

COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2018 Sunrise Review: Pharmacy Technicians

October 15, 2018



COLORADO Department of Regulatory Agencies Executive Director's Office

October 15, 2018

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 General Assembly established the sunrise review process in 1985 as a way to determine whether regulation of a certain profession or occupation is necessary before enacting laws for such regulation and to determine the least restrictive regulatory alternative consistent with the public interest. Since that time, Colorado's sunrise process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

Section 24-34-104.1, Colorado Revised Statutes, directs the Department of Regulatory Agencies to conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. Accordingly, COPRRR has completed its evaluation of the sunrise application for regulation of pharmacy technicians and is pleased to submit this written report.

The report discusses the question of whether there is a need for regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm, and whether the public can be adequately protected by other means in a more costeffective manner.

Sincerely,

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Marguerite Salazar Executive Director



Table of Contents

Background	1
Licensure	1
Certification	2
Registration	2
Title Protection	2
Regulation of Businesses	3
Sunrise Process	3
Methodology	4
Profile of the Profession	5
Pharmacy Technician Certification Board	6
National Healthcareer Association	7
Proposal for Regulation	9
Summary of Current Regulation	. 10
Federal Laws and Regulations	. 10
The Colorado Regulatory Environment	. 11
Regulation in Other States	. 11
Analysis and Recommendations	. 12
Public Harm	. 12
Need for Regulation	. 17
Alternatives to Regulation	. 17
Collateral Consequences	. 18
Conclusion	. 19
Recommendation - Require all pharmacy technicians practicing in Colorado to obtain and maintain certification by a nationally recognized certification board obtain a minimum number of hours of experiential training or possess a degree from an accredited pharmacy training program.	d, m

Background

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

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

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

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

There are also several levels of regulation.

Licensure

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

Certification

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

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

Registration

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

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency - depending upon the prescribed preconditions for use of the protected title(s) - and the public is alerted to the qualifications of those who may use the particular title(s). Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

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

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

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

Sunrise Process

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA's Colorado Office of Policy, Research and Regulatory Reform (COPRRR) must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:¹

(I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;

(II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence;

¹ § 24-34-104.1(4)(b), C.R.S.

(III) Whether the public can be adequately protected by other means in a more cost-effective manner; and

(IV) Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation.

Methodology

During the sunrise review process, COPRRR staff performed a literature search; contacted and interviewed the sunrise applicant; reviewed licensure laws in other states; and interviewed pharmacy technicians, pharmacists and other stakeholders. To determine the number and types of complaints filed against pharmacy technicians in Colorado, COPRRR staff contacted the Attorney General's Office, Consumer Protection Section and the Colorado State Board of Pharmacy staff.

Profile of the Profession

Pharmacy technicians perform a variety of pharmacy-related tasks in various settings, such as retail, hospital, and compounding pharmacies. Specifically, pharmacy technicians are responsible for the following duties, including, but not limited to:

- Receiving and confirming prescription orders,
- Preparing and filling prescriptions,
- Interacting with consumers and answering questions,
- Managing inventory and performing organizational tasks, and
- Other various specialized tasks.

Commonly, prescriptions for medication from a physician are created and sent to a pharmacy via an e-prescription. Pharmacy technicians retrieve e-prescriptions via computer software, and they must also verify patient insurance (if applicable) prior to the patient picking up the prescription.²

Although less common, written prescriptions are still utilized. Pharmacy technicians are responsible for, among other things, ensuring the correct spelling of the patient's name, and verifying his or her address, phone number, date of birth, drug allergies, if any, and insurance information.³

Pharmacy technicians are also responsible for preparing and filling various prescriptions for patients. Medications come in various forms, such as a pill or capsule, or creams, ointments and compounds. A compound medication is a drug that is specifically prepared for a patient, where different ingredients are mixed together to create an individualized medication in a specific strength and dosage form.⁴

In most settings where pharmacy technicians work, they regularly interact with customers and answer various questions related to medications and/or insurance. Pharmacy technicians offer assistance in purchasing prescriptions, locating over-the-counter medication, answering basic medical questions or referring them to a pharmacist.⁵

Additionally, pharmacy technicians manage inventory within the pharmacy and perform various organizational tasks. Managing inventory may include tasks such as

⁴ GoodRx. What are Compounded Medications? Retrieved June 26, 2018, from

² Rasmussen College. 5 Key Pharmacy Technician Duties you Can Expect on the Job. Retrieved June 26, 2018, from https://www.rasmussen.edu/degrees/health-sciences/blog/pharmacy-technician-duties-you-can-expect/ ³ Rasmussen College. 5 Key Pharmacy Technician Duties you Can Expect on the Job. Retrieved June 26, 2018, from https://www.rasmussen.edu/degrees/health-sciences/blog/pharmacy-technician-duties-you-can-expect/

https://www.goodrx.com/blog/what-are-compounded-medications/

⁵ Rasmussen College. 5 Key Pharmacy Technician Duties you Can Expect on the Job. Retrieved June 26, 2018, from https://www.rasmussen.edu/degrees/health-sciences/blog/pharmacy-technician-duties-you-can-expect/

performing regularly scheduled inventory counts on specific medications, stocking inventory and checking for expired medications.⁶

Importantly, pharmacy technicians, regardless of the setting, work under the supervision of a licensed pharmacist. Specifically, section 12-42.5-119, Colorado Revised Statutes, states,

a pharmacist may supervise up to six persons who are either pharmacy interns or pharmacy technicians, of whom no more than two may be pharmacy interns. If three or more pharmacy technicians are on duty, the majority must be certified by a nationally recognized certification board, possess a degree from an accredited pharmacy training program or have completed 500 hours of experiential training.

The Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA) offer pharmacy technician certifications.

Pharmacy Technician Certification Board

Currently, the PTCB offers the Certified Pharmacy Technician (CPhT) and the Certified Compound Sterile Preparation Technician (CSPT) certifications. To qualify for a CPhT certification, an applicant must satisfy the following requirements:⁷

- Possess a high school diploma or equivalent educational diploma,
- Disclose all criminal and state board of pharmacy registration or licensure actions,
- Comply with all applicable PTCB certification policies, and
- Pass the Pharmacy Technician Certification examination (PTCE).

Once the minimum requirements highlighted above have been satisfied, a candidate is eligible to take the PTCE examination. The PTCE examination is a computer-based examination consisting of 90 multiple-choice questions (80 questions are scored and 10 are unscored).⁸ A candidate must complete the examination within two hours.

The total cost for the application and examination for the (CPhT) certification is \$129.

Pharmacy technicians who possess a CPhT certification must re-certify every two years. To maintain a CPhT certification, a pharmacy technician must complete a

⁷ Pharmacy Technician Certification Board. *Certification Guidelines and Requirements: A Candidate Guidebook*. Retrieved May 10, 2018, from https://www.ptcb.org/docs/default-source/get-certified/Guidebook.pdf

⁶ Rasmussen College. 5 Key Pharmacy Technician Duties you Can Expect on the Job. Retrieved June 26, 2018, from https://www.rasmussen.edu/degrees/health-sciences/blog/pharmacy-technician-duties-you-can-expect/

⁸ Pharmacy Technician Certification Board. *Certification Guidelines and Requirements: A Candidate Guidebook*. Retrieved May 10, 2018, from https://www.ptcb.org/docs/default-source/get-certified/Guidebook.pdf

minimum of 20 hours of continuing education (CE).⁹ If a CPhT-certified pharmacy technician is in good standing and has completed the referenced CE, he or she is eligible to re-certify the CPhT.

The PTCB also offers a Certified Compound Sterile Preparation Technician (CSPT) certification. To qualify for the CSPT certification a candidate must be an active PTCB CPhT in good standing and satisfy one of the following pathways:

- Complete or be enrolled in a PTCB-recognized sterile compounding training program and possess one year of full-time continuous compound sterile preparation work experience, or
- Possess three years of full-time continuous compound sterile preparation work experience.

Once a candidate fulfills one of the aforementioned requirements, he or she is eligible to take the CSPT examination. The CSPT examination is a multiple-choice examination consisting of 75 questions (60 scored).¹⁰ The examination must be completed within two hours.

The cost for the application and CSPT examination is \$199.

CSPT-certified pharmacy technicians are required to re-certify annually. Requirements for re-certification include completion of a minimum of five hours of sterile compounding-specific CE.¹¹

National Healthcareer Association

The NHA offers the Exam for the Certification of Pharmacy Technicians (ExCPT) certification. In order to qualify for the ExCPT certification, a candidate must satisfy the following requirements:¹²

- Have successfully completed or be within no more than 60 days of successful completion of all requirements needed to obtain a high school diploma or equivalent, and
- Have successfully completed a training program or have relevant work experience (1,200 hours of supervised pharmacy-related experience).

handbook4d5de88694956aeb8535ff0f00b0a11e.pdf

⁹ Pharmacy Technician Certification Board. *Certification Guidelines and Requirements: A Candidate Guidebook*. Retrieved May 10, 2018, from https://www.ptcb.org/docs/default-source/get-certified/Guidebook.pdf

¹⁰ Pharmacy Technician Certification Board. *Certification Guidelines and Requirements: A Candidate Guidebook*. Retrieved May 10, 2018, from https://www.ptcb.org/docs/default-source/get-certified/Guidebook.pdf

¹¹ Pharmacy Technician Certification Board. *Certification Guidelines and Requirements: A Candidate Guidebook*. Retrieved May 10, 2018, from https://www.ptcb.org/docs/default-source/get-certified/Guidebook.pdf

¹² National Healthcareer Association. *Candidate Handbook*. Retrieved July 3, 2018, from https://www.nhanow.com/docs/default-source/pdfs/handbooks/nha-candidate-

Training programs must be offered by an accredited or state-recognized institution or provider or the U.S. military.¹³ Training programs registered by the U.S. Department of Labor are also acceptable.¹⁴ Additionally, employer-based training programs offered by a national pharmacy association may fulfill the training requirement for certification.¹⁵

Once a candidate for certification has completed the requirements highlighted above, he or she is eligible to take the ExCPT examination. The examination consists of 100 scored multiple-choice questions and 20 pretest multiple-choice questions and must be completed within 2 hours and 10 minutes.¹⁶

The fee to take the examination is \$117.

¹³ National Healthcareer Association. *Candidate Handbook*. Retrieved July 3, 2018, from https://www.nhanow.com/docs/default-source/pdfs/handbooks/nha-candidate-handbook4d5de88694956aeb8535ff0f00b0a11e.pdf

¹⁴ National Healthcareer Association. *Candidate Handbook*. Retrieved July 3, 2018, from https://www.nhanow.com/docs/default-source/pdfs/handbooks/nha-candidate-handbook4d5de88694956aeb8535ff0f00b0a11e.pdf

¹⁵ National Healthcareer Association. *Candidate Handbook*. Retrieved July 3, 2018, from https://www.nhanow.com/docs/default-source/pdfs/handbooks/nha-candidate-handbook4d5de88694956aeb8535ff0f00b0a11e.pdf

¹⁶ National Healthcareer Association. *Test Plan for the ExCPT Exam*. Retrieved July 3, 2018, from https://www.nhanow.com/docs/default-source/pdfs/exam-documentation/test-plans/nha-2016-excpt-test-plan_public_detail.pdf?sfvrsn=2

Proposal for Regulation

The Colorado Pharmacist Society (Applicant) submitted a sunrise application to the Colorado Office of Policy, Research and Regulatory Reform within the Department of Regulatory Agencies for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes. The application identifies registration of pharmacy technicians as the appropriate level of regulation. The application further proposes that in order for pharmacy technicians to become registered by the State of Colorado, they should obtain certification by the Pharmacy Technician Certification Board or other nationally recognized certifying authority.

The Applicant asserts that registering pharmacy technicians:

- May minimize drug diversion by preventing individuals with a history of drug diversion from being rehired at another pharmacy.
- Will enable the State Board of Pharmacy to possess a list of pharmacy technicians working in various pharmacies for tracking purposes.
- Will provide uniformly trained, competent pharmacy technicians, which would enable pharmacists to provide more patient consultations, which are proven to reduce medication errors.

The Applicant also requested mandatory continuing education for pharmacy technicians. The application did not delineate the number of continuing education hours that should be required; however, the most common requirement in the vast majority of states that regulate pharmacy technicians is 20 hours every two years.

Summary of Current Regulation

Federal Laws and Regulations

Currently, there is no federal law requiring pharmacy technicians to be licensed, certified or registered. The federal Controlled Substances Act (Act), however, embodies the federal drug policy that regulates the manufacture and distribution of controlled substances such as hallucinogens, narcotics, depressants and stimulants.¹⁷ The Act, among other things, requires every person who manufactures, distributes, imports and exports a drug to register with the U.S. Drug Enforcement Administration (DEA). The DEA is responsible for enforcement of the Act and ensuring registrants abide by security controls and storage requirements set forth by the Act.¹⁸

The Act categorizes drugs into five "schedules" or classifications based on, among other things, potential for abuse and medical benefits they may provide.¹⁹ The potential for abuse of drugs decreases with each schedule or classification. For instance, schedule 1 drugs have a greater potential for abuse than schedule 2 drugs. The five schedules are as follows:²⁰

- Schedule 1: Examples of schedule 1 drugs include Ecstasy, Heroin and Marijuana. Schedule 1 drugs have no currently accepted medical use. These drugs have a high potential for abuse and cannot be prescribed or dispensed to consumers.
- Schedule 2: Examples of schedule 2 drugs include methadone, meperidine and oxycodone.
- Schedule 3: Examples of schedule 3 drugs include anabolic steroids, Vicodin and Marinol.
- Schedule 4: Examples of schedule 4 drugs include Ambien, Xanax and Valium.
- Schedule 5: Examples of schedule 5 drugs include Lyrica and cough suppressants.

 ¹⁷ FindLaw. *The Controlled Substances Act (CSA): Overview*. Retrieved July 9, 2018, from https://criminal.findlaw.com/criminal-charges/controlled-substances-act-csa-overview.html
¹⁸ FindLaw. *The Controlled Substances Act (CSA): Overview*. Retrieved July 9, 2018, from https://criminal.findlaw.com/criminal-charges/controlled-substances-act-csa-overview.html
¹⁹ FindLaw. *The Controlled Substances Act (CSA): Overview*. Retrieved July 9, 2018, from https://criminal.findlaw.com/criminal-charges/controlled-substances-act-csa-overview.html
¹⁹ FindLaw. *The Controlled Substances Act (CSA): Overview*. Retrieved July 9, 2018, from https://criminal.findlaw.com/criminal-charges/controlled-substances-act-csa-overview.html
²⁰ FindLaw. *The Controlled Substances Act (CSA): Overview*. Retrieved July 9, 2018, from https://criminal.findlaw.com/criminal-charges/controlled-substances-act-csa-overview.html

The Colorado Regulatory Environment

Colorado does not license, certify or register pharmacy technicians. However, they function under the supervision of licensed pharmacists. In fact, the statute enables up to six pharmacy technicians to work while under the supervision of a pharmacist. Specifically, section 12-42.5-119, Colorado Revised Statutes, states,

a pharmacist may supervise up to six persons who are either pharmacy interns or pharmacy technicians, of whom no more than two may be pharmacy interns. If three or more pharmacy technicians are on duty, the majority must be certified by a nationally recognized certification board, possess a degree from an accredited pharmacy training program or have completed 500 hours of experiential training.

Regulation in Other States

According to the sunrise application, 41 states currently regulate pharmacy technicians. In an attempt to understand the regulatory environment in other states, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) staff contacted several states contiguous to Colorado. Specifically, Arizona, Kansas, Oklahoma, Nebraska, Wyoming and Utah were contacted for this sunrise review.

Information obtained for this sunrise review was sparse; however, a common theme among respondents to requests for information was that pharmacy technicians are regulated by the board of pharmacy in each of the states contacted.

COPRRR requested information related to disciplinary actions imposed on pharmacy technicians in each of the states referenced above; none of the states responded with the requested information.

Analysis and Recommendations

Public Harm

The first sunrise criterion asks:

Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

Before moving forward in the analysis of harm concerning pharmacy technicians, it is important to identify what constitutes harm to the public. Pharmacy technicians serve an important role in the day-to-day operations within pharmacies, including receiving and confirming prescription orders and preparing and filling prescriptions.

There are a variety of situations where pharmacy technicians could harm consumers, such as providing incorrect medication to consumers or offering incorrect information concerning medications.

There are also instances when pharmacy technicians have diverted drugs either for their own use or to possibly sell to individuals. Diversion is an issue that is not exclusive to pharmacy technicians.

In order to determine whether the regulation of pharmacy technicians is necessary in Colorado, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) staff requested that the sunrise applicant provide specific examples of harm, which are highlighted below, accompanied by COPRRR's analysis.

<u>Example 1</u>

In Ohio, a young girl was diagnosed with a yolk sac tumor, roughly the size of a grapefruit inside her abdomen. During her treatment, she received an improperly compounded chemotherapy medication. A pharmacy technician did not use a standard prepared bag of sodium chloride solution, which contains less than one percent of sodium chloride. Instead, the pharmacy technician compounded the medication with a concentrated sodium chloride solution of 23.4 percent. Tragically, the young girl died after receiving the incorrect sodium chloride solution dosage.

<u>Analysis</u>

This example clearly delineates an instance where a young girl died due to the improper actions of a pharmacy technician. According to articles related to this situation, the pharmacy technician, while compounding the solution,

thought something was not "right." However, she administered the incorrect solution to the young girl.

The incident occurred in 2006 when pharmacy technicians were not formally regulated in Ohio. The Ohio legislature passed legislation in 2008 to regulate pharmacy technicians.

Further, although this example did not occur in Colorado, it demonstrates the seriousness of the work pharmacy technicians perform. A regulatory framework provides two important safeguards for consumers. First, regulation often requires practitioners to possess a minimum level of competency prior to working, which could serve to enhance consumer protection. Regulation also enables states to impose discipline on practitioners who violate a practice act. Discipline can prevent a practitioner from practicing, which serves to insulate consumers from harm.

Although it is unclear the level of training the pharmacy technician possessed, in this example, regulation would have required the pharmacy technician to demonstrate a minimum level of competency, which may have prevented the tragic death of the child. Implementing a regulatory structure for pharmacy technicians would have also provided a formal mechanism to discipline the pharmacy technician.

<u>Example 2</u>

In October through December 2016, the California Board of Pharmacy denied applications or revoked pharmacy technicians' registrations 48 times. Some of the issues cited for the application denial or registration revocation included: heroin use, diversion of controlled substances, bringing controlled substances to jail facilities, and credit card fraud (the pharmacy technician obtained more than 40 customer credit card numbers while employed as a pharmacy technician and inappropriately used the numbers for personal gain).

<u>Analysis</u>

The example highlighted above illustrates several situations where regulators in California prevented pharmacy technicians from being able to practice at pharmacies due to the aforementioned issues. This example illustrates instances when regulators are able to prevent practitioners from practicing in their respective state, which could result in enhanced consumer protection. Importantly, these situations appear to be intentional acts by pharmacy technicians and not competency-related.

Example 3

In a hospital pharmacy, cardioplegia solution was compounded incorrectly by a pharmacy technician. Specifically, the pharmacy technician did not measure the correct amount of potassium chloride, which resulted in the patient remaining on cardiac bypass for several hours longer than necessary.

<u>Analysis</u>

This example illustrates an instance related to the competency of the pharmacy technician who compounded medication for a patient's prescription. The example does not disclose whether the patient was harmed by the incorrect compounding of the medication other than remaining on cardiac bypass longer than necessary. However, this example appears to be related to the competency of the pharmacy technician. Importantly, it is unclear the level of training the pharmacy technician possessed. If competency was, in fact, the issue in this situation, the State of Colorado could require a certain level of knowledge to practice in Colorado, such as requiring certification by a national certifying body, obtaining a minimum number of hours of experiential training or possessing a degree from an accredited pharmacy training program. Doing so would ensure that pharmacy technicians demonstrate a minimum level of competency prior to practicing.

Example 4

In a hospital pharmacy, a pharmacy technician incorrectly filled a Pyxis medication with Torsemide 100 milligram (mg) versus 10 mg tablets. The patient experienced a four-fold overdose, necessitating transfer and several days in the Intensive Care Unit of the hospital.

<u>Analysis</u>

This example demonstrates an instance where the actions of a pharmacy technician caused harm to a consumer. Clearly, the example shows that the pharmacy technician filled the prescription with the incorrect medication dosage. It is unclear, however, whether the actions of the pharmacy technician were a competency issue or carelessness. It is also unclear the level of training that the pharmacy technician possessed. If competency was the issue, requiring pharmacy technicians to possess a minimum level of competency may serve to enhance consumer protection. Obtaining certification by a national certifying entity or other demonstration of competency could address any competency-related issues concerning pharmacy technicians.

Example 5

In a community pharmacy, a pharmacy technician illegally authorized refills for her son's medications by turning off the "auto fax" functionality so the doctor's office was never contacted.

<u>Analysis</u>

This example illustrates the illegal actions of a pharmacy technician, which presumably, could have been forwarded to law enforcement instigating legal ramifications. Also, this example appears to be an intentional act and not competency-related concerning the pharmacy technician.

Example 6

In a community pharmacy, a pharmacy technician filled a prescription for a child's medication and performed the initial verification of the medication without the pharmacist's knowledge. The dosage of the medication was too high, which resulted in the child suffering respiratory depression and death.

<u>Analysis</u>

This example clearly highlights a pharmacy technician's actions that contributed to the death of a child. This tragic situation may not have occurred if the pharmacy technician had followed the correct protocols with the pharmacist. Also, it is unclear whether the actions of the pharmacy technician were related to competency. However, the implementation of a regulatory structure in Colorado would enable formal discipline of the pharmacy technician, which could prevent future tragic situations from occurring.

<u>Example 7</u>

In an outpatient community pharmacy, a pharmacy technician confused two medications with similar names and dispensed the wrong medication to the patient without realizing the error.

<u>Analysis</u>

This example does not detail whether a consumer was harmed by the actions of the pharmacy technician; however, it does illustrate an instance during which a consumer could have been harmed. It is also unclear if the example was a case in which the pharmacy technician was simply careless or whether competency was an issue. Additionally, the example does not highlight the level of training, if any, the pharmacy technician possessed. If competency was the issue, the implementation of a requirement for all pharmacy technicians to obtain a certification from a national certifying entity would to help ensure that practitioners achieved a minimum level of competency prior to practicing.

Example 8

In a community pharmacy, over a period of several months, a pharmacy technician stole several hundred hydrocodone/acetaminophen pills. The pharmacy technician took one to two pills from each prescription she filled.

<u>Analysis</u>

The example presented above highlights a potential safety issue to the public. It is unclear is if the pharmacy technician was stealing the medication for her own personal consumption, or whether she was taking them to sell or give them to someone. Regardless, stealing medication from a pharmacy is a public safety concern and is illegal. The pharmacy technician could face legal consequences for her actions.

<u>Example 9</u>

In a community pharmacy in Ft. Collins, a pharmacy technician diverted approximately 2,100 oxycodone pills over several months. The pharmacy technician was ultimately caught and terminated from employment.

<u>Analysis</u>

This example demonstrates that the pharmacy technician was clearly participating in an illegal activity, which may lead to criminal charges. The example also appears to be an intentional act and not competency-related.

Other Examples of Harm

During the course of this sunrise review, COPRRR staff contacted representatives of the Colorado State Board of Pharmacy (Pharmacy Board) in an attempt to identify instances of consumer harm in Colorado.

Since pharmacy technicians are not formally regulated by the Pharmacy Board, staff was not able to quantify the number of complaints the Pharmacy Board received in the past several years. However, anecdotally, staff stated that approximately 20 percent of dispensing errors and controlled substance accountability cases involve pharmacy technicians. Further, staff stated that pharmacy technicians are involved in most pharmacy-related errors.

On an annual basis, Pharmacy Board staff reviews hundreds of complaints related to pharmacies and the information provided for this sunrise review justifies the exploration of implementing a certification requirement for pharmacy technicians in Colorado. Pharmacy Board staff have witnessed many complaints against pharmacy technicians in the past; however, there was not an avenue to formally discipline pharmacy technicians by the Pharmacy Board. Instead, the complaints are dismissed for lack of jurisdiction.

This sunrise review identified instances where pharmacy technicians harmed consumers due to competency-related issues. As such, requiring pharmacy technicians to be certified by a national certifying entity, obtaining a minimum number of hours of experiential training or completion of a degree from an accredited pharmacy training program could adequately address competency-related errors.

Need for Regulation

The second sunrise criterion asks:

Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence.

This criterion addresses the proposition of whether the state should require a certain level of education and/or impose a requirement that pharmacy technicians pass an examination before practicing in Colorado.

During this sunrise review, there was evidence presented via examples of harm provided by the sunrise applicant that certain pharmacy technicians do not possess adequate skills, education or competence to practice safely. Specifically, many of the examples provided were related to pharmacy technicians compounding drugs incorrectly and incorrectly filling prescriptions. As a result, the implementation of minimum requirements, such as the passage of an examination, possessing a minimum level of experiential training or education to practice as a pharmacy technician in Colorado may adequately address competency issues related to pharmacy technicians.

Alternatives to Regulation

The third sunrise criterion asks:

Whether the public can be adequately protected by other means in a more cost-effective manner.

Public protection for consumers who need various medications, which are dispensed from pharmacies with the assistance of pharmacy technicians, could be realized in a cost-effective manner by requiring certification by either the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA). Generally, to obtain a certification by PTCB or NHA, candidates are required to pass an examination and complete annual continuing education.

Obtaining a certification from either the PTCB or NHA ensures that pharmacy technicians are uniquely qualified to practice as pharmacy technicians. Consequently, the certifications offered by PTCB and NHA appear to insulate consumers from incompetent practitioners.

The certifications offered by PTCB and NHA are utilized by many practitioners throughout the country, including Colorado. Therefore, certification by one of the aforementioned organizations may be a viable option and alternative to state regulation.

Importantly, the State of Colorado currently requires pharmacy technicians to be certified in certain instances. Specifically, section 12-42.5-119, Colorado Revised Statutes, states,

a pharmacist may supervise up to six persons who are either pharmacy interns or pharmacy technicians, of whom no more than two may be pharmacy interns. If three or more pharmacy technicians are on duty, the majority must be certified by a nationally recognized certification board, possess a degree from an accredited pharmacy training program or have completed 500 hours of experiential training.

Collateral Consequences

The fourth sunrise criterion asks:

Whether the imposition of any disqualifications on applicants for licensure, certification, re-licensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

The sunrise application proposed using an applicant's criminal history as a disqualifier for pharmacy technician regulation. During the sunrise review, there were instances where pharmacy technicians were participating in criminal activity, such as stealing medications while working in a pharmacy setting. The implementation of a criminal history background check could serve to provide increased public protection by prohibiting pharmacy technicians with a criminal history from practicing in Colorado.

Conclusion

The sunrise application requested registration of pharmacy technicians in Colorado. Further, the sunrise application states that regulating pharmacy technicians:

- May minimize drug diversion by preventing individuals with a history of drug diversion from being rehired at another pharmacy.
- Will enable the Pharmacy Board to possess a list of pharmacy technicians working in various pharmacies for tracking purposes.
- Will provide uniformly trained, competent pharmacy technicians, which would enable pharmacists to provide more patient consultations, which are proven to reduce medication errors.

The vast majority of transactions concerning medications in a pharmacy setting include the services of pharmacy technicians. As a result, the proper actions of a pharmacy technician, both in competency and integrity, are essential. Consumers rely heavily on the actions of pharmacy technicians to ensure, among other things, that the correct medications are dispensed to consumers at the proper dose.

It is important to note that Colorado law enables pharmacists to supervise up to six pharmacy technicians in the pharmacy setting, and the pharmacist is ultimately responsible for all pharmacy related activities. However, many pharmacies fill an extraordinary amount of prescriptions annually, and as illustrated in the examples of harm provided for this sunrise review, consumers were harmed by things such as compounding of drug errors, dispensing incorrect medications to consumers and criminal activity (diverting drugs).

In order to ensure that consumers who have prescriptions filled by pharmacies are insulated from harm, pharmacy technicians should be required to obtain and maintain certification by a national certifying entity, such as the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA). Doing so serves two purposes. First, in order to obtain either certification, a candidate is required to pass an examination. The examination ensures a minimum level of competency to practice as a pharmacy technician. This sunrise review identified several instances where pharmacy technicians were negligent in their duties while working in a pharmacy setting, such as compounding the incorrect medications, harming consumers, and, in some instances, resulting in death.

Importantly, requiring pharmacy technicians to obtain and maintain certification does not address issues related to diversion. However, stealing drugs is an illegal activity, and a pharmacy technician who steals from his or her employer may be subject to criminal charges. Regulation is an inherently weak response to intentional criminal behavior.

In sum, the evidence of harm presented during the course of research for this sunrise review demonstrates examples of physical harm and illegal activity. As such, the State of Colorado should implement a requirement for pharmacy technicians to obtain and maintain a certification from the PTSB or NHA, obtain a minimum number of hours of experiential training or possess a degree from an accredited pharmacy technician training program. These requirements may increase public protection in areas such as compounding and dispensing of medications in the least restrictive manner without imposing unnecessary regulation. Also, implementing the aforementioned requirements will align with the current requirements for pharmacy technicians when there are three or more technicians on duty at the same time.

Recommendation – Require all pharmacy technicians practicing in Colorado to obtain and maintain certification by a nationally recognized certification board, obtain a minimum number of hours of experiential training or possess a degree from an accredited pharmacy training program.