill 10-1260, § 29.

Administrative Recommendation 1 – The Board should re-consider the number of drugs permitted in emergency kits.

Expanding the "other outlet" registration to include long-term care facilities, as set forth in Recommendation 4 of this report, provides an additional option for facilities that choose to increase their supply of prescription drugs and controlled substances and become registered as an "other outlet" by the Board to serve their patients.

However, there are circumstances where long-term care facilities do not want, nor do they need, to secure an "other outlet" registration from the Board. Rather, they utilize the medications within their emergency kits, when necessary, to adequately serve their customers. Further, there are other long-term care facilities that need an additional number of drugs to adequately serve their patients, but they do not need to obtain an "other outlet" registration.

Thus, there are three different categories of long-term care facilities concerning emergency kits: (i) facilities that have enough patients and demand to seek an "other outlet" registration from the Board, which is addressed in Recommendation 4 of this report; (ii) facilities that are satisfied with the current amount of drugs authorized (60 – with a maximum of 12 controlled substances); and (iii) facilities that simply need more than the 60 drugs authorized by the Board in the emergency kits.

Recall that the Act authorizes the Board, via rule, to establish the appropriate amount of drugs within emergency kits. According to Division of Registrations staff within DORA, the Board has not increased the number of drugs authorized in emergency kits in several years – at least since 2003. Since the Act provides authority to the Board to establish the amount of drugs in emergency kits via rule, it should re-evaluate the current amount of drugs allowed in emergency kits via the rulemaking process.

It is important to note that long-term care facilities that are at present satisfied with the current allowable drugs in emergency kits are not required to obtain an "other outlet" registration, as discussed in Recommendation 4 of this report, nor will facilities be required to increase the amount of drugs in their emergency kits if any such increase is in fact not needed.

Appendix A –Licensing, Registration and Fee Information

Licensing Summary

Licenses Issued						
Fiscal Year	Exam / Original	License Transfer or Endorsement	Transfer of Grades	Renewal	Reinstatement	Active Licenses*
05-06	536	132	10	5,951	46	8,527
06-07	922	161	0	1,445	29	8,925
07-08	770	132	0	6,562	54	8,937
08-09	836	139	0	1,937	73	9,632
09-10	869	164	0	6,619	44	9,839

Renewals are shown each year since Pharmacists and Pharmacy Interns renew in October of odd numbered years and Pharmacy Businesses renew in October of even numbered years.

Pharmacist

Licenses Issued						
Fiscal Year	Exam	License Transfer or Endorsement	Transfer of Grades	Renewal	Reinstatement	Active Licenses
05-06	127	132	10	5,481	35	5,823
06-07	154	161	0	0	15	6,145
07-08	198	132	0	5,698	33	6,061
08-09	196	139	0	0	36	5,412
09-10	195	164	0	6,078	31	6,468

Fees - Pharmacist

Fiscal Year	Exam / Original	Endorsement	Reinstatement	Renewal
05-06	$150	$150	$155	$189
06-07	$150	$225	$165	0
07-08	$225	$225	$271	$256
08-09	$225	$225	$271	0
09-10	$225	$225	$193	$236

Pharmacy Intern

Licenses Issued					
Fiscal Year	Exam	Endorsement	Renewal	Reinstatement	TOTAL
05-06	288	0	470	10	755
06-07	272	0	0	6	882
07-08	318	0	502	13	816
08-09	305	0	0	9	973
09-10	449	0	541	9	979

Prior to the 2005 renewal, Pharmacy Interns renewed annually.

* "Active Licenses = the total of licenses active on June 30 of the Fiscal Year.

Fees – Pharmacy Intern

Fiscal Year	Exam / Original	Reinstatement	Renewal
05-06	$26	$67	$52
06-07	$26	$67	0
07-08	$26	$67	$52
08-09	$26	$67	0
09-10	$26	$47	$32

Prescription Drug Outlet – In State (Business)

Licenses Issued				
Fiscal Year	Original	Renewal	Reinstatement	Active Licenses
05-06	43	0	0	908
06-07	36	890	1	907
07-08	40	0	0	924
08-09	39	917	0	939
09-10	31	0	0	939

Prescription Drug Outlet– Out of State (Business)

Licenses Issued				
Fiscal Year	Original	Renewal	Reinstatement	Active Licenses
05-06	36	0	1	399
06-07	74	306	6	381
07-08	53	0	4	393
08-09	69	328	9	387
09-10	70	0	4	426

Fees – Prescription Drug Outlet – In and Out of State (Business)

Fiscal Year	Original	Reinstatement	Renewal
05-06	$250	0	0
06-07	$450	$465	$450
07-08	$450	$465	0
08-09	$450	$465	$450
09-10	$450	$465	0

Wholesaler – In State (Business)

Licenses Issued				
Fiscal Year	Original	Renewal	Reinstatement	TOTAL
05-06	N/A	N/A	N/A	N/A
06-07	63	0	0	63
07-08	3	59	3	65
08-09	6	61	0	65
09-10	4	0	0	68

Wholesaler – Out of State (Business)

Licenses Issued				
Fiscal Year	**Original**	**Renewal**	**Reinstatement**	**TOTAL**
05-06	N/A	N/A	N/A	N/A
06-07	272	0	0	272
07-08	149	303	1	400
08-09	208	370	13	582
09-10	108	0	0	680

SB06-230 created the Pharmacy Wholesalers In-State and Out-of-State licenses types which became effective on January 1, 2007. Their first renewal was October 2008 and they initially renewed on an annual basis. In October 2009 they were changed to renew every two years at the same time as all other pharmacy businesses.

Fees – Wholesalers – In and Out of State (Business)

Fiscal Year	Original	Reinstatement	Renewal
05-06	$250	0	0
06-07	$300	$315	$225
07-08	$300	$240	0
08-09	$450	$465	$450
09-10	$450	$465	0

Manufacturer (Business)

Licenses Issued				
Fiscal Year	**Original**	**Renewal**	**Reinstatement**	**Active Licenses**
05-06				
06-07	15	0	0	15
07-08	0	0	0	15
08-09	5	14	0	19
09-10	4	0	0	23

Fees – Manufacturer (Business)

Fiscal Year	Original	Reinstatement	Renewal
05-06	$250	0	0
06-07	$450	$465	$450
07-08	$450	$465	0
08-09	$450	$465	$450
09-10	$450	$465	0

Other Outlet (Business)

Licenses Issued				
Fiscal Year	**Original**	**Renewal**	**Reinstatement**	**Active Licenses**
05-06	10	0	0	208
06-07	12	206	1	212
07-08	9	0	0	215
08-09	8	205	4	211
09-10	7	0	0	211

Fees – Other Outlet (Business)

Fiscal Year	Original	Reinstatement	Renewal
05-06	$250	0	0
06-07	$100	$115	$100
07-08	$100	$115	0
08-09	$100	$115	$100
09-10	$100	$115	0

Limited License (Business)

Licenses Issued				
Fiscal Year	Original	Renewal	Reinstatement	Active Licenses
05-06	2	0	0	48
06-07	2	46	0	48
07-08	0	0	0	48
08-09	0	42	0	44
09-10	1	0	0	45

Fees – Limited License (Business)

Fiscal Year	Original	Reinstatement	Renewal
05-06	$25	0	0
06-07	$25	$65	$50
07-08	$25	$65	0
08-09	$75	$65	$50
09-10	$25	$65	0