COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2020 Sunset Review

State Board of Pharmacy

October 15, 2020

COLORADO
Department of Regulatory Agencies
Executive Director's Office

October 15, 2020

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

Dear Members of the General Assembly:

The Colorado General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Pursuant to section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) at the Department of Regulatory Agencies (DORA) undertakes a robust review process culminating in the release of multiple reports each year on October 15.

A national leader in regulatory reform, COPRRR takes the vision of their office, DORA and more broadly of our state government seriously. Specifically, COPRRR contributes to the strong economic landscape in Colorado by ensuring that we have thoughtful, efficient and inclusive regulations that reduce barriers to entry into various professions and that open doors of opportunity for all Coloradans.

As part of this year's review, COPRRR has completed an evaluation of the State Board of Pharmacy. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2021 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Parts 1, 2 and 3 of Article 280 of Title 12, C.R.S. The report also discusses the effectiveness of the Board in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes for the review and discussion of the General Assembly.

To learn more about the sunset review process, among COPRRR's other functions, visit coprrr.colorado.gov.

Sincerely,

Patty Salazar
Executive Director

COLORADO
Department of Regulatory Agencies
Colorado Office of Policy, Research & Regulatory Reform

October 15, 2020

FACT SHEET

Sunset Review: State Board of Pharmacy

Background

What is regulated?
Pharmacy encompasses the practice of preparing, compounding and dispensing prescription drugs by pharmacists in addition to the manufacturing, distribution and sale of prescription drugs by businesses.

Why is it regulated?
The practice of pharmacy is regulated to protect the public from harmful practices, such as:

- Dispensing the wrong medication or wrong dose of a medication
- Failing to use sterile methods
- Improperly storing drugs
- Allowing drugs to be sold or diverted for illicit purposes

Who is regulated?
Fiscal year 18-19:

- 8,678 pharmacists
- 1,552 pharmacy interns
- 4,479 pharmacy technicians
- 2,330 provisional pharmacy technicians
- 978 in-state pharmacies
- 69 in-state wholesalers
- 31 manufacturers

How is it regulated?
The State Board of Pharmacy (Board), located in the Division of Professions and Occupations in the Department of Regulatory Agencies, oversees the practice of pharmacy conducted by pharmacists, pharmacy interns, pharmacy technicians, manufacturers, wholesalers and pharmacies in Colorado. In order to practice, pharmacists and pharmacy interns must obtain a license; pharmacy technicians must obtain certification; and pharmacies, wholesalers and manufacturers must register with the Board. Pharmacy interns and pharmacy technicians must be supervised by a licensed pharmacist.

What does it cost?
In fiscal year 18-19, the total expenditures to oversee the program were $1,663,806, and 7.85 FTE were dedicated to the program.

What disciplinary activity is there?
In fiscal year 18-19, the Board took the following disciplinary actions against pharmacists, interns and pharmacy businesses:

- 18 revocations
- 37 surrendered licenses/registrations
- 405 stipulated agreements or final agency orders
- 60 letters of admonition
- 18 cease and desist orders

Key Recommendations

- **Continue Parts 1, 2 and 3 of the Act for nine years, until 2030.**
- **Align the Act with the federal Drug Quality and Security Act.**
- **Clarify that out-of-state prescription drug outlets do not need to register with the Board when distributing drugs to registered prescription drug outlets in Colorado when such transfers are for inventory control purposes. Require that the prescription drug outlets share common ownership and that the drugs remain in the original manufacturer's packaging and are not compounded.**
- **Provide explicit authority for the Board to inspect out-of-state pharmacies, wholesalers and 503B compounding facilities.**
- **Authorize pharmacists to make minor adaptions to prescriptions.**
- **Increase the amount of medication that may be dispensed to an emergency room patient from a 24-hour supply to a 72-hour supply.**

Table of Contents

Background

Sunset Criteria

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 Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within 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 guided by statutory criteria and sunset reports are organized so that a reader may consider these criteria while reading. While not all criteria are applicable to all sunset reviews, the various sections of a sunset report generally call attention to the relevant criteria. For example,

- In order to address the first criterion and determine whether a particular regulatory program is necessary to protect the public, it is necessary to understand the details of the profession or industry at issue. The Profile section of a sunset report typically describes the profession or industry at issue and addresses the current environment, which may include economic data, to aid in this analysis.
- To ascertain a second aspect of the first sunset criterion--whether conditions that led to initial regulation have changed--the History of Regulation section of a sunset report explores any relevant changes that have occurred over time in the regulatory environment. The remainder of the Legal Framework section addresses the third sunset criterion by summarizing the organic statute and rules of the program, as well as relevant federal, state and local laws to aid in the exploration of whether the program's operations are impeded or enhanced by existing statutes or rules.
- The Program Description section of a sunset report addresses several of the sunset criteria, including those inquiring whether the agency operates in the public interest and whether its operations are impeded or enhanced by existing statutes, rules, procedures and practices; whether the agency performs efficiently and effectively and whether the board, if applicable, represents the public interest.
- The Analysis and Recommendations section of a sunset report, while generally applying multiple criteria, is specifically designed in response to the tenth criterion, which asks whether administrative or 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.

These are but a few examples of how the various sections of a sunset report provide the information and, where appropriate, analysis required by the sunset criteria. Just as not all criteria are applicable to every sunset review, not all criteria are specifically highlighted as they are applied throughout a sunset review. While not necessarily exhaustive, the table below indicates where these criteria are applied in this sunset report.

Sunset Criteria	Where Applied
(I) Whether regulation by the agency is necessary to protect the public health, safety, and welfare; whether the conditions that led to the initial regulation have changed; and whether other conditions have arisen that would warrant more, less, or the same degree of regulation;	• Profile. • Legal Framework. • Recommendations 1 and 7.
(II) If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms, and whether agency rules enhance the public interest and are within the scope of legislative intent;	• Legal Framework. • Recommendations 2, 3, 5, 6, 7 and 8.
(III) Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters;	• Legal Framework. • Program Description. • Recommendations 2, 4, 8, 9, 10, 11 and 12.
(IV)Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;	• Program Description. • Recommendation 2, 4, 11 and 12.
(V) Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;	• Program Description.
(VI) The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;	• Profile.
(VII) Whether complaint, investigation, and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;	• Program Description.
(VIII) Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel and whether entry requirements encourage affirmative action;	• Legal Framework. • Program Description.

(IX) Whether the agency through its licensing or certification process imposes any sanctions or disqualifications on applicants based on past criminal history and, if so, whether the sanctions or disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subsection (5)(a) of this section must include data on the number of licenses or certifications that the agency denied based on the applicant's criminal history, the number of conditional licenses or certifications issued based upon the applicant's criminal history, and the number of licenses or certifications revoked or suspended based on an individual's criminal conduct. For each set of data, the analysis must include the criminal offenses that led to the sanction or disqualification.	• Program Description.
(X) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.	• Analysis and Recommendations.

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 on COPRRR's website at: coprrr.colorado.gov.

The functions of the State Board of Pharmacy (Board) as enumerated in Parts 1, 2 and 3 of Article 280 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2021, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR 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 the currently prescribed regulation should be continued and to evaluate the performance of the Board. During this review, the Board must demonstrate that the program serves the public interest. COPRRR's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, COPRRR staff attended Board meetings; reviewed records; interviewed Board staff, officials with state and national professional associations, and other stakeholders; reviewed Colorado statutes and rules; and reviewed the laws of other states.

Major contacts made during this review include, but are not limited to:

- Colorado Hospital Association
- Colorado Medical Society

- Colorado Pharmacists Society
- Colorado Retail Council
- Colorado Society of Family Physicians
- Colorado Veterinary Medical Association
- Department of Agriculture
- Division of Professions and Occupations
- Office of the Attorney General
- Peer Assistance Services, Inc.
- Pharmacy Technician Certification Board
- National Association of Boards of Pharmacy
- National Association of Chain Drug Stores
- Regis University, School of Pharmacy
- State Board of Pharmacy
- University of Colorado, Skaggs School of Pharmacy and Pharmaceutical Sciences
- Veterinary Pharmaceutical Advisory Committee

Profile of Pharmacy

In a sunset review, COPRRR is guided by the sunset criteria located in section 24-34-104(6)(b), C.R.S. The first criterion asks 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.

In order to understand the need for regulation, it is first necessary to understand what the profession does, where they work, who they serve and any necessary qualifications.

Pharmacists

A pharmacist is a licensed professional who prepares and dispenses medication that is prescribed by a licensed health-care provider (e.g., a physician, dentist or advanced practice nurse).[2]

Some duties of a pharmacist may include:[3]

- Filling prescriptions,
- Checking for possible negative interactions with other drugs or conditions of the patient,
- Advising patients on how and when to take medications and possible side effects,
- Giving flu shots and other vaccinations, and

[2] The Free Dictionary. *Pharmacist*. Retrieved November 25, 2019, from https://medical-dictionary.thefreedictionary.com/pharmacist
[3] U.S. Bureau of Labor Statistics. *Pharmacists.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacists.htm

- Supervising pharmacy technicians and interns.

Pharmacists may also compound ingredients to create customized medications for patients.[4]

About 43 percent of pharmacists are employed by pharmacies and drug stores, and 26 percent are employed by hospitals. Pharmacists may also be employed by the government, military and other organizations.[5]

Training to practice pharmacy covers a broad spectrum of subjects including physics, chemistry, biology, bacteriology, physiology, pharmacology and other specialized courses.[6]

In order to become a pharmacist, an individual must obtain a Doctor of Pharmacy degree from an accredited pharmacy program. As of August 2017, the Accreditation Council for Pharmacy Education accredited 128 pharmacy programs in the United States,[7] two of which are located in Colorado.[8]

The Pharmacy College Admissions Test is a prerequisite for most pharmacy programs. Once enrolled in a pharmacy program, a student must complete an internship in a hospital, retail pharmacy or another setting.[9]

While some graduates participate in residency programs, they are not available for all graduating pharmacists and completion of a residency program is not a licensure requirement.

The sixth sunset criterion requires COPRRR to evaluate the economic impact of regulation. One way this may be accomplished is to review the projected salary and growth of the profession.

Unlike other health-care professions, the employment of pharmacists is not expected to grow between 2018 and 2028. While demand for pharmacists will likely grow in hospitals and clinics, the employment of pharmacists in pharmacies and drug stores is expected to decline for two reasons: an increase in sales from mail order and online

[4] U.S. Bureau of Labor Statistics. *Pharmacists.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacists.htm
[5] U.S. Bureau of Labor Statistics. *Pharmacists.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacists.htm
[6] Encyclopaedia Britannica. *Pharmacy.* Retrieved November 25, 2019, from https://www.britannica.com/science/pharmacy
[7] U.S. Bureau of Labor Statistics. *Pharmacists.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacists.htm
[8] Accreditation Council for Pharmacy Education. *Programs by State.* Retrieved October 5, 2020, from https://www.acpe-accredit.org/accredited-programs-by-state/
[9] U.S. Bureau of Labor Statistics. *Pharmacists.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacists.htm

pharmacies and an increase in the utilization of pharmacy technicians. As of May 2018, the median annual wage for pharmacists was $126,120.[10]

All states require pharmacists to be licensed. In order to obtain a license, a candidate must obtain a Doctor of Pharmacy degree, complete an internship and pass the North American Pharmacist Licensure Examination and a jurisprudence examination. Internship requirements vary by state. Most states also require pharmacists who administer vaccinations to be certified by the American Pharmacists Association.[11]

Pharmacy Interns

A pharmacy intern works under the supervision of a licensed pharmacist in order to obtain experience while studying to become a pharmacist. A pharmacy intern may be responsible for weighing, packaging and counting pills, as well as providing information to customers.[12]

Pharmacy Technicians

A pharmacy technician assists a pharmacist in a retail pharmacy or hospital with dispensing prescription medication.[13] Pharmacy technicians may only conduct the following tasks under the supervision of a licensed pharmacist:[14]

- Collect information to fill a prescription,
- Measure medication for prescriptions,
- Package and label medications,
- Take inventory,
- Collect payment and process insurance claims,
- Enter patient information,
- Answer phone calls, and
- Refer patients with questions about medication or health matters to pharmacists.

Pharmacists must review prescriptions before they are dispensed to patients.[15]

[10] U.S. Bureau of Labor Statistics. *Pharmacists.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacists.htm
[11] U.S. Bureau of Labor Statistics. *Pharmacists.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacists.htm
[12] PayScale. *Pharmacy Intern.* Retrieved November 25, 2019, from https://www.payscale.com/research/US/Job=Pharmacy_Intern/Hourly_Rate
[13] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[14] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[15] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm

Like pharmacists, pharmacy technicians primarily work in retail pharmacies and hospitals.[16]

Typically, pharmacy technicians are required to have a high-school diploma and obtain on-the-job training. Some pharmacy technicians may complete an education or training program in pharmacy technology, which may be completed in one year or less, or, in some cases, they may obtain an associate degree. Pharmacy technology programs cover recordkeeping, methods of dispensing and pharmacy laws and ethics, and they also address the names, uses and doses of medication.[17]

The sixth sunset criterion requires COPRRR to evaluate the economic impact of regulation. One way this may be accomplished is to review the projected salary and growth of the profession.

Between 2018 and 2028, the employment of pharmacy technicians is expected to grow by about seven percent, which is faster than average for all occupations. In May 2018, the median annual wage for a pharmacy technician was $32,700.[18]

Most states require pharmacy technicians to obtain a state license or registration, and many states additionally require private, professional certification.[19] Requirements to be licensed or registered vary by state and may require passing an examination or completing a formal education or training program.[20]

In 2017, there were 309 pharmacy technician programs accredited by the American Society of Health-Systems Pharmacists,[21] of which five are located in Colorado.

Pharmacies

A pharmacy is an establishment where medicine is compounded or dispensed.[22] There are several kinds of pharmacies, among them:

- Retail pharmacies,
- Hospital pharmacies,

[16] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[17] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[18] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[19] Pharmacy Technician Certification Board. *State Regulations Map*. Retrieved September 14, 2020, from https://www.ptcb.org/resources/state-regulations-and-map
[20] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[21] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[22] The Free Dictionary. *Pharmacy*. Retrieved November 25, 2019, from https://medical-dictionary.thefreedictionary.com/pharmacy

- Compounding pharmacies,
- Mail order pharmacies, and
- Specialty pharmacies.

In 2019, 43.8 million retail prescriptions were filled at pharmacies in Colorado,[23] amounting to a total of $6.7 billion in sales.[24]

All states have laws regulating pharmacies, including licensure requirements for facilities. State pharmacy laws typically address requirements for secure storage, recordkeeping, forms or pads for patient prescriptions, labeling and safety protocols.[25]

[23] Kaiser Family Foundation. *Number of Retail Prescription Drugs Filled at Pharmacies by Payer*. Retrieved September 14, 2020, from https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[24] Kaiser Family Foundation. *Retail Sales for Prescription Drugs Filled at Pharmacies by Payer*. Retrieved September 14, 2020, from https://www.kff.org/health-costs/state-indicator/total-sales-for-retail-rx-drugs/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[25] National Conference of State Legislators. *State Regulation of Compounding Pharmacies.* Retrieved November 25, 2019, from http://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx

Legal Framework

History of Regulation

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The first sunset criterion questions 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 that would warrant more, less or the same degree of regulation.

One way that COPRRR addresses this is by examining why the program was established and how it has evolved over time.

Colorado has regulated the practice of pharmacy since 1887 when the General Assembly created the State Board of Pharmacy (Board). Since then, the regulation of the pharmacy profession has continually evolved.

In 1986, the General Assembly adopted a sunset recommendation to require pharmacists to pass a jurisprudence examination. Following a sunset review in 1995, the General Assembly expanded the Board's authority for confidential letters of concern, and in 2003, the General Assembly adopted a sunset recommendation to authorize the Board to fine businesses registered by the Board.

Following a sunset review in 2011, the General Assembly adopted several recommendations, the most significant of which:

- Created 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 from the main hospital,
- Authorized the Board to issue letters of admonition to businesses registered by the Board,
- Established that a pharmacist's or pharmacy intern's failure to properly address his or her own health condition is grounds for discipline, and
- Authorized the Board to enter into confidential agreements with pharmacists and pharmacy interns to address any health conditions that impact their ability to practice safely.

Since then, the General Assembly has passed 36 bills to amend the laws governing the practice of pharmacy. The most significant of these changes:

- Created a Veterinary Pharmaceuticals Advisory Committee;
- Authorized a pharmacist to provide health-care services by entering into a collaborative agreement with a licensed physician or an advanced practice nurse;

- Created a Statewide Protocol Process in order to grant limited independent prescriptive authority to pharmacists for specified medications and devices;
- Increased the number of pharmacy technicians and interns a pharmacist may supervise from three to six;
- Required pharmacy technicians to obtain certification from the Board;
- Expanded the grounds for discipline to include possessing, selling, dispensing, giving, receiving or administering a drug or device that is adulterated, misbranded or counterfeit, and also added additional penalties for such conduct; and
- Authorized pharmacists to dispense emergency medication without a prescription to an individual with a chronic health condition if the medication is necessary to maintain health or may be necessary to save his or her life.

During the 2019 legislative session, the General Assembly recodified Title 12, C.R.S. At that time, Article 42.5 was repealed and reenacted as Article 280. Though there were changes in the manner in which the law reads and many provisions of law were combined with common elements of other laws, none of those changes affected the implementation or enforcement of the Act.

Legal Summary

The second and third sunset criteria question

> 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; and
>
> 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.

A summary of the current statutes and rules is necessary to understand whether regulation is set at the appropriate level and whether the current laws are impeding or enhancing the agency's ability to operate in the public interest.

Federal Law

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.

The federal government divides controlled substances into five categories based on their medical use, potential for abuse and the likelihood they may result in dependence.[26] The categories are:[27]

- **Schedule I** includes substances, such as heroin, LSD and peyote, which do not have any accepted medical use, are unsafe and have a high potential for abuse.

- **Schedule II** includes narcotics and stimulants, such as OxyContin, Percocet, codeine and amphetamine, which have a high potential for abuse and may result in severe psychological or physical dependence.

- **Schedule III** includes substances, such as Tylenol with codeine, ketamine and anabolic steroids, which have less potential for abuse; however, they may result in moderate or low physical dependence and high psychological dependence.

- **Schedule IV** includes substances, such as Xanax, Valium and Ativan, which have less potential for abuse than Schedule III drugs.

- **Schedule V** includes preparations with limited amounts of narcotics, such as cough syrup with codeine.

Schedule II through V substances are only permitted to be dispensed to consumers through a prescription or chart order from a prescriber who has obtained a federal Drug Enforcement Administration registration. Schedule I substances are deemed to have no accepted medical use and a high potential for abuse, and they may not be dispensed to consumers.

Federal Drug Supply Chain Safety Act

Congress adopted the federal Drug Supply Chain Safety Act in 2013 in order to create an electronic system to detect and remove dangerous drugs from the supply chain. It also directs the federal Food and Drug Administration to adopt national standards for wholesale distributors and third-party logistics providers.[28]

Federal Food, Drug and Cosmetic Act

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

[26] U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division. *Controlled Substance Schedules*. Retrieved February 12, 2020, from https://www.deadiversion.usdoj.gov/schedules/
[27] FindLaw. *What is a Controlled Substance?* Retrieved September 14, 2020, from https://criminal.findlaw.com/criminal-charges/what-is-a-controlled-substance.html
[28] U.S. Food and Drug Administration. *Drug Supply Chain Security Act*. Retrieved September 14, 2020, from https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

State Law

The Pharmacists, Pharmacy Business and Pharmaceuticals Practice Act (Act), section 12-280-101, *et seq.*, C.R.S., is composed of the following six parts:

- **Part 1,** which concerns the general provisions related to Board membership and its powers and duties, and the regulation of pharmacists, pharmacy businesses and pharmaceuticals by the Board;
- **Part 2,** which concerns the Pharmacy Peer Health Assistance Diversion Program (peer assistance program);
- **Part 3,** which concerns the regulation of wholesale drug outlets (wholesalers);
- **Part 4,** which concerns the Electronic Prescription Drug Monitoring Program (Colorado PDMP);
- **Part 5,** which concerns therapeutic interchange and therapeutically equivalent selections; and
- **Part 6,** which concerns collaborative pharmacy practice and statewide protocols.

This sunset review considers only Parts 1, 2 and 3 of the Act. Part 4 of the Act, which concerns the Colorado PDMP, is undergoing a separate sunset review at this time, and Parts 5 and 6 of the Act are not scheduled for a sunset review.

PART 1 OF THE ACT

The Act defines pharmaceutical care as[29]

> the provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. In addition to the preparation, dispensing and distribution of medications, "pharmaceutical care" may include assessment and evaluation of the patient's medication-related needs and development and communication of a therapeutic plan with defined outcomes in consultation with the patient and the patient's other health-care professionals to attain the desired outcome. This function includes efforts to prevent, detect and resolve medication-related problems for individual patients. "Pharmaceutical care" does not include prescriptive authority; except that a pharmacist may prescribe only over-the-counter medications to a recipient under the "Colorado Medical Assistance Act" as authorized pursuant to section 25.5-5-322 or pursuant to a collaborative pharmacy practice agreement as defined in section 12-280-601(1)(b).

[29] § 12-280-103(34), C.R.S.

The practice of pharmacy is defined by the Act as[30]

> The interpretation, evaluation, implementation and dispensing of orders; participation in drug and device selection, drug administration, drug regimen reviews and drug or drug-related research; provision of patient counseling; and the provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care; the preparation, mixing, assembling, packaging, labeling or delivery of a drug or device; proper and safe storage of drugs or devices; and the maintenance of proper records for the drugs and devices.

State Board of Pharmacy

The Board, located within the Division of Professions and Occupations in the Department of Regulatory Agencies, is vested with the authority to regulate the practice of pharmacy[31] and promulgate rules to administer and enforce the Act.[32]

Specifically, the Board is entrusted with the following powers and duties:

- Overseeing the practice of pharmacy conducted by pharmacists, pharmacy interns, pharmacy technicians and pharmacy businesses;
- Maintaining a list of approved schools of pharmacy;[33]
- Inspecting all outlets and investigating violations of the Act;[34]
- Controlling and regulating prescription drugs in Colorado, including retail sales, dispensing, compounding, and purity and quality control;[35]
- Controlling and regulating prescription devices, except for veterinary devices that are disposable and any other veterinary device that the Board deems unnecessary to regulate;[36] and
- Detaining or embargoing any drug, device or over-the-counter medication that has been adulterated or misbranded.[37]

The Board members are appointed by the Governor and consist of five licensed pharmacists and two public members. The Board members who are pharmacists must have actively practiced pharmacy in Colorado for at least five years. The public members may not have any financial interest in the practice of pharmacy.[38]

[30] § 12-280-103(39), C.R.S.
[31] § 12-280-104(1), C.R.S.
[32] § 12-280-107, C.R.S.
[33] § 12-280-113, C.R.S.
[34] § 12-280-108(1)(a), C.R.S.
[35] § 12-280-109(1), C.R.S.
[36] § 12-280-109(2), C.R.S.
[37] § 12-280-108(4)(a), C.R.S.
[38] § 12-280-105(1), C.R.S.

Board members serve four-year terms and may not serve more than two consecutive terms.[39]

In appointing Board members, the Governor must seek to balance the Board membership by selecting appointees from:[40]

- Rural and urban areas,
- Different geographic areas of the state, and
- Various types of practices.

The Board membership may not consist of more than four members from the same political party,[41] and the Governor may remove any member for misconduct, incompetence or neglect of duty.[42]

Each Board member may receive a per diem of $50 for attending Board meetings and be reimbursed for any actual and necessary expenses.[43]

Veterinary Pharmaceutical Advisory Committee

The Board is required to refer all business related to veterinary pharmaceuticals to the Veterinary Pharmaceutical Advisory Committee (Advisory Committee), including:[44]

- Licensing and registration,
- Investigations,
- Complaints,
- Disciplinary actions, and
- Rulemaking.

The Board, however, is not required to refer urgent cases that require prompt action.[45]

The Advisory Committee must consider all referred business and make recommendations to the Board. When the Board concludes that material and substantial evidence or information exists that warrants action different from an Advisory Committee recommendation, the Board must document its reasons for doing so.[46]

The Advisory Committee consists of three members who are appointed by the State Veterinarian in the Department of Agriculture:[47]

[39] § 12-280-105, C.R.S.
[40] § 12-280-105, C.R.S.
[41] § 12-280-105, C.R.S.
[42] § 12-280-105, C.R.S.
[43] §§ 12-280-105(3) and 12-20-103(6), C.R.S.
[44] § 12-280-106(2)(a), C.R.S.
[45] § 12-280-106(2)(a), C.R.S.
[46] § 12-280-106(2)(c), C.R.S.
[47] § 12-280-106(1)(a)(I), C.R.S.

- A licensed large-animal veterinarian,
- A licensed pharmaceutical wholesaler who distributes animal drugs or a licensed veterinarian, and
- An individual with a background in agriculture.

The licensed members of the Advisory Committee must have licenses in good standing and have been actively engaged in practice in Colorado for at least five years.[48] No more than two members may be from the Front Range.[49]

The Advisory Committee members serve three-year terms, and they serve without compensation or reimbursement of expenses.[50]

Licensed Individuals

Pharmacists

A pharmacist is an individual licensed by the Board to engage in the practice of pharmacy.[51] To be licensed as a pharmacist, an applicant must complete the following steps:[52]

- Graduate from a school of pharmacy approved by the Board,
- Pass a written examination,
- Pass a Board-approved jurisprudence examination that tests the applicant's knowledge of state laws, and
- Complete 1,500 hours of experience as an intern.

An individual who was trained at a foreign school must submit a Foreign Pharmacy Graduate Equivalency Certificate and pass the written and jurisprudence examinations in order to be licensed as a pharmacist.[53]

A pharmacist may also be licensed by endorsement if he or she:[54]

- Has been licensed for at least one year in another state or has completed the requirements for an internship in another state,
- Has a license in good standing in all states in which he or she holds a pharmacist license, and
- Has passed the Board-approved jurisprudence examination.

[48] § 12-280-106(1)(a)(I), C.R.S.
[49] § 12-280-106(1)(a)(II), C.R.S.
[50] § 12-280-106(1)(b), C.R.S.
[51] § 12-280-103(35), C.R.S.
[52] 3 CCR § 719-1, 4.00.30, State Board of Pharmacy Rules.
[53] 3 CCR § 719-1, 4.00.30, State Board of Pharmacy Rules.
[54] 3 CCR § 719-1, 4.00.40, State Board of Pharmacy Rules.

Once licensed, a pharmacist is required to complete at least 24 hours of continuing education every two years.[55] A continuing education program must be approved by the American Council on Pharmaceutical Education or an equivalent approved by the Board.[56]

A pharmacist may supervise as many as six pharmacy technicians or interns; however, a pharmacist may not supervise more than two interns.[57]

Pharmacy Interns

To be eligible to obtain a pharmacy intern license, an applicant must have:[58]

- Graduated from or be enrolled in an accredited school or college of pharmacy and be in good standing;
- Obtained a Foreign Pharmacy Graduate Equivalency Certificate; or
- Hold an active, unrestricted license in another state if awaiting licensure in Colorado.

Pharmacy Technicians

A pharmacist is responsible for the supervision of and delegation of pharmacy tasks and duties to a pharmacy technician. A pharmacy technician may engage in any of the following:[59]

- Receiving and entering orders;
- Preparing, mixing, assembling, packaging, labeling or delivering a drug or device;
- Storing drugs or devices;
- Maintaining pharmacy records;
- Transferring prescriptions; and
- Other activities permitted by the Board.

A pharmacy technician must be certified by the Board in order to work as a pharmacy technician.[60] The requirements for certification are:[61]

- Possession of private, professional certification approved by the Board, and
- Passage of a criminal history record check by the Board or through an employer or a certifying organization.

[55] § 12-280-117(1), C.R.S.
[56] § 12-280-117(4), C.R.S.
[57] § 12-280-122(1), C.R.S.
[58] 3 CCR § 719-1, 4.00.20, State Board of Pharmacy Rules.
[59] § 12-280-103(38.5)
[60] § 12-280-115.5(1), C.R.S.
[61] § 12-280-115.5(2), C.R.S.

The Board may grant a pharmacy technician provisional certification for a period of 18 months while an individual is working on obtaining private, professional certification. Provisional certification may not be renewed, but the Board may grant an extension for hardship circumstances.[62]

If a pharmacist is supervising three or more pharmacy technicians, a majority must have full certification.[63]

Registered Businesses

Any business engaged in the practice of pharmacy must be registered with the Board as a:[64]

- Prescription drug outlet (pharmacy), which compounds and dispenses prescriptions,[65] and may be either an in-state pharmacy or out-of-state pharmacy; [66]
- Wholesaler, which distributes prescription drugs to persons or entities that are not consumers or patients; or
- Manufacturing drug outlet (manufacturer), which manufactures prescription drugs.

A business is not required to register with the Board in order to sell nonprescription drugs.[67]

The Act requires registered businesses to:[68]

- Have adequate facilities to handle and store controlled substances, and
- Maintain control of controlled substances in order to prevent drug diversion.

As a condition of registration, a pharmacy is required to employ a pharmacist manager who is in charge of the pharmacy,[69] and pharmacy staff must wear a badge identifying his or her role when on duty, for example:[70]

- Pharmacist,
- Pharmacy intern,
- Pharmacy technician,
- Pharmacy clerk,

[62] § 12-280-115.5(3), C.R.S.
[63] § 12-280-122(1), C.R.S.
[64] § 12-280-119(1), C.R.S.
[65] § 12-280-103(43), C.R.S.
[66] 3 CCR § 719-1, 5.00.01, State Board of Pharmacy Rules.
[67] § 12-280-119(5), C.R.S.
[68] § 12-280-119(13), C.R.S.
[69] § 12-280-118, C.R.S.
[70] 3 CCR § 719-1, 4.06.00, State Board of Pharmacy Rules.

- Store manager, and
- Assistant store manager.

Any pharmacy located in another state that ships, mails or delivers prescription drugs or devices to Colorado must register with the Board.[71] In order to register, the Board requires an out-of-state pharmacy to submit evidence of a current pharmacy license from the state where the applicant is located and a copy of its most current inspection report.[72]

Dispensing Drugs

A pharmacist is required to have a prescription or a chart order to dispense any prescription drug,[73] with the exception of an opiate antagonist.[74]

With some limitations, a pharmacist may substitute a drug or biologic product,[75] unless a prescriber has indicated that substitutions are not allowed.[76]

If a pharmacist has made reasonable efforts to contact a practitioner and failed, and continued use of the medication is necessary for the patient's health, safety and welfare, a pharmacist may refill a prescription without authorization. The refill may only be in an amount necessary until the practitioner may be reached and may not exceed a 72-hour supply. However, an emergency refill is prohibited if the prescription specifies that one is not allowed.[77]

A pharmacist may also dispense an emergency supply of medication for a chronic medical condition without a current, valid prescription if the circumstances meet certain conditions.[78]

Any drug dispensed by prescription must contain a label that provides the following information:[79]

- 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 prescriber, and
- Any directions for use or cautionary statements specified in the prescription.

[71] § 12-280-133(1), C.R.S.
[72] 3 CCR 719-1 § 5.00.15, State Board of Pharmacy Rules.
[73] § 12-280-123(1), C.R.S.
[74] § 12-280-123(3), C.R.S.
[75] §§ 12-280-125(1)(a) and (b), C.R.S.
[76] § 12-280-125(2)(a), C.R.S.
[77] § 12-280-123(2), C.R.S.
[78] § 12-280-125.5(1), C.R.S.
[79] § 12-280-124(2), C.R.S.

Any drug compounded and dispensed by a chart order for a patient in a hospital must be labeled with:[80]

- The name of the outlet,
- The name and location of the patient, and
- The name of the drug.

If applicable, labels for such drugs must also detail:[81]

- Any control numbers,
- The expiration date,
- Any warnings, and
- Any precautions.

The Board is directed by statute to adopt rules for opioids prescribed for outpatient use which must include a warning of the risks (e.g., overdose and addiction).[82] To address this statutory requirement, the Board rules require a label or container to state: "Caution: Opioids carry a risk of overdose and addiction."[83]

Anyone licensed or registered by the Board must maintain records for at least two years of any prescription drugs that were received, distributed or disposed of. These records are subject to Board inspection.[84]

Disciplinary Authority

If an applicant, licensee, certificate holder or registrant has engaged in conduct that is grounds for discipline, the Board may deny, suspend or revoke a license, certificate or registration. The Board may also place a licensee, certificate holder or registrant on probation,[85] and it may issue, against a registrant, an administrative fine of no less than $500 and no more than $5,000 per violation.[86]

The grounds for discipline include conduct such as:[87]

- Violating the Act, Board rules or any state or federal law related to drugs;
- Failing to meet the generally accepted standards of practice;
- Having a felony conviction;

[80] § 12-280-124(1)(a), C.R.S.
[81] § 12-280-124(1)(a), C.R.S.
[82] § 12-280-124(3), C.R.S.
[83] 3 CCR 719-1 § 3.00.30, State Board of Pharmacy Rules.
[84] § 12-280-134(1)(a), C.R.S.
[85] §§ 12-280-127(1) and 12-20-404(1), C.R.S.
[86] § 12-280-127(5), C.R.S.
[87] § 12-280-126(1), C.R.S.

- Having a substance use disorder or engaging in the habitual or excessive use or abuse of alcohol or drugs;
- Engaging in advertising that is misleading, deceptive or false;
- 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 certificate in another state within 30 days after the discipline.

The grounds for discipline also include the following conduct:[88]

- Failing to notify the Board of a health condition that affects the individual's ability to practice safely,
- Failing to Act within the limitations created by the health condition, and
- Failing to comply within the conditions of a confidential agreement with the Board.

The Board is also authorized to enter into a confidential agreement with a licensee who has a health condition that impacts his or her ability to practice safely so that the licensee may continue to practice within the limitations of the health condition.[89] A confidential agreement is not considered disciplinary action, but the Board may take disciplinary action against a licensee who violates a confidential agreement.

The Board may issue a letter of admonition if it finds that a licensee, certificate holder or registrant has committed any acts that are grounds for discipline. The Board is also authorized to issue a letter of concern if it finds that conduct does not warrant formal disciplinary action and should be dismissed, but the conduct could lead to serious consequences if not corrected.[90]

The Act delineates several unlawful acts, such as practicing without a license or dispensing a drug by forging an order.[91] Anyone who commits an unlawful act may be assessed a civil fine of no less than $1,000 and no more than $10,000 per violation.[92]

Anyone who practices pharmacy or practices as a pharmacy technician without a license or certification, commits a Class 2 misdemeanor, which is punishable by a prison sentence of three months to 364 days or a fine of $250 to $1,000, or both. Any subsequent offense is a Class 6 felony, punishable by a prison sentence of one to two years or a fine of $1,000 to $100,000, or both.[93]

[88] § 12-280-126(1)(r), C.R.S.
[89] §§ 12-280-136(1) and 12-30-108(2)(a), C.R.S.
[90] §§ 12-280-127(1) and 12-20-404(4) and (5), C.R.S.
[91] § 12-280-129(1), C.R.S.
[92] § 12-280-129(2)(a), C.R.S.
[93] §§ 12-280-130(1) and (2), 12-20-407(1)(a), 18-1.3-501 and 18-1.3-401, C.R.S.

PART 2 PHARMACY PEER HEALTH ASSISTANCE DIVERSION PROGRAM

The pharmacy peer assistance program was created to provide assistance to practitioners who are experiencing impaired practice due to psychiatric, psychological or emotional problems or excessive alcohol or drug use or addiction.[94]

The Board may utilize the peer assistance program as an alternative to or in conjunction with formal discipline of a licensed pharmacist or intern.[95] 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 to support the peer assistance program.[96]

Under the peer assistance program, the Board may select one or more organizations to provide the following services to licensees:[97]

- Education related to recognition and prevention of physical, emotional and psychological problems;
- Evaluation of physical, emotional and psychological problems;
- Referrals for treatment of these conditions;
- Monitoring licensees who have been referred for treatment; and
- Counseling and support to licensees who are in treatment.

PART 3 WHOLESALERS

Under the Act, a wholesaler is defined as:[98]

> a person engaged in the wholesale distribution of prescription drugs to persons, other than consumers, who are entitled to possess prescription drugs, including: repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; pharmacy buying cooperative warehouses; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

Part 3 of the Act 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 within Colorado.[99]

[94] § 12-280-201(1), C.R.S.
[95] § 12-280-201(2), C.R.S.
[96] § 12-280-201(2)(a), C.R.S.
[97] § 12-280-203(2)(b), C.R.S.
[98] § 12-280-103(55), C.R.S.02.
[99] § 12-280-303(1)(a), C.R.S.

A wholesaler must obtain a license for each facility that is used to distribute prescription drugs.[100] Each wholesale facility must have a designated representative, and a wholesaler must report the names of each designated representative to the Board upon application for a license and during license renewal. Wholesalers must also submit a personal information statement and fingerprints for each designated representative.[101]

The Board may conduct a physical inspection of wholesale facilities prior to issuing a license. The inspection may also be conducted by another state or a Board-approved accreditation body.[102]

A wholesale facility is required to keep an inventory and records of all prescription drugs that it receives and distributes. If the distribution of a prescription drug takes place outside the normal distribution channel,[103] then the facility records must include a pedigree of the prescription drug. An example of the normal distribution channel is from manufacturer to wholesale facility to pharmacy to patient.[104] A pedigree of a prescription drug must provide detailed information related to the drug's chain of distribution.[105]

Anyone who violates Part 3 of the Act may be fined as much as $50,000, and anyone who knowingly violates Part 3 of the Act may be fined as much as $500,000.[106]

[100] § 12-280-303(6), C.R.S.
[101] § 12-280-303(3)(a)(VII), C.R.S.
[102] § 12-280-303(4), C.R.S.
[103] § 12-280-306(1), C.R.S.
[104] § 12-280-301(6), C.R.S.
[105] § 12-280-306(3), C.R.S.
[106] §§ 12-280-307(1) and (2), C.R.S.

Program Description and Administration

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The third, fourth and fifth sunset criteria question:

> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures 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; and
>
> 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.

In part, COPRRR utilizes this section of the report to evaluate the agency according to these criteria.

The State Board of Pharmacy (Board), located within the Division of Professions and Occupations (Division) in the Department of Regulatory Agencies, is entrusted with regulating the practice of pharmacy.[107] The Board consists of seven members, including five licensed pharmacists and two public members, who are appointed by the Governor. The Board meets six times a year to discuss policy issues, conduct rulemaking and consider licensing, complaint and disciplinary matters.

Table 1 illustrates the Board expenditures and full-time equivalent (FTE) employees associated with the regulation of the practice of pharmacy over a five-year period.

Table 1
Fiscal Information

Fiscal Year	Expenditures	FTE
14-15	$1,383,890	7.75
15-16	$1,399,841	5.75
16-17	$1,240,738	7.05
17-18	$1,463,756	7.15
18-19	$1,663,806	7.85

[107] § 12-280-101, C.R.S.

Fluctuations in expenditures are primarily attributed to legal expenses which change from year to year depending on the types and number of disciplinary cases before the Board. In fiscal year 16-17, the decrease in expenditures is due, in part, to the manner in which resources were allocated.

The FTE numbers in Table 1 do not include employees in the centralized offices of the Division, which provide licensing, administrative, technical and investigative support to the program. However, the cost of these employees is reflected in the total program expenditures.

As of July 1, 2019, 7.85 FTE were dedicated to the Board, including:

- Program Director, Program Management II (0.30 FTE)—who manages the program, personnel, complaint resolution process, stakeholder engagement, Board member recruitment, outreach and education;
- Pharmacist III (1.0 FTE)—who is responsible for overall management of the pharmacy program, personnel management, complaint resolution, stakeholder engagement, Board member recruitment, outreach and education;
- Pharmacist II (4.0 FTE)—who conduct pharmaceutical compliance and performance audits, inspect registered pharmaceutical outlets, investigate complaints and possible fraud and conduct drug accountability audits of registered outlets;
- Administrator III (0.05 FTE)—who is responsible for complaint intake, Board packet preparation and follow-up, referrals to the Office of Investigations and Expedited Settlement Program and issuing disciplinary correspondence;
- Technician IV (0.30 FTE)—who is responsible for case management, correspondence, case summary preparation, practice monitoring, board packet preparation, board follow-up, initial decision follow-up and referrals to the Expedited Settlement Program and Office of the Attorney General;
- Technician III (0.70 FTE)—who is responsible for statute and rule review, case summary preparation and case management; and
- Administrative Assistant III (1.5 FTE)—who are responsible for complaint intake, correspondence, case summary preparation and final action processing.

The Board issues licenses to pharmacists and interns, and it registers pharmacies, wholesalers and manufacturers. The licensing and registration fees may be found in Appendix A.

The Board began issuing certificates to pharmacy technicians in 2020, and the certification fee for pharmacy technicians is $57.

Licenses, certificates and registrations expire on October 31 every other year. Pharmacists, interns and pharmacy technicians renew in even numbered years, and entities renew in odd numbered years.

Pharmacists and interns must also pay a surcharge on their license fees to fund a peer assistance program for pharmacists who experience health conditions or substance abuse problems that require evaluation and monitoring in order to continue to practice safely. The surcharge in fiscal year 20-21 is $40.

Licensing and Certification

An individual must be licensed by the Board in order to engage in the practice of pharmacy. An individual may be licensed as pharmacist or an intern, and a pharmacy technician must be certified by the Board in order to practice as a pharmacy technician.

The qualifications necessary to be licensed as a pharmacist are:

- A doctorate degree from a school of pharmacy,
- Passage of a written examination to demonstrate competency and a jurisprudence examination, and
- Completion of an internship of at least 1,500 hours.

To be licensed as a pharmacy intern, an applicant must be enrolled in or have graduated from an accredited school of pharmacy.

The qualifications required to obtain Board certification as a pharmacy technician include private, professional certification and passage of a criminal history record check. A pharmacy technician may obtain provisional certification from the Board so that they may work as a pharmacy technician while they are completing the requirements for private, professional certification.

In order to obtain a license or certificate, an applicant must complete and submit an application, application fee and supporting documentation to the Division's Licensing Section. A licensing specialist reviews the application and notifies the applicant of any deficiencies. Once the application is complete, a licensing specialist evaluates the application to ensure the applicant meets the requirements. If all the requirements are satisfied, the license is issued. If not, the licensing specialist notifies the applicant in writing, and the application is kept on file for one year.

An application with any issues, such as one or more felony convictions, is sent to the Board for consideration. The Board may approve or deny the application, or it may open an investigation.

Table 2 illustrates the total number of licenses issued to pharmacists over a five-year period.

Table 2
Pharmacist Licenses

Fiscal Year	Initial	Endorsement	Renewal	Reinstatement	Active
14-15	248	242	n/a*	22	7,683
15-16	253	231	7,249	27	7,650
16-17	218	225	n/a	37	8,149
17-18	232	258	7,625	25	8,093
18-19	228	258	n/a	18	8,678

*Not applicable

The total number of actively licensed pharmacists increased by approximately 13 percent over the five-year period.

A pharmacy intern is a student who works at a pharmacy under the supervision of a licensed pharmacist in order to obtain experience. A pharmacy intern may be responsible for weighing, packaging and counting pills, as well as providing information to customers.[108]

Table 3 demonstrates the total number of licenses issued to pharmacy interns over a five-year period.

Table 3
Pharmacy Intern Licenses

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	414	n/a*	12	1,503
15-16	440	855	10	1,276
16-17	396	n/a	10	1,526
17-18	430	754	7	1,235
18-19	398	n/a	6	1,552

*Not applicable

The total number of actively licensed pharmacy interns fluctuates depending on whether it is a renewal year or not. Pharmacy interns must complete four years of education, obtain 1,500 hours of experience as a pharmacy intern and pass an examination in order to obtain full licensure, and it may take a pharmacy intern several years to complete these requirements. In renewal years, the number of actively licensed pharmacy interns would likely decrease because pharmacy interns who have

[108] PayScale. *Pharmacy Intern.* Retrieved November 25, 2019, from https://www.payscale.com/research/US/Job=Pharmacy_Intern/Hourly_Rate

completed the requirements for full licensure would not need to renew their intern licenses.

A pharmacy technician assists a pharmacist in a retail pharmacy or hospital with dispensing prescription medication.[109] Pharmacy technicians may only conduct certain tasks under the supervision of a licensed pharmacist, such as:[110]

- Collecting information to fill a prescription,
- Measuring medication for prescriptions,
- Packaging and labeling prescriptions,
- Taking inventory,
- Collecting payment and processing insurance claims,
- Entering customer or patient information,
- Answering customer phone calls, and
- Referring customers with questions about medication or health matters to pharmacists.

Pharmacy technicians were statutorily required to obtain certification as of March 30, 2020. However, due to COVID-19, the Board extended the deadline to August 29, 2020.

As of June 1, 2020, the Board had issued 4,479 certificates and 2,330 provisional certificates to pharmacy technicians.

Registration

Any business that engages in the practice of pharmacy in Colorado must be registered by the Board as one of the following:

- A prescription drug outlet (pharmacy),
- A wholesaler, or
- A manufacturer.

Table 4 shows the total number of in-state pharmacies registered in Colorado over a five-year period.

[109] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm
[110] U.S. Bureau of Labor Statistics. *Pharmacy Technicians.* Retrieved November 25, 2019, from https://www.bls.gov/ooh/healthcare/print/pharmacy-technicians.htm

Table 4
In-State Pharmacy Registrations

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	27	918	0	947
15-16	25	n/a	0	946
16-17	28	968	0	925
17-18	23	n/a	0	949
18-19	25	966	0	978

*Not applicable

While the number of actively licensed in-state pharmacies declined from fiscal year 14-15 to fiscal year 16-17, Colorado experienced a slight increase over the five-year period. The Division did not have any direct knowledge as to the reason for the decrease in actively registered in-state pharmacies in fiscal year 16-17.

Table 5 provides the total number of in-state wholesalers registered in Colorado over a five-year period.

Table 5
In-State Wholesaler Registrations

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	2	67	0	67
15-16	5	n/a	0	69
16-17	7	63	1	69
17-18	3	n/a	0	69
18-19	4	65	0	69

*Not applicable

The number of actively licensed in-state wholesalers increased by two in fiscal year 15-16, but remained constant over the following years.

Table 6 illustrates the total number of manufacturers registered in Colorado over a five-year period.

Table 6
Manufacturer Registrations

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	4	24	0	27
15-16	2	n/a	0	29
16-17	7	25	0	31
17-18	2	n/a	0	30
18-19	1	30	1	31

Over the five-year period, the number of actively licensed manufacturers increased by about 15 percent.

Data related to additional registration types, such as other outlets, out-of-state pharmacies and out-of-state wholesalers, may be found in Appendix B.

Examinations

The eighth sunset criterion questions whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

In order to obtain a license as a pharmacist in Colorado, an applicant must pass two examinations, the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE). Both examinations are developed by the National Association of Boards of Pharmacy (NABP) and administered by Pearson Vue.

The purpose of the NAPLEX is to assess a candidate's knowledge of the practice of pharmacy,[111] and the purpose of the MPJE is to assess a candidate's ability to evaluate situations involving federal and state laws that govern the practice of pharmacy. An applicant must take the MPJE for each state in which he or she is seeking licensure.[112]

The NAPLEX is a computer-based examination that consists of 250 questions, of which 200 are scored. The additional 50 questions, which are scattered throughout the examination, are considered for future examinations. The examination consists of scenario-based questions and stand-alone questions. The NAPLEX is a fixed-form

[111] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), p. 25.
[112] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), pp. 31-32.

examination, so each question must be answered in the order presented. A candidate has six hours to complete the examination.[113]

The NAPLEX is scored on a scale of 0 to 150, using a weighted scoring model. The minimum passing score is 75.[114]

The MPJE is also a computer-based examination that consists 100 scored questions and 20 unscored questions. The additional questions are considered for future examinations. The MPJE is an adaptive examination, in which the ability of a candidate is assessed based on his or her responses and the questions that follow are adjusted accordingly. A candidate has two and a half hours to complete the examination.[115]

The passing score for the MPJE is 75, based on a scale of 100.[116]

Both examinations are offered at Pearson Vue testing centers located in:[117]

- Colorado Springs,
- Fort Collins,
- Greenwood Village, and
- Westminster.

The NAPLEX costs a total of $575, including the application and the examination fees, and the MPJE costs a total of $250.[118]

In some states, including Colorado, the NABP confirms whether a candidate is eligible to sit for the examination and charges an additional fee of $85.[119]

Table 7 provides the total number of NAPLEX and MPJE examinations administered in Colorado for all test-takers and the pass rates for both examinations over a five-year period.

[113] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), p. 25.
[114] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), p. 39.
[115] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), p 31.
[116] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), p. 31.
[117] Pearson Vue. *Find a Test Center*. Retrieved on September 14, 2020, from https://home.pearsonvue.com/Test-takers.aspx *See page, enter NABP into search field and then enter Colorado to find test centers.*
[118] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), p. 3.
[119] *NAPLEX & MPJE 2020 Candidate Bulletin,* National Association of Boards of Pharmacy (2020), p. 13.

Table 7
NAPLEX & MPJE

Fiscal Year	NAPLEX Examinees	NAPLEX Pass Rates	MPJE Examinees	MPJE Pass Rates
14-15	198	94%	542	94%
15-16	238	90%	567	92%
16-17	228	80%	627	84%
17-18	211	88%	562	85%
18-19	195	93%	610	85%

The pass rates for the NAPLEX and the MPJE fluctuate from year to year. On average the pass rates are about 89 percent for the NAPLEX and 88 percent for the MPJE, which are somewhat high and may indicate that examinees are well prepared.

Complaint and Disciplinary Activity

The seventh sunset criterion requires COPRRR to examine 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.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

Anyone, including patients, families of patients and other health-care providers, can file a complaint with the Board, or the Board may open a complaint upon its own motion.

Table 8 provides the total number of complaints filed against licensed pharmacists broken down by type over a five-year period.

Table 8
Complaints Filed Against Pharmacists

Type	Fiscal Years				
	14-15	15-16	16-17	17-18	18-19
Violation of federal or state laws	108	143	138	124	106
Having a felony conviction	1	2	11	2	2
Incompetent to practice pharmacy	9	14	16	11	9
Habitual or excessive use or abuse of alcohol, a habit-forming drug, or a controlled substance	9	1	4	14	11
License revoked or suspended in another state	0	0	3	1	2
Failure to notify the Board of a criminal conviction	4	1	1	6	1
Failure to notify the Board of discipline in another state	0	0	0	0	7
Engaging in unlawful acts	0	0	2	0	0
Dispensing without a prescription	0	0	0	0	4
Dispensing without a proper label	0	0	0	0	1
Violating rules regarding initial interpretation and final evaluation of orders or prescriptions	26	0	0	0	0
Failing to secure dispensing/compounding areas	8	0	0	0	0
Failure to ensure drugs procured from authorized source.	0	1	0	0	0
Failure to notify the Board of legal proceedings	3	0	0	0	0
Violation of a Board order	8	2	0	14	9
Unlicensed practice	5	13	8	3	8
Other	0	3	23	0	0
Total	**181**	**177**	**183**	**175**	**160**

"Violations of federal or state laws," which is how the vast majority of complaints in Table 8 are characterized, cover a broad array of allegations, so it is difficult to ascertain what those complaints specifically alleged.

The statutory citations provided to COPRRR for the complaints reported as "Other" in Table 8, refer to statutes that were repealed in 2003 and generally discuss types of disciplinary actions, as opposed to alleged violations that could have led to disciplinary

action. These are not tabulated in the total number of complaints but are reported here for reference only since they were reported by the Division as alleged violations.

Regardless, it is apparent from Table 8 that the Board consistently fields complaints against pharmacists related to felony convictions, incompetence, and drug and alcohol use.

Table 9 provides the number of complaints filed against pharmacy interns broken down by type over a five-year period.

Table 9
Pharmacy Interns

Type	Fiscal Years				
	14-15	15-16	16-17	17-18	18-19
Misrepresentation, fraud or deceit; Having a felony conviction; or Violating the Act, the Board rules or federal law	2	2	7	0	0
Failure to meet the standards of practice	0	1	0	15	13
Incompetent to practice pharmacy	0	0	0	5	2
Habitual or excessive use or abuse of alcohol, a habit-forming drug, or a controlled substance	0	0	1	0	0
Violation of a Board order	0	0	1	4	5
Other	0	0	1	0	0
Total	**2**	**3**	**9**	**24**	**20**

"Misrepresentation, fraud or deceit; Having a felony conviction; or Violating the Act, the Board rules or federal law," which is how many complaints in Table 9 are characterized, covers a broad array of allegations, so it is difficult to ascertain what those complaints specifically alleged.

The statutory citation provided to COPRRR for the complaint reported as "Other" in Table 9, refers to a statutory provision that was repealed in 2003 and generally discusses disciplinary action, as opposed to an alleged violation that could have led to disciplinary action. This complaint is not tabulated in the total number of complaints but is reported here for reference only since it was reported by the Division as an alleged violation.

However, it is apparent that, in the two most recent fiscal years, "failure to meet the standards of practice" was the most commonly reported complaint.

Table 10 provides the number of complaints, broken down by type, filed against pharmacy businesses, including in-state and out-of-state pharmacies, wholesalers and manufacturers, over a five-year period.

Table 10
Complaints Filed Against Pharmacy Businesses

Type	Fiscal Years				
	14-15	15-16	16-17	17-18	18-19
Misrepresentation, fraud or deceit; Having a felony conviction; or Violating the Act, the Board rules or federal law	145	220	142	532	223
Failing to meet the standard of practice	0	0	0	503	363
Substituting a drug with incorrect or wrong criteria	1	0	0	0	0
Incompetent to practice pharmacy	0	1	9	0	0
Habitual or excessive use or abuse of alcohol, a habit-forming drug, or a controlled substance	0	1	4	0	0
License revoked or suspended in another state	0	0	5	0	3
Failing to notify the Board of discipline in another state	0	0	0	68	30
Failure to notify Board of legal proceedings	10	0	0	10	0
Failure to submit required information to the Board	11	0	0	0	0
Failure to disclose/update information	0	0	0	0	1
Failure to have supervising pharmacist	0	0	0	14	13
Refilling a prescription without an order	0	0	0	0	4
Failing to properly label a prescription	0	0	0	0	8
Failing to properly label drug	2	0	0	0	0
Dispensing the wrong drug or brand	0	0	0	0	1
Violating initial interpretation and final evaluation rules	15	1	0	0	0
Failing to properly record or retain records of initial interpretation/final evaluation of an order	1	0	0	0	0
Failing to properly secure dispensing/compounding area	16	3	1	0	0
Violation of a Board order	0	0	2	0	3
Unauthorized practice of pharmacy	0	0	0	0	2
Other	0	1	22	2	23
Total	**201**	**226**	**163**	**1,127**	**651**

"Misrepresentation, fraud or deceit; Having a felony conviction; or Violating the Act, the Board rules or federal law," which is how the vast majority of complaints in Table

10 are characterized, covers a broad array of allegations, so it is difficult to ascertain what those complaints specifically alleged.

The statutory citations provided to COPRRR for the complaints reported as "Other" in Table 10, refer to statutes that were repealed in 2003 and generally discuss types of disciplinary actions, as opposed to alleged violations that could have led to disciplinary action. They are not tabulated in the Total complaints but are reported here for reference only since they were reported by the Division as alleged violations.

Table 11 provides the number and type of final agency actions against pharmacists taken by the Board over a five-year period.

Table 11
Final Agency Actions
Pharmacists

Type	Fiscal Years				
	14-15	15-16	16-17	17-18	18-19
Denial	0	1	2	0	0
Revocation	0	0	1	2	5
Voluntary Surrender/Relinquishment	3	4	4	2	5
Suspension	1	0	0	0	0
Stipulation/Final Agency Order	43	18	47	34	9
Letter of Admonition	1	0	3	8	7
Confidential Agreement	0	1	0	1	1
Injunction	0	0	0	0	0
Cease & Desist Order	7	6	3	0	2
Total Disciplinary Actions	**55**	**30**	**60**	**47**	**29**
Dismissal	21	35	42	48	35
Confidential Letter of Concern	44	49	37	50	63
Total Dismissals	**65**	**84**	**79**	**98**	**98**

Over the five-year period, the Board denied three licenses to pharmacists, and it entered into three confidential agreements with pharmacists who agreed to limit their practice because they had health conditions that impaired their ability to practice safely.

The Board also took the following disciplinary actions: 19 letters of admonition, 8 license revocations, 151 stipulated agreements or final agency orders and one license suspension. Additionally, 18 pharmacists voluntarily surrendered or relinquished their

licenses. The Board also issued 18 cease and desist orders for practicing without a license.

The fluctuations in the number of stipulated agreements in Table 11 may be due to the volume of complaints in previous years since complaints may be received in one year but may not be settled during the same year.

Table 12 provides the number and type of final agency actions taken by the Board against pharmacy interns over a five-year period.

Table 12
Final Agency Actions
Pharmacy Interns

Type	Fiscal Years				
	14-15	15-16	16-17	17-18	18-19
Denial	0	0	0	0	0
Revocation	0	0	0	0	0
Voluntary Surrender/Relinquishment	0	0	3	0	1
Suspension	0	0	0	0	0
Letter of Admonition	0	0	0	0	2
Stipulation/Final Agency Order	1	0	0	1	1
Confidential Agreement	0	0	0	0	0
Injunction	0	0	0	0	0
Cease & Desist Order	0	0	0	0	0
Total Disciplinary Actions	**1**	**0**	**3**	**1**	**4**
Dismissal	1	0	4	7	6
Confidential Letter of Concern	1	1	0	5	2
Total Dismissals	**2**	**1**	**4**	12	**8**

The Board took few actions against pharmacy interns over the five-year period, and it denied no pharmacy intern licenses. The Board entered into three stipulated agreements or final agency orders with pharmacy interns and issued two letters of admonition. Four pharmacy interns voluntarily surrendered or relinquished their licenses.

Table 13 provides the number and type of final agency actions taken against registered businesses by the Board over a five-year period.

Table 13
Final Agency Actions
Registered Businesses

Type	Fiscal Years				
	14-15	15-16	16-17	17-18	18-19
Denial	0	0	0	0	0
Revocation	1	0	0	7	2
Voluntary Surrender/Relinquishment	4	0	6	0	5
Suspension	0	0	0	0	0
Stipulation/Final Agency Order	49	33	82	23	64
Letter of Admonition	1	0	2	12	24
Injunction	0	0	0	0	0
Cease & Desist Order	0	0	0	0	0
Total Disciplinary Actions	**55**	**33**	**90**	**42**	**95**
Dismissal	37	38	69	78	142
Confidential Letter of Concern	69	68	38	64	392
Total Dismissals	**106**	**106**	**107**	**142**	**534**

The Board issued 39 letters of admonition against registered businesses and entered into 251 stipulated agreements or final agency orders. It also revoked the registration of 10 businesses, and 15 businesses voluntarily surrendered or relinquished their registration.

The increase in revocations in fiscal year 17-18 and letters of admonition in fiscal year 18-19 may be related to enforcement actions taken by the Board for illegal distribution of compounded drugs into Colorado.

The fluctuations in the number of stipulated agreements in Table 13 may be attributed to the volume of complaints in previous years since complaints may be received in one year but may not be settled in the same year.

Fining Activity

The seventh sunset criterion requires COPRRR to examine 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.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The Board does not have the authority to issue administrative fines against pharmacists, pharmacy interns or pharmacy technicians. However, it may seek civil fines against them. It does, however, have the authority to issue administrative fines against registered businesses.

Table 14 illustrates the total number and amount of civil fines paid by pharmacists.

Table 14
Licensed Pharmacists
Civil Fines Paid

Fiscal Year	Number	Amount
14-15	0	0
15-16	0	0
16-17	2	$14,000
17-18	2	$4,000
18-19	3	$4,000

The basis for the fining activity above was related to unlawful use of the Colorado PDMP. The number and amount of civil fines assessed against pharmacists for each fiscal year of the five-year period were not available during the review.

The Board assessed 36 fines totaling $46,000 against registered businesses in fiscal year 18-19. No additional detail was available regarding the number of fines or the reasons for them.

Inspections

The seventh sunset criterion requires COPRRR to examine 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.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The Board conducts inspections of each registered business located in Colorado at least once a year if possible.

When inspecting a pharmacy, inspectors check for dispensing errors, such as dispensing the wrong drug, the wrong dose of a drug or providing incorrect instructions on the label. They verify that areas where drugs are being compounded are sterile and that expired drugs are not being used. Inspectors also carefully examine pharmacy records to uncover possible indications of drug diversion, among other things.

At a wholesaler, inspectors verify that drugs are being stored at the correct temperature and under proper conditions. They confirm that a wholesaler has a designated representative in charge who is responsible for complying with pharmacy laws. Inspectors also examine records to verify that wholesalers are only shipping medicated food stock to animals with valid prescriptions.

When inspectors find deficiencies, the Board may order a re-inspection depending on the number and severity of the deficiencies. In most cases, the Board inspectors note deficiencies on an inspection report and discuss the findings with the pharmacy manager. The Board offers registered businesses an opportunity to remedy deficiencies over time. When inspectors uncover a pattern of deficiencies that remain uncorrected by a pharmacy, the Board considers disciplinary action. If the deficiencies are related to areas that could affect the public health, such as problems related to compounding drugs, the Board may issue a higher fine than for other deficiencies, such as problems with recordkeeping or other administrative errors.

Table 15 shows the total number of inspections conducted by the Board over a five-year period.

Table 15
Inspections

Fiscal Year	Inspections
14-15	1,380
15-16	1,112
16-17	886
17-18	1,200
18-19	1,411

The low number of inspections in fiscal year 16-17 is attributed to the allocation of resources. Not including fiscal year 16-17, the Board inspects on average about 1,275 registered businesses a year.

Collateral Consequences – Criminal Convictions

The ninth sunset criterion requires COPRRR to examine whether the agency under review, through its licensing processes, imposes any sanctions or disqualifications based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The Board has the authority to deny, revoke or suspend a license. The Board may also require an applicant or a licensee to enter into a stipulated agreement in which the licensee is subject to requirements such as probation, continuing education, substance abuse treatment and monitoring, or other requirements to ensure the licensee is competent to practice. In Table 16, these are referred to as conditional licenses.

Table 16 illustrates, over a five-year period, the number and type of license disqualifications or conditional licenses entered into with pharmacists that were based on criminal conduct.

Table 16
Collateral Consequences—License Disqualifications Based on Criminal Conduct
Pharmacists

Nature of Disqualifications	FY 14-15	FY 15-16	FY 16-17	FY 17-18	FY 18-19
Denials	0	0	0	0	0
Revocations	0	0	0	0	0
Suspensions	0	0	0	0	0
Interim Cessation of Practice	0	0	0	0	0
Conditional Licenses	0	0	1	0	0
Total	**0**	**0**	**1**	**0**	**0**

The Board issued one conditional license to a pharmacist on the basis of having a felony conviction.

No pharmacy intern licenses were disqualified based on criminal conduct.

As the Board only began issuing certificates to pharmacy technicians in 2020, disqualifications based on criminal conduct for pharmacy technicians is not reported in this section. However, in future reports, any license disqualifications related to pharmacy technicians will be reported here.

Analysis and Recommendations

The final sunset criterion questions whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest. The recommendations that follow are offered in consideration of this criterion, in general, and any criteria specifically referenced in those recommendations.

Recommendation 1 – Continue Parts 1, 2 and 3 of the Pharmacists, Pharmacy Business and Pharmaceuticals Practice Act for nine years, until 2030, and schedule Part 5 and 6 for sunset review concurrently with the other parts of the Act.

The Pharmacists, Pharmacy Business and Pharmaceuticals Practice Act (Act), is located in section 12-280-101, *et seq.*, Colorado Revised Statutes (C.R.S.), and is composed of the following six parts:

- **Part 1,** which concerns the general provisions related to the State Board of Pharmacy (Board) membership and its powers and duties, and the regulation of pharmacists, pharmacy businesses and pharmaceuticals by the Board;
- **Part 2,** which concerns the Pharmacy Peer Health Assistance Diversion Program (peer assistance program);
- **Part 3,** which concerns the regulation of wholesale drug outlets (wholesalers);
- **Part 4,** which concerns the Colorado Electronic Prescription Drug Monitoring Program (Colorado PDMP);
- **Part 5,** which concerns therapeutic interchange and therapeutically equivalent selections; and
- **Part 6,** which concerns collaborative pharmacy practice and statewide protocols.

This sunset review considers only Parts 1, 2 and 3 of the Act. Part 4 of the Act, which governs the Colorado PDMP, is currently undergoing a separate sunset review, and Parts 5 and 6 of the Act are not scheduled for a sunset review.

The Board, which is housed in the Division of Professions and Occupations (Division) in the Department of Regulatory Agencies, is entrusted with the enforcement of the Act.

Sunset reviews are guided by statutory criteria found in section 24-34-104, C.R.S., and the first criterion asks whether regulation is necessary to protect the health, safety and welfare of the public.

Part 1 of the Act protects the public by ensuring that pharmacists, pharmacy interns and pharmacy technicians are qualified and by vesting the Board with the authority to discipline pharmacists who violate the Act or the Board rules.

A pharmacist is a professional who prepares and dispenses medication prescribed by a licensed health-care provider. Pharmacists may fill prescriptions, check for possible negative interactions with other drugs, advise patients on how and when to take medications, administer flu shots and other vaccinations, and supervise pharmacy technicians and interns. Pharmacists may also mix ingredients to create customized medications for patients.

A pharmacist may harm a patient by dispensing the wrong medication or the wrong dose of a medication. A pharmacist who compounds medications may fail to use sterile methods and cause the medication to be contaminated, which can cause serious health problems and may be fatal. A pharmacist may also harm a patient by dispensing a medication that should not be combined with other medications prescribed to the patient. Considering this, it is especially important to ensure that pharmacists are competent to practice.

Part 1 of the Act requires applicants to have a doctorate from a school of pharmacy approved by the Board, pass the North American Pharmacist Licensure Examination and the Multistate Pharmacy Jurisprudence Examination, and complete 1,500 hours of experience as a pharmacy intern in order to be licensed.

Since a pharmacist requires a high level of education in order to practice and substandard practice may result in lifelong health problems and may even be fatal, licensure is the appropriate level of regulation.

Over a five-year period, the Board protected the public by enforcing the Act and taking the following disciplinary actions against pharmacists: 3 denied licenses, 8 revoked licenses, 151 stipulated agreements and 19 letters of admonition. Additionally, 18 pharmacists voluntarily surrendered or relinquished their licenses. The Board also took the following disciplinary actions against pharmacy interns: entered into 3 stipulated agreements and issued 2 letters of admonition. Four pharmacy interns voluntarily surrendered or relinquished their licenses.

Parts 1 and 3 of the Act also protect the public by requiring businesses that are engaged in the practice of pharmacy in Colorado to be registered with the Board as prescription drug outlets (pharmacies), wholesalers or manufacturers.

Board inspections of registered businesses uncover problems that have a direct effect on public health and help to bring registered businesses into compliance. Board inspections may uncover problems related to unsterile conditions for compounding, unsafe storage conditions, diversion of controlled substances and other problems that may have devastating consequences for patients and communities.

Over a five-year period, the Board protected the public by enforcing the Act and taking the following disciplinary actions against registered businesses: revoked the registration of 10 businesses, entered into 251 stipulated agreements and issued 39 letters of

admonition. Additionally, 15 registered businesses voluntarily surrendered or relinquished their registration.

Regulation of the practice of pharmacy is necessary to protect the public, and Parts 1 and 3 of the Act should be continued.

Part 2 of the Act is concerned with the peer assistance program, which provides services to practitioners who are experiencing impaired practice due to psychiatric, psychological, emotional or substance use disorders. The services provided by the peer assistance program include an evaluation of practitioners' health conditions, referrals for treatment of these conditions and monitoring practitioners who have been referred for treatment, in addition to other services. The peer assistance program is necessary to provide practitioners with certain health conditions the support that they need so they may safely return to practice, and Part 2 should be continued.

Considering the breadth and complexity of the Act, this sunset review resulted in relatively few recommendations, many of which are necessary to clean up the Act and will not impact the regulation of the practice significantly. As evidenced by the sheer number of bills passed to amend the Act in between sunset reviews, stakeholders face little difficulty in finding sponsors to pass legislation when necessary. Additionally, stakeholders reported that they are able to work with the Board when they are seeking changes to the rules and that the Board treats such requests fairly and reasonably. For these reasons, a nine-year continuation is appropriate.

During the sunset review, several issues related to Parts 5 and 6 of the Act were raised by stakeholders. Part 5 of the Act is concerned with therapeutic interchange and therapeutically equivalent selections, and Part 6 of the Act is concerned with collaborative pharmacy practice and statewide protocols. At this time, these parts of the Act and the related issues do not fall under the purview of this sunset review. Parts 5 and 6 are relatively new, so it is possible that no changes are necessary at this time. However, it would be reasonable to consider potential changes to Parts 5 and 6 during the next sunset review.

As regulation is necessary to protect the public, the General Assembly should continue Parts 1, 2 and 3 of the Act for nine years, until 2030, and it should also schedule Parts 5 and 6 for sunset review concurrently with the other parts of the Act.

Recommendation 2 – Align the Act with the federal Drug Quality and Security Act.

The federal Drug Quality and Security Act (DQSA), which amends the Food, Drug and Cosmetic Act, was passed by Congress in 2013. Among other things, the bill changed federal regulations related to compounding drugs, created a federal drug tracking and tracing system, and established licensing standards for wholesalers and third-party logistic providers.

Many portions of the Act no longer align with the federal provisions established by the DQSA. Because federal law preempts state law, certain parts of the Act are no longer enforceable, which impedes the Board's ability to protect the public.

Moreover, individuals and businesses regulated by the Board must comply with two sets of requirements, thereby creating an unnecessary, confusing and expensive regulatory burden. For example, state law allows compounded drugs to go directly from a pharmacy to a physician, as long as both are based in Colorado, but the federal law prohibits this, which is confusing for registered businesses and increases their exposure to regulatory actions. In other cases, the state law is more stringent than the federal law even when there is little risk of harm to the public. Aligning the Act with the DQSA would reduce the burden of the regulated community.

To align with the DQSA, the Act should be amended related to:

- **Third-party logistics providers**, by creating a license type specific to third-party logistics providers and removing the requirement that third-party logistics providers be licensed by the Board as wholesale distributors;

- **Pedigree requirements**, by replacing current pedigree requirements documenting the movements of a drug (from a manufacturer to a pharmacy) with new product tracing, product identification and product verification requirements;

- **Investigations of suspicious drugs**, by requiring that pharmacies, manufacturers, repackagers and wholesale distributors investigate any suspect products, as defined in the DQSA and as per the investigation, employ documentation and reporting procedures specified in the DQSA;

- **Definitions related to prescription drug wholesale distribution**, by including exemptions specified in the DQSA, for specific products (such as certain intravenous fluids, sterile water and medical gas), as well as for transfers of drugs between certain types of entities (such as the distribution of a drug by a charitable organization to a nonprofit affiliate of the organization); and

- **Compounding requirements**, by creating a new, separate license type for in-state and out-of-state 503B compounding facilities.

The sections of affected statutes span the Act, including, but not limited to:

- Section 12-280-103, C.R.S.;
- Section 12-280-119, C.R.S.;
- Section 12-280-120, C.R.S.; and
- Part 3 of Article 280 of Title 12, C.R.S.

Amending the Act to align with the DQSA would be consistent with other states. It would streamline regulations and create uniformity for regulated businesses, especially those that must follow the laws of several other states.

The second, third and fourth sunset criteria question:

> Whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest,
>
> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, and
>
> Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively.

Aligning the state law with the federal law will not compromise public protection; instead, it will create a more efficient and effective regulatory program and decrease the burden on the regulated community.

Therefore, the General Assembly should align the Act with the federal DQSA.

Recommendation 3 – Clarify that out-of-state prescription drug outlets do not need to register with the Board when distributing drugs to registered prescription drug outlets in Colorado when such transfers are for inventory control purposes. Require that the prescription drug outlets share common ownership and that the drugs remain in the original manufacturer's packaging and are not compounded.

In general, prescription drugs may lawfully enter Colorado by one of two ways. First, a nonresident prescription drug outlet (a pharmacy) may send a specific medication to a specific patient pursuant to a prescription drug order. Alternatively, a wholesaler may send drugs to an in-state wholesaler or to an in-state pharmacy.

On occasion, an in-state pharmacy may run out of a particular drug that a nearby, but out-of-state pharmacy under the same ownership has in stock. To meet customer demand and expeditiously dispense needed medications, the out-of-state pharmacy would like to transport the drug to the in-state pharmacy.

However, a series of laws and rules complicate this matter and cloud the issue as to whether the out-of-state pharmacy must register with the Board.

First, "wholesale distribution" means the "distribution of prescription drugs to persons or entities other than a consumer or patient."[120] Thus, the out-of-state pharmacy would

[120] § 12-280-103(54)(a), C.R.S.

appear to be acting as a wholesaler since it would be distributing the drugs to an entity that is not a consumer or patient.

The Act further requires,

> A wholesaler that does not reside in this state must be licensed in this state prior to engaging in the wholesale distribution of prescription drugs in this state.[121]

This indicates that the out-of-state pharmacy must register as a wholesaler in order to transfer the drugs to the in-state pharmacy.

To implement this provision, the Board has adopted Rule 1.00.24, which states,

> . . . a prescription drug outlet shall ensure that all prescription drugs and controlled substances are procured from another entity or person registered by the Board.[122]

At the same time, there are exceptions to the definition of "wholesale distribution." One exception is:

> Intracompany sales or transfers of prescription drugs, including a transaction or transfer between a division, subsidiary, parent, or affiliated or related company under common ownership or control of an entity[123]

This would seem to allow the nonresident pharmacy to ship drugs to its sister in-state pharmacy without the transaction being considered a wholesale distribution. However, the Board has interpreted this exception to require the nonresident entity to be licensed in its state of domicile as a wholesaler. Thus, this exception is inapplicable to the scenario under discussion here.

Another exception to the definition of "wholesale distribution" is:

> The sale or transfer or a drug for medical reasons by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage[124]

While this exception would seem to address the scenario under discussion here, the Board's interpretation and the precedent it has established by issuing orders to cease and desist such practices, render this exception inapplicable as well.

The second sunset criterion asks whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest.

In this case, the public interest is best served by patients receiving the medications that they need promptly so long as consumers are not at an increased risk of harm. The

[121] § 12-280-303(1)(a), C.R.S.
[122] 3 CCR § 719-1-1.00.24, State Board of Pharmacy Rules.
[123] § 12-280-103(54)(b)(I), C.R.S.
[124] § 12-280-103(54)(b)(III), C.R.S.

various statutes cited here, as well as others, seem to indicate that the General Assembly agrees. The highly technical interworking of statutory provisions, regulations and interpretations thereof, however, have rendered this intent impossible to implement.

One solution is to amend the second exception highlighted above to more specifically address the scenario under discussion here. For example, the statute could be amended to read:

> (III) The sale or transfer of a PRESCRIPTION drug, WHICH IS NOT COMPOUNDED OR PREPACKAGED BY THE SELLING OR TRANSFERRING PHARMACY EXCEPT AS ALLOWED PURSUANT TO SECTION 12-280-120(15)(b)(I), (II) and (III), C.R.S., for medical reasons by ~~a retail~~ AN IN-STATE OR UNREGISTERED NONRESIDENT pharmacy to ~~another retail~~ A SEPARATE IN-STATE pharmacy UNDER COMMON OWNERSHIP to alleviate a temporary shortage.

While making a change like this is less restrictive, at the same time, it is unlikely to increase the risk of harm to consumers.

Therefore, the General Assembly should clarify that nonresident prescription drug outlets do not need to register with the Board when distributing drugs to resident prescription drug outlets. To ensure drug safety and to ensure that this happens only when necessary, such transfers should be limited to those that are necessary for inventory control purposes. The General Assembly should also require that such transfers occur only among prescription drug outlets that share common ownership, and that the drugs remain in the original manufacturer's packaging and are not compounded.

Recommendation 4 – Provide explicit authority for the Board to inspect out-of-state pharmacies, wholesalers and out-of-state wholesalers, following a risk-based assessment.

Section 12-280-108(1)(a), C.R.S., authorizes the Board to inspect "all outlets." However, without clear authority, the Board has interpreted the Act to limit inspections to those facilities located within Colorado.

Currently, the Board receives alerts from the Federal Drug Administration when nationwide distributors may be a cause for concern, such as when high-risk drugs, especially compounds, have sterility concerns. Similarly, during regular inspections of Colorado pharmacies, Board inspectors may uncover concerns with medications distributed from a pharmacy or wholesaler based in another state.

When pharmacies and wholesalers distributing medications into Colorado are located in other states, the Board relies on the state where the registered business resides to conduct appropriate inspections; however, some states do not have the resources or the authority to conduct timely and appropriate inspections.

If the Board were provided clear authority to inspect out-of-state pharmacies and wholesalers, the Board would have the ability to protect consumers from drugs that may be contaminated. Because the Board has limited resources and staff, this authority would only be used when the Board has exhausted all other efforts and an out-of-state inspection is absolutely necessary to protect the public. Therefore, this authority should only be exercised following a risk-based assessment.

In 2011, inspections of several pharmacies in Colorado revealed problems with compounded sterile products manufactured by New England Compounding (NEC), a Massachusetts-based pharmacy acting as a wholesaler. Based on the problems identified and the fact that NEC was not authorized to distribute compounded drugs into Colorado, the Board issued a cease-and-desist order to NEC. At the time, neither the FDA nor the Massachusetts Board of Registration in Pharmacy took any action against NEC related to the issues identified in Colorado.

In violation of the Colorado cease-and-desist order, NEC continued to distribute the contaminated drugs into Colorado, which led to several consumer deaths, and also caused some consumers to suffer ongoing health problems. By 2012, 753 patients in 20 states were diagnosed with fungal meningitis related to NEC's tainted drugs and 64 of those patients died.

The third and fourth sunset criteria ask:

> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, and
>
> Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively.

In the above case, if the Board had clear authority to inspect NEC, it would have been in a better position to take more effective action to prevent the continued distribution of problematic drugs into Colorado.

The Board has seen similar cases, in which it would have been useful to have unambiguous authority to inspect out-of-state pharmacies or wholesalers. In most cases, the Board does not require this authority because it can depend on other states, but occasionally other states are uncooperative or they lack the necessary resources or authority to conduct inspections. In these cases, it is critical that the Board have explicit authority to conduct out-of-state inspections.

While the Board already has authority to inspect wholesalers authorized to do business in Colorado according to section 12-280-303, C.R.S., it would be reasonable to clarify this under the part of the Act that details the Board's powers and duties, and to explicitly authorize inspections of out-of-state wholesalers.

Therefore, the General Assembly should provide clear authority in section 12-280-108(1)(a), C.R.S., for the Board to inspect out-of-state pharmacies and in-state and out-of-state wholesalers, following a risk-based assessment.

Also, in Recommendation 2, COPRRR proposes aligning the Act with the federal DQSA. If the General Assembly adopts this recommendation, then this authority should also clearly apply to in-state and out-of-state 503B compounding facilities.

Recommendation 5 – Authorize pharmacists to make minor adaptions to prescriptions.

Pharmacists are required to obtain a doctorate in pharmacy, complete 1,500 hours of experience as a pharmacy intern and pass a national examination in order to practice. During this time, the focus of their education is on the study of drugs including, among other things, their therapeutic uses and toxicology.

Specifically, entry-level pharmacists must demonstrate that they are competent in obtaining, interpreting, assessing and evaluating information from patient interviews and medical records.[125] They are also required to demonstrate competency in developing and implementing individualized treatment plans, taking into consideration:[126]

- Specific uses, indications and dosing for drugs;
- Pharmacologic classes and characteristics of drugs;
- Actions and mechanisms of actions of drugs;
- Drug interactions;
- Contraindications, warnings and precautions;
- Pharmacodynamic,[127] pharmacokinetic,[128] and pharmacogenomic[129] principles;
- Pharmacokinetic data to determine equivalence among drug products; and
- Routes and methods of administration, dosage forms and delivery systems.

Additionally, entry-level pharmacists must demonstrate competency in assessing and modifying individualized treatment plans, considering:[130]

[125] National Association of the Boards of Pharmacy. *NAPLEX Competency Statements.* Retrieved August 31, 2020, from https://nabp.pharmacy/naplex-competency-statements/
[126] National Association of the Boards of Pharmacy. *NAPLEX Competency Statements.* Retrieved August 31, 2020, from https://nabp.pharmacy/naplex-competency-statements/
[127] Pharmacodynamic: Relating to the actions and effects of drugs on the body. Retrieved August 31. 2020, from https://www.thefreedictionary.com/Pharmacodymanics
[128] Pharmacokinetic: Relating to the absorption, distribution, metabolism and elimination of drugs in the body. Retrieved August 31. 2020, from https://medical-dictionary.thefreedictionary.com/pharmacokinetic
[129] Pharmacogenomic: Relating to genetic factors that affect a patient's response to a particular drug. Retrieved August 31. 2020, from https://medical-dictionary.thefreedictionary.com/pharmacogenomic
[130] National Association of the Boards of Pharmacy. *NAPLEX Competency Statements.* Retrieved August 31, 2020, from https://nabp.pharmacy/naplex-competency-statements/

- Therapeutic goals and outcomes,
- Safety of therapy,
- Efficacy of therapy, and
- Medication non-adherence or misuse.

As pharmacists are experts in medications and what they do to the body, they should be able to make minor adjustments to prescriptions when a physician has already completed a diagnosis and prescribed a specific drug. For example, if a patient has difficulty taking pills, it may benefit the patient for a pharmacist to change the form of a prescription from a pill to a liquid.

Authorizing pharmacists to make minor adaptions to prescriptions can reduce the time a patient must wait to fill a prescription. Today, when a pharmacist finds an obvious error such as a prescription for a three-day supply of blood pressure medication, he or she is required to call the prescriber in order to obtain approval to increase the prescription to 30 days. This is time consuming for the pharmacist, the prescriber and the patient.

Another example of a medication adaption is when a patient has several prescription drugs for chronic health conditions and a pharmacist extends a prescription for an additional seven days so that the patient can refill all his or her medications at the same time. When pharmacists synchronize prescriptions for patients who have multiple prescriptions they must fill, it can help to increase medication adherence. Patients are less likely to forgo filling medications when they can obtain them all at once, which is better for their health and could reduce unnecessary emergency room visits.

The second sunset criterion questions whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, and the eighth sunset criterion questions whether the scope of practice of the regulated community contributes to the optimum use of personnel.

Allowing pharmacists to use their professional judgement to make minor adaptions to prescriptions is well within the education and training of pharmacists and will benefit patients by increasing the likelihood that patients will adhere to the medication program, which should result in lower health-care costs overall. It would also allow prescribers to spend more time with their patients and less time on the phone with pharmacists, resulting in a more efficient health-care system throughout the state.

Therefore, the General Assembly should authorize a pharmacist who is acting in good faith, using professional judgement and exercising reasonable care, and who has obtained informed patient consent to make the following minor adaptions to prescriptions:

- Change the prescribed dosage form or directions for use if the change achieves the intent of the prescribing medical practitioner;

- Change the prescribed quantity if the prescribed quantity is not a package size commercially available from the manufacturer;
- Extend the quantity of a maintenance drug for the limited quantity necessary to achieve medication refill synchronization for the patient; and
- Complete missing information on the prescription order if there is sufficient evidence to support the change.

The General Assembly should require any pharmacist who adapts a prescription to document the adaptation in the patient's pharmacy record with the original prescription and the justification for the change, and notify the prescriber of any adaptation made. Also, a prescriber should be authorized to prohibit medication adaption strategies by writing "do not adapt" on the prescription.

Recommendation 6 – Increase the amount of medication that may be dispensed to an emergency room patient from a 24-hour supply to a 72-hour supply.

Under section 12-280-120(10), C.R.S., a medical practitioner may dispense a 24-hour supply of drugs to an emergency room patient. The purpose of this provision is to provide a patient with enough medication to maintain health until he or she can fill a prescription at a pharmacy. However, in rural areas, the 24-hour limit can be a problem.

The second sunset criterion questions whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest.

In remote areas of the state, a pharmacy may close over the weekend, over a holiday and during extreme weather conditions, and a patient may be required to travel a long distance in order to reach an open pharmacy. If a patient cannot find another pharmacy nearby, he or she may decide to forgo filling a prescription until the local pharmacy opens which could put his or her health at risk and may result in another emergency room visit.

A 72-hour supply, in such cases, would provide patients with enough medication to maintain their health until they can fill their prescriptions and may also help to reduce unnecessary health-care costs.

Therefore, the General Assembly should increase the amount of medications that may be dispensed to an emergency room patient to a 72-hour supply.

Recommendation 7 – Repeal the requirement that the purpose for an anabolic steroid appear on the label.

Section 12-280-124, C.R.S., concerns labeling requirements for prescription drugs. Among these, the Act requires the purpose for an anabolic steroid to be included on the label. It is questionable, however, whether this is necessary to protect the public.

While requiring the purpose for an anabolic steroid to appear on the label was likely well intentioned, it is unlikely to prevent misuse. For instance, while a physician may in fact prescribe steroids to enhance performance or for other nonmedical reasons, he or she may instead write another reason on the prescription.

This labeling requirement was enacted prior to the creation of the Colorado PDMP. Anabolic steroids are listed as controlled substances, and all controlled substances that are dispensed by pharmacists are entered into the Colorado PDMP, which is a statewide database. All pharmacists and prescribing practitioners may access the Colorado PDMP, and regulatory boards and law enforcement that are investigating a case related to misuse of controlled substances also have access to it. If an individual is obtaining an unusual quantity of anabolic steroids or obtaining them from several different practitioners, a pharmacist should be able to uncover this by looking at a patient's prescription history in the Colorado PDMP.

It is also grounds for discipline for a physician to prescribe an anabolic steroid without medical necessity. If there is a question about a physician's prescribing practices, he or she may be investigated by the Colorado Medical Board.

The first and second sunset criterion question:

> Whether the conditions that led to the initial regulation have changed and whether other conditions have arisen that would warrant more, less or the same degree of regulation; and
>
> Whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest.

The requirement for the purpose of an anabolic steroid to be included on the label may have provided some protection against steroid misuse at one time; however, today, it is likely obsolete. Moreover, Colorado does not require the purpose for any other prescription medication to be included on a label, and other controlled substances may be just as dangerous as anabolic steroids and many are more dangerous.

For these reasons, the General Assembly should repeal the requirement that the purpose for an anabolic steroid appear on a label.

Recommendation 8 – Repeal language related to substance use disorder in the grounds for discipline and simply prohibit habitual or excessive use or abuse of alcohol, drugs or controlled substances.

Under section 12-280-126(1)(e), C.R.S., a licensee may be disciplined upon the finding that he or she:

> Has a substance use disorder, as defined in section 27-81-102, or engages in the habitual or excessive use or abuse of alcohol, a habit-forming drug, or a controlled substance, as defined in section 18-18-102(5).

This provision should be amended to instead prohibit the habitual or excessive use or abuse of alcohol, a habit-forming drug or a controlled substance, and references to a "substance use disorder" should be repealed.

In *Robinson v. California*, 370 U.S. 660 (1962), the U.S. Supreme Court held that narcotic addiction is an illness and that any state law that seeks to punish a person because of an illness violates the Fourteenth Amendment. Although this case involved a criminal prohibition, it may be considered persuasive in the administrative context.

Furthermore, in *Colorado State Board of Nursing v. Crickenberger*, 757 P.2d 1167 (Colo. App. 1988), the Colorado Court of Appeals addressed a provision in the Nurse Practice Act substantially similar to the one at issue here. In vacating the Board's disciplinary action, the court held that the plain language of the statute requires addiction at the time of hearing.

These two cases, taken together, suggest that disciplinary action based on addiction is not the best way to discipline practitioners who abuse alcohol or controlled substances.

In *Colorado State Board of Medical Examiners v. Davis*, 893 P.2d 1365 (Colo. App. 1995), the Colorado Court of Appeals held that disciplinary action based on excessive use of alcohol or a controlled substance does not require current addiction or use of alcohol or controlled substances at the time of the disciplinary hearing.

The second and third sunset criteria ask:

> Whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, and
>
> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes.

Since it may be unconstitutional to discipline a practitioner based on addiction to controlled substances or alcohol and since "excessive use" does not require current addiction or use at the time of the disciplinary hearing, the existing language should be amended.

Several other practice acts have similar language in the grounds for discipline.

For these reasons, the General Assembly should align the grounds for discipline with other practice acts which prohibit habitual or excessive use or abuse of alcohol, habit forming drugs or controlled substances and repeal language referring to a substance use disorder.

Recommendation 9 – Require pharmacists and pharmacies to report malpractice settlements and judgments to the Board, and clarify in Title 10 that malpractice insurance carriers must also do so.

Currently, licensees and registered businesses are not required to report to the Board any malpractice settlements entered into on their behalf or malpractice judgments that have been entered against them.

The third sunset criterion asks whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes.

Malpractice cases often provide important information about whether a practitioner is competent to practice. If the underlying facts of a case demonstrate that harm was caused by substandard practice, the Board should be able to determine whether any steps are necessary to protect the public.

The statutes regulating other health-care professions, such as acupuncturists, dentists, physicians and podiatrists, require licensees to report malpractice settlements and judgments to the respective regulatory authority. As health-care providers, pharmacists should be subject to the same requirement.

Additionally, insurance companies who underwrite professional liability insurance for pharmacists and pharmacies should also be required to report this information to the Board. Unfortunately, self-reported information is not always reliable, so it is reasonable to also require the insurance companies to report settlements and judgments. Several other practice acts are structured this way.

In 12-280-111, C.R.S., the Act currently contains a section that requires insurance companies to report this information to the Board. However, since the Board does not have enforcement authority over insurance companies, this requirement would be better placed under Title 10, which governs insurance companies.

By placing this requirement in Title 10, insurance companies would be more likely to be aware of the requirement and to comply with it.

Therefore, the General Assembly should require pharmacists and pharmacies to report any malpractice settlements or judgments to the Board within 30 days, and it should

also include a similar requirement in Title 10 for insurance companies who underwrite professional liability insurance for pharmacists and pharmacies to also report this information to the Board.

Recommendation 10 – Clarify that the Board has the authority to enter into stipulations with licensees and registrants.

In 2019, House Bill 1172 recodified and reorganized Title 12, which included the creation of a common provisions section. Individual practice acts typically include references to common provisions and the common provisions section also specifically lists any professions to which the common provisions are not applicable.

Stipulations are included in a common provision under section 12-20-405(3), C.R.S. While this section is not referenced in the Act, the common provisions also does not list the profession under the exclusions to this authority, which seems to indicate that the Board does have the authority to enter into stipulations.

The third sunset criterion questions whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes.

Prior to recodification, the Board did have clear authority to enter into stipulated agreements.[131] The authority for stipulations is commonly granted to regulatory entities and necessary for the Board to effectively regulate the practice of pharmacy.

For this reason, the General Assembly should clarify in the Act that the Board does have the authority to enter into stipulations according to section 12-20-405(3), C.R.S.

Recommendation 11 – Repeal the requirement to send a letter of admonition by certified mail.

Section 12-280-127(6), C.R.S., requires the Board to send a letter of admonition via certified mail. While this delivery method allows Board staff to verify that a delivery attempt was made, it does not guarantee that the licensee actually receives the letter. The licensee can decline to sign for or pick up the letter and then claim he or she never received it. This defeats the purpose of sending a letter by certified mail.

Sending a letter by certified mail also costs more than sending one by first-class mail or emailing it.

This requirement should be repealed. The Board requires licensees to notify the Board of a change of address within 30 days, which may be submitted in writing or through the Board's online system. If the Board is notified of an address change as required, it

[131] *See Colorado Revised Statutes 2018: § 12-42.5-124(11), C.R.S.*

is very unlikely that the licensee would not receive a properly addressed letter of admonition.

The third and fourth sunset criteria question:

> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, and
>
> Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively.

Repealing this requirement would save money and streamline the administrative process for letters of admonition without compromising the Board's enforcement authority.

Therefore, the General Assembly should repeal the requirement that a letter of admonition be sent by certified mail.

Recommendation 12 – Repeal the requirement that the Board justify its reasons for differing from a recommendation of the Veterinary Pharmaceutical Advisory Committee.

The Board is required to refer all business related to veterinary pharmaceuticals to the Veterinary Pharmaceutical Advisory Committee (Advisory Committee). The Advisory Committee must consider all referred business and make recommendations to the Board.

However, when the Board concludes that material and substantial evidence or information exists that warrants action different from an Advisory Committee recommendation, the Board must document its reasons for doing so.

Advisory committees are created to provide information to a board or commission that the members of a board or commission may not already have. However, a board or commission is the entity that is vested with enforcement authority, not the advisory committee. It is, therefore, unnecessary to require a board or commission to justify its reasons when it does not agree with the recommendations made by an advisory committee.

In all, the Board has received seven recommendations from the Advisory Committee, and it has agreed with all but one recommendation.

The third and fourth sunset criteria question:

> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, and

Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively.

It is an inefficient use of state resources to require the Board to justify its reasons for ruling on a case when it differs from the recommendation of an advisory committee, and requiring it to do so unnecessarily increases the cost of regulation.

In order to create a more efficient regulatory program and to streamline the operations of the Board, the General Assembly should repeal the requirement that the Board justify its reasons for differing from an Advisory Committee recommendation.

Recommendation 13 – Make technical amendments to the Act.

The Act has been in place for many decades. As with any law, it may contain instances of outdated, duplicative and confusing language, and the Act should be revised to eliminate obsolete references and to reflect current terminology and administrative practices. These changes are technical in nature, so they will have no substantive impact on the regulation of the practice of pharmacy.

Therefore, the General Assembly should make the following technical changes:

- **Section 12-280-201, *et seq*., C.R.S.** Repeal the term "diversion" from the name of the peer health assistance program since it is a confusing and outdated term in this context.
- **Section 12-280-301, *et seq*., C.R.S.** Clarify in Part 3 that wholesalers are "registered" rather than "licensed" to be consistent with the administrative practices of the Board and the other parts of the Act.

Appendix A - Licensing and Registration Fees

The following tables provide the licensing and registration fees for individuals and businesses that engage in the practice of pharmacy in Colorado.

Pharmacists Licensing Fees

Fiscal Year	Initial	Renewal	Reinstatement	Reactivation
14-15	$194	n/a*	$ 156	$ 156
15-16	$194	$138	$ 153	$153
16-17	$194	n/a	$ 153	$153
17-18	$194	$138	$ 155	$155
18-19	$194	n/a	$ 155	$155

*Not applicable

Pharmacy Intern Licensing Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$40	n/a*	$50
15-16	$40	$32	$47
16-17	$40	n/a	$47
17-18	$40	$32	$49
18-19	$40	n/a	$49

*Not applicable

Pharmacy Registration Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$450	$240	$258
15-16	$450	n/a*	$258
16-17	$450	$340	$355
17-18	$450	n/a	$355
18-19	$450	$430	$447

*Not applicable

Wholesaler Registration Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$450	$240	$258
15-16	$450	n/a*	$258
16-17	$450	$340	$355
17-18	$450	n/a	$355
18-19	$450	$430	$447

*Not applicable

Manufacturer Registration Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$450	$240	$258
15-16	$450	n/a*	$258
16-17	$450	$340	$355
17-18	$450	n/a	$355
18-19	$450	$430	$447

*Not applicable

Other Outlet Registration Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$150	$148	$166
15-16	$150	n/a*	$166
16-17	$150	$148	$163
17-18	$150	n/a	$163
18-19	$150	$188	$205

*Not applicable

Limited License Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$50	$240	$258
15-16	$50	n/a*	$258
16-17	$50	$54	$69
17-18	$50	n/a	$69
18-19	$50	$68	$85

*Not applicable

Specialized Prescription Drug Outlet Registration Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$150	$148	$166
15-16	$150	n/a*	$166
16-17	$150	$148	$163
17-18	$150	n/a	$163
18-19	$150	$188	$205

*Not applicable

Hospital Satellite Pharmacy Registration Fees

Fiscal Year	Initial	Renewal	Reinstatement
14-15	$150	$148	$166
15-16	$150	n/a*	$166
16-17	$150	$148	$163
17-18	$150	n/a	$163
18-19	$150	$188	$205

*Not applicable

Appendix B - Additional Registered Businesses

The following tables illustrate the total number of businesses engage in the practice of pharmacy that are registered as:

- Other outlets,
- Limited licenses,
- Specialized pharmacies,
- Hospital satellite pharmacies,
- Out-of-state pharmacies, and
- Out-of-state wholesalers.

Other Outlet Registrations

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	27	206	4	229
15-16	29	n/a*	2	258
16-17	22	253	1	274
17-18	12	n/a	1	282
18-19	13	274	2	278

*Not applicable

Limited Licenses

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	0	47	4	47
15-16	0	n/a*	0	47
16-17	0	45	6	45
17-18	0	n/a	0	44
18-19	0	38	4	41

*Not applicable

Specialized Pharmacies

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	13	12	0	21
15-16	33	n/a*	0	55
16-17	22	56	1	68
17-18	44	n/a	0	85
18-19	46	74	1	120

*Not applicable

Hospital Satellite Pharmacies

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	2	4	0	8
15-16	3	n/a*	0	11
16-17	0	10	0	10
17-18	0	n/a	0	9
18-19		8	1	9

*Not applicable

Out-of-State Pharmacies

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	218	728	19	934
15-16	146	n/a*	3	1,013
16-17	172	872	10	981
17-18	163	n/a	8	1,100
18-19	163	921	9	1,064

*Not applicable

Out-of-State Wholesalers

Fiscal Year	Initial	Renewal	Reinstatement	Active
14-15	82	769	4	818
15-16	55	n/a*	3	862
16-17	94	792	1	865
17-18	76	n/a	1	913
18-19	96	843	3	923

*Not applicable