

	2013	2014	2015	Aug-15
Administrative Filings	37	52	26	3
Criminal Filing/Felony	3	0	0	1
Letter of Concern	60	146	64	5
Referred to Diversion	1	2	0	0
PR/Outreach	3	4	0	0
Cases Received	710	567	394	51
Case Assigned	676	555	390	50
Closed Cases	731	595	373	44
Citations Issued	103	60	49	6
Pharmacy Inspections	225	335	166	23
Pharmacy Alerts	191	261	144	21
Dr. Shopper Letters	209	571	879	153

NOTES: Pharmacy Group

Administrative Action / Criminal Felony Filing	Pharmacist was extorting and exploiting a patient who had presented a prescription to him at the pharmacy where he was employed. He was charged criminally regarding this case on or about June 17, 2014, and entered a no contest plea to a 3rd Degree Felony charge of falsely dispensing a prescription. The elements of the crime for which the no contest plea was entered are as follows: On or about October 2011, the Pharmacist intentionally and knowingly dispensed a prescription for a controlled substance to a person known to be attempting to acquire it by fraud. The Pharmacist has now satisfied all conditions placed on him by the court, and the charge has now been dismissed and his record expunged. On August 17, 2015, the Pharmacist, with representation by his attorney, entered into a Stipulated Agreement with the Division as follows: his license to practice as a pharmacist is suspended for 2 years and the suspension is stayed. The Pharmacist is on probation for 2 years and fined \$4,000.00 with \$2,000.00 stayed upon successful completion of the probationary period.
Administrative Action	During an inspection, numerous violations were found. The Pharmacy signed a Stipulation and Order, placed on Probation for two years, and was fined \$14,000, \$7,500 of the amount was stayed, leaving \$6,500 to be paid to the Division.
Administrative Action	During an inspection, numerous violations were found. The Pharmacy was Publicly Reprimanded, and was fined \$10,000, \$2,000 was suspended, leaving \$8,000 to be paid to the Division.
Citation	Pharmacy was issued a Citation with a \$1,050 fine for Pharmacy Violations found during a Random Inspection.
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- Larry Pinson & Nevada Board of Pharmacy (8am 09/15/15)
 - Nevada doing a lot with drug abuse awareness and prevention
 - Nalxone: good Samaritan law & distribution of naloxone kits 2015; pharmacist dispensing without prescription (protocol with Health Department)
 - Looking at criminal justice and intervention methods as well
- Ed McGinley, NABP President message (8am 09/15/15)
 - Review of who is in NABP including international members (Bahamas is the newest)
 - Reviewed his role as President (chief elected officer; keeping members informed; encourage member participation)
 - Joint Commission of Pharmacy Practitioners (JCPP); standardized pharmacists' patient care process; collaborate; communicate; document
 - 111th NABP Annual Meeting: working with FDA; DEA; VPP; updated NAPLEX competency statements (to be implemented in November, 2015)
 - .pharmacy implementation for more patient safety due to rogue internet sites
 - NABP Executive Committee: working on the strategic plan
 - 2 task forces: Pharmacist Prescriptive Authority & Regulation of Pharmacist Care Services
 - 2015 Survey on Pharmacy Care Services
 - Upcoming activities: see NABP website for details
 - PCOA (Pharmacy Curriculum Outcomes Assessment): 2016 ACPE standard to use this "exam" for students; can see more information on the NABP website; provided at no cost to students nearing completion of their didactic curriculum
 - Presidential Initiatives:
 - 1-facilitate cooperation amongst regulators so that pharmacists can practice at the top of their profession; trying to remove those barriers that are hindering pharmacists to do this
 - 2-provide pharmacists with the tools to make a difference, one person at a time, in their role as drug experts in dealing with drug abuse, drug diversion, and associated challenges, pain, and tragedy that result. Need to actively engage our patients, our families and our neighbours in this fight. He discussed the problem and statistics including 90% of Americans that are addicted began that behaviour prior to age 18 (smoking, drinking, etc.). One death every 22 minutes associated with prescription opioid analgesics and heroin. **USE THE AWARE WEBSITE AND INFORMATION ON THE NABP WEBSITE!** Take the pledge on the website and receive tools to help. Get 5 other colleagues to pledge.
- Cynthia Boyle: AACP President (8am 09/15/15)
 - She got the Utah School on Alcohol Abuse and Other Drug Dependencies to continue to work. They were in jeopardy of discontinuing the program.
 - AACP working on lots of areas to keep educators and students connected by increasing communication.
 - "Brand" pharmacy education.
 - 136 Schools/Colleges of Pharmacy: 2 new ones this year - California (Chatham?) and Tyler Texas
 - Use of PHARMCAS increasing
 - Faculty retention and promotion
 - One focus is on "citizenship": getting the students to engage themselves in being a good citizen and involved in their communities: Being good advocates for their profession
- Open Microphone (9:15am 09/15/15)
 - Need to work on LEADERSHIP training; should NABP and AACP collaborate on a leadership training course and also have a national certification for pharmacy preceptors? Will this add too much to a curriculum? What about entrepreneurship - how do we teach or train for that?
 - North Carolina Dental Board vs. FTC: questioning immunity of Board members who are part of the profession that oversee the profession. How do we apply this decision? (Tooth whitening in shopping malls needing to be licensed - lower courts said yes, Supreme Court said no - they were blocking trade.) The NC Dental Board overstepped their authority by issuing a cease and desist order based on enforcing the practice act when in fact tooth whitening was not part of the scope of practice in the act. Some states are very concerned. Oklahoma thinks their legislation will change the make up to majority public members (5 to 4 professional).
 - MOU: John Kirtley - doesn't think there is a workable MOU.
 - Nevada: RPH dispensing naloxone without a prescription. Maybe use the Director of the Department of Health as the signer of the collaborative practice agreement to dispense/write prescription. Do the normal rules apply as to getting patient name, address, etc.
 - Oregon: RPH prescriptive authority for oral and transdermal contraceptives. Algorithm vs. protocol. Also, the ability to bill for this service. Will require a certificate training program.
 - California: working with payers to determine if they will allow a pharmacist NPI to be the prescriber. Also, if the naloxone is given to a family member, is it the patient's coverage or the caregivers coverage that will pay for it?
 - Washington: RPH's need to look at the legal aspects of prescribing and liability.
- Practice Through the Years - Panel Presentation (10:45am 09/15/15)
 - Goal is to give perspective on generational differences of practice perspective.

- Steve Abel: <797> (1:30pm 09/15/15)
 - Discussed what various States are doing with <797> rules
 - Discussed CriticalPoint <797> Boot Camp
 - Presented a simulation-based training program using a virtual cleanroom
- First Business Meeting (2:30pm 09/15/15)
 - Meeting funds should be ok for this meeting but no reserve left over for next meeting.
 - Resolution on new types of practice settings utilizing technological advances (pharmacist without a pharmacy) interstate licensure.
 - Resolution on Leadership and what it takes to be a PIC. Many concerns about young untrained RPh's becoming managers.
 - Utah to host the next time District 8 needs to be the host for District 6,7,8. Utah Board must select a Chairperson for the meeting. Meeting will be in 2018. Nevada meeting used up all reserves so lots of fundraising will need to happen.
 - 2016 Meeting: Portland, OR (District 7 to host); September 11-14, 2016 (2016 is the 125th anniversary of the Oregon State Board)
 - 2017 Meeting: San Antonio, TX (District 6 to host); date TBD
 - District 8 "selected" Roger Fitzpatrick the Chairperson for this upcoming year to run the meeting in Portland. LuGina Mendez-Harper (NM) will serve a Secretary. (New Treasurer, too, but didn't catch his name.)
- Assessment in Pharmacy Education - Panel Discussion (8:15am 09/16/15)
 - Pete Vlasses (ACPE Executive Director) briefly presented the new 2016 ACPE pharmacy program standards including the PCOA (Pharmacy Curriculum Outcomes Assessment) process
 - Panel discussion on where and how to implement PCOA
- ACPE Update: What Regulators and Academics Need to Know - Pete Vlasses (9:45am 09/16/15)
 - Topics presented and discussed included:
 - Professional degree program accreditation standards: 2007 vs. 2016
 - What's happening with the ASHP-ACPE collaboration for pharmacy technician education training accreditation
 - NOTE: we need to review the great work that was done last year with Utah Rules and make sure our wording matches the changes that are taking place
 - PTCB changes for 2020 to include a requirement that all candidates complete an ASHP/ACPE-accredited training program to be able to sit for the PTCB exam
 - PTCB re-certification has made changes to types of CE programs they will accept
 - Utilizing the CPE Monitor for auditing records – wait at least 60-days after the close of a CE period before auditing records to allow providers to submit all attendance records
 - Trend of more participants in homestudy activities (3X) than live programs even though there are 3X as many live programs as homestudy programs
 - ACPE is furthering their discussions on requiring Continuing Professional Development and not just Continuing Pharmacy Education
- Second Business Meeting (10:30am 09/16/15)
 - District 8 Executive Committee Representative Report (Richard Mazzoni – NM BOP)
 - 18 New State Executive Directors this year
 - Encouraged all new State Exec's to attend the Interactive Executive Officer Forum in Northbrook, IL on October 13-14, 2015. It will be at no cost to the Executive Officer (Dane??)
 - District 7 Resolution: create a task force to study the technicians/pharmacist working from home or remote work site.
 - District 6 Resolution: Recognition to Nevada for hosting this meeting
- Open Microphone (11:30am 09/16/15)
 - Technician Training Requirements:
 - Louisiana=600 hours and nationally accredited program completion
 - Need to only use PTCB exam as that will be the standard through ACPE/ASHP Accreditation of programs
 - PTCB 2020 Initiative: how is Utah going to be ready (i.e., Pharmacy Tech University, etc.)?
 - Look at the ACPE/ASHP hour requirements (600 broken down into didactic, simulation, experiential)
 - Substance Abuse and over prescribing:
 - Lots of discussion about pharmacists not filling Rx's because they are "scared"
- The Medicine Cabinet and Pharmaceutical Controlled Substance Disposal (8:15am 09/17/15)
 - DEA Diversion Program Manager discussed the 2010 Secure and Responsible Drug Disposal Act in great detail
- Is it Really Medical Marijuana? (9:15am 09/17/15)
 - Discussed the 23+1 states that have something on the books for medical marijuana (+1 = D.C.)
 - Reviewed the FDA, THC and Cannabidiol status

PRELIMINARY LEGAL ISSUES REGARDING RECYCLING PRESCRIPTION DRUGS IN UTAH

A prescription drug recycling program necessarily involves redistribution of prescription drugs after these drugs have already been distributed. The provisions in Utah that specifically address redistribution of previously dispensed prescription drugs are Utah Code Ann. §§ 58-17b-502(5) and 503(2), which state in relevant part as follows:

Subsection 58-17b-502(5)

"Unprofessional conduct" includes:

(5) except as provided in Section 58-17b-503, accepting back and redistributing of any unused drug, or a part of it, after it has left the premises of any pharmacy, unless the drug is in a unit pack, as defined in Section 58-17b-503, or the manufacturer's sealed container, as defined in rule;

Subsection 58-17b-503(2)

(2) Notwithstanding the provisions of Subsection 58-17b-502(5), a pharmacist may accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy if:

(a) the drug was prescribed to a patient in a nursing care facility, a licensed intermediate care facility for people with an intellectual disability, or state prison facility, county jail, or state hospital;

(b) the drug was stored under the supervision of a licensed health care provider according to manufacturer recommendations;

(c) the drug is in a unit pack or in the manufacturer's sealed container;

(d) the drug was returned to the original dispensing pharmacy;

(e) the drug was initially dispensed by a licensed pharmacist or licensed pharmacy intern; and

(f) accepting back and redistribution of the drug complies with Federal Food and Drug Administration and Drug Enforcement Administration regulations.¹

Subsection 58-17b-503(2)(d), emphasized above, currently does not permit a drug recycling program which involves unused prescription drugs being recycled in any way unless the unused prescription drugs are first returned to the "original dispensing pharmacy." In other words, without a legislative change, a charitable drug recycling program is not legal in Utah if the program does not require the unused drugs to first be returned to the original dispensing pharmacy.

In fact, even laying aside Subsection 503(2)(d), Utah statutory law neither contemplates nor allows the implementation of a drug recycling program without further legislation designed to provide for, or to allow, such a program. Noting that the preliminary list included herein is by no means intended to present all the necessary elements or requirements, a law in Utah designed to permit a drug recycling program should provide for, or should otherwise address, the following issues:

¹ Emphasis added.

1. Proper drug identification and certification by a pharmacy or pharmacist of unused prescription drugs provided for drug recycling.
 - a. Consider including redundant criteria designed to double check the identification of drugs (e.g. Oklahoma statute requires that a drug identification book be maintained (or the use of a computer program or similar online service)).
 - b. Consider requiring special training for any pharmacy or pharmacist eligible to identify and certify unused prescription drugs provided for drug recycling before these may be included in dispensing stock.
 - c. Insure adequate records of unused drugs received and thereafter dispensed, held in dispensing stock, or destroyed.
 - d. Prohibit theft, diversion, or any other inappropriate use of unused prescription drugs provided for use in the drug recycling program.
2. Appropriate inspection and certification of expiration/beyond use dates and product integrity by a pharmacy or pharmacist of unused prescription drugs provided for drug recycling.
 - a. Insure recalled, expired, adulterated, unidentifiable, or otherwise unacceptable drugs are not included in dispensing stock and are not dispensed.
 - b. Insure proper destruction of unacceptable drugs.
3. Provide criteria for eligibility of participating charitable/non-profit pharmacies.
 - a. Consider requiring special registration for any eligible, participating pharmacies in addition to specific eligibility requirements.
4. Insure appropriate and legal collection, custody, storage, and transportation of any unused prescription drugs donated for the recycling program.
5. Provide specific labeling requirements for the recycling program.
 - a. Insure compliance with patient privacy laws and HIPPA regulations; and, insure that previous patient information and pharmacy labeling is not included on unused drugs that are recycled and then dispensed.
 - b. Provide for labeling requirements (perhaps by reference to current provisions) for prescription drugs dispensed pursuant to the drug recycling program.
 - c. Consider stringent requirements for expiration dates on labels of drugs dispensed pursuant to the recycling program, including a requirement that the earliest expiration date be utilized.

6. Consider provision designed to relieve participants in the program from liability to the extent participants comply with specific requirements.

7. Consider including limitations regarding eligible recipients of prescription drugs dispensed pursuant to the drug recycling program.

R156-17b-614a. Operating Standards - General Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), the following operating standards apply to all Class A and Class B pharmacies, which may be supplemented by additional standards defined in this rule applicable to specific types of Class A and B pharmacies. The general operating standards include:

(a) shall be well lighted, well ventilated, clean and sanitary;

(b) if transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;

(c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;

(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and

(f) if dispensing controlled substances, be equipped with a security system to:

(i) permit detection of entry at all times when the facility is closed; and

(ii) provide notice of unauthorized entry to an individual; and

(g) be equipped with a lock on any entrances to the facility where drugs are stored.

(2) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. If a refrigerator or freezer is necessary to properly store drugs at the pharmacy, the pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain each log entry for at least three years.

(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

(a) shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations;

(b) may compound in anticipation of receiving prescriptions in limited amounts;

(c) bulk active ingredients shall:

(i) be procured from a facility registered with the federal Food and Drug Administration; and

(ii) not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness;

(d) All facilities that dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section.

([d]e) a [master worksheet sheet] master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once

approved, a duplicate of the ~~[master worksheet sheet]~~ master formulation record shall be used as the ~~[preparation worksheet sheet]~~ compounding record from which each batch is prepared and on which all documentation for that batch occurs. The ~~[master worksheet sheet]~~ master formulation record may be stored electronically and shall contain at a minimum:

- (i) ~~[the formula]~~ official or assigned name;
 - (ii) ~~[the components]~~ strength;
 - (iii) ~~[the compounding directions]~~ dosage form of the preparation;
 - (iv) ~~[a sample label information]~~ calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;
 - (v) ~~[evaluation and testing requirements]~~ description of all ingredients and their quantities;
 - (vi) ~~[sterilization methods, if applicable]~~ compatibility and stability information, including references when available;
 - (vii) ~~[specific equipment used during preparation such as specific compounding device]~~ equipment needed to prepare the preparation;
 - (viii) ~~[storage requirements;]~~ mixing instructions shall include:
 - a. order of mixing;
 - b. mixing temperatures or other environmental controls;
 - c. duration of mixing; and
 - d. other factors pertinent to the replication of the preparation as compounded.
 - (ix) sample labeling information, which shall contain, in addition to legally required information:
 - a. generic name and quantity or concentration of each active ingredient
 - b. assigned beyond use date
 - c. storage conditions
 - d. prescription or control number, whichever is applicable;
 - (x) container used in dispensing;
 - (xi) packaging and storage requirements;
 - (xii) description of final preparation; and
 - (xiii) quality control procedures and expected results.
- ([e] f) a ~~[preparation worksheet sheet]~~ compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following:
- (i) ~~[identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes]~~ official or assigned name;
 - (ii) ~~[manufacturer lot number for each component]~~ strength and dosage of the preparation;
 - (iii) ~~[component manufacturer or suitable identifying number]~~ Master Formulation Record reference for the preparation;
 - (iv) ~~[container specifications (e.g. syringe, pump cassette)]~~ names and quantities of all components;
 - (v) ~~[unique lot or control number assigned to batch]~~ sources, lot numbers, and expiration dates of components;
 - (vi) ~~[beyond use date of batch prepared products]~~ total quantity compounded;
 - (vii) ~~[date of preparation]~~ name of the person who prepared the preparation;
 - (viii) ~~[name, initials or electronic signature of the person or persons involved in the preparation]~~ name of the compounder who approved the preparation;

(ix) [~~names, initials or electronic signature of the responsible pharmacist or DMP~~] name of the person who performed the quality control procedures;

(x) [~~end-product evaluation and testing specifications, if applicable; and~~] date of preparation;

(xi) [~~comparison of actual yield to anticipated yield, when appropriate~~] assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;

(xii) assigned beyond use date;

(xiii) duplicate label as described in the Master Formulation Record;

(xiv) description of final preparation;

(xv) results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids); and

(xvi) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

(fg) the label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:

(i) the unique lot number assigned to the batch;

(ii) all active solution and ingredient names, amounts, strengths and concentrations, when applicable;

(iii) quantity;

(iv) beyond use date and time, when applicable;

(v) appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and

(vi) device-specific instructions, where appropriate;

(h) all prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in UCA 58-17b-602L the following.

(i) generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation.

(ii) assigned compounding record or lot number.

(iii) "this is a compounded preparation" or similar language shall be indicated.

(gi) the beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;

(i) sources of drug stability information shall include the following:

(A) references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;

(B) manufacturer recommendations; and

(C) reliable, published research;

(ii) when interpreting published drug stability information, the pharmacist or DMP shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and

(iii) methods for establishing beyond use dates shall be documented; and

([h]j) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

(4) The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

- (a) Title 58, Chapter 1, Division of Occupational and Professional Licensing Act
- (b) R156-1, General Rule of the Division of Occupational and Professional Licensing;
- (c) Title 58, Chapter 17b, Pharmacy Practice Act;
- (d) R156-17b, Utah Pharmacy Practice Act Rule;
- (e) Title 58, Chapter 37, Utah Controlled Substances Act;
- (f) R156-37, Utah Controlled Substances Act Rule;
- (g) Title 58, Chapter 37f, Controlled Substance Database Act;
- (h) R156-37f, Controlled Substance Database Act Rule;
- (i) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USP DI Drug Reference Guides;
- (j) current FDA Approved Drug Products (orange book); and
- (k) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable for inspection by the Division and may be maintained in paper or electronic form.

(6) Facilities shall have a counseling area to allow for confidential patient counseling, where applicable.

(7) A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist or DMP is physically present and immediately available in the facility.

(8) Only a licensed Utah pharmacist, DMP or authorized pharmacy personnel shall have access to the pharmacy when the pharmacy is closed.

(9) The facility or parent company shall maintain a record for not less than 5 years of the initials or identification codes that identify each dispensing pharmacist or DMP by name. The initials or identification code shall be unique to ensure that each pharmacist or DMP can be identified; therefore identical initials or identification codes shall not be used.

(10) The pharmacy facility shall maintain copy 3 of DEA order form (Form 222) that has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents.

(11) If applicable, a hard copy of the power of attorney authorizing a pharmacist, DMP, or DMP designee to sign DEA order forms (Form 222) shall be available to the Division whenever necessary.

(12) A pharmacist, DMP or other responsible individual shall verify that controlled substances are listed on the suppliers' invoices and were actually received by clearly recording their initials and the actual date of receipt of the controlled substances.

(13) The pharmacy facility shall maintain a record of suppliers' credit memos for controlled substances.

(14) A copy of inventories required under Section R156-17b-605 shall be made available to the Division when requested.

(15) The pharmacy facility shall maintain hard copy reports of surrender or destruction of controlled substances and legend drugs submitted to appropriate state or federal agencies.

(16) If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling,

the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy.

New Item #1, Dispensing Naloxone Kits – Nick Weaver, PharmD.

R156-17b-614e. Class B – Dispensing Drugs from an Emergency Department and Upon Discharge from a Rural Hospital Pharmacy

The "Guidelines for Hospital Pharmacies and Emergency Department Treatment" document, adopted May 21, 2012, by the Division in collaboration with the Utah State Board of Pharmacy, as posted on the Division website, is the guideline or standard to be utilized by rural hospital emergency departments dispensing a short course of necessary medications to patients when a pharmacy is not open to fill their prescriptions.

58-17b-507. Opiate antagonist -- Immunity from liability. (1) A person licensed under this chapter who dispenses an opiate antagonist as defined in Section 26-55-102 to an individual with a prescription for an opiate antagonist is not liable for any civil damages resulting from the outcomes that result from the eventual administration of the opiate antagonist to a person who another person believes is suffering an opiate-related drug overdose as defined in Section 26-55-102. (2) The provisions of this section do not establish a duty or standard of care in the prescribing, dispensing, or administration of an opiate antagonist. (3) It is not unprofessional conduct or unlawful conduct for a licensee under this chapter to dispense an opiate antagonist to a person on behalf of another person if the person obtaining the opiate antagonist has a prescription for the opiate antagonist from a licensed prescriber.



**DRUG OVERDOSE PREVENTION
FACT SHEET**

Utah Overdose Prevention Legislation

Background

Drug overdose is a nationwide epidemic that claims the lives of over 43,000 Americans every year.¹ Utah ranks fifth in the nation in per capita drug overdose deaths,² and more than 500 Utahns were killed by drug overdose in 2012.³ Three-quarters (75 percent) of these deaths involved opioids, and 268 were due to prescription opioids such as OxyContin and hydrocodone.⁴ The majority of these deaths were preventable.

Opioid overdose can be reversed through the timely administration of naloxone, a medication that blocks the effects of opioids in the brain, and the provision of other emergency care as necessary.⁵ However, some current laws limit access to naloxone by making it difficult for those likely to be in a position to aid an overdose victim to access the medication. Existing law can also discourage those witnessing an overdose from calling for help.⁶ As one step toward reducing the unprecedented increase in preventable overdose deaths in the United States, the majority of states have amended their laws to increase access to this life-saving medication.⁷

In 2014, Utah passed a law aimed at increasing emergency medical care for overdose victims by providing limited protection from certain controlled substance offenses to a person who seeks medical assistance in good faith for an individual experiencing a drug-related overdose.⁸ The same protections apply to the victim. This "Overdose Good Samaritan" law went into effect on March 20, 2014. Later that same year, Utah passed a separate law designed to increase access to naloxone in the community. House Bill 119, known as the Emergency Administration of Opiate Antagonist Act, was passed overwhelmingly by the legislature and went into effect on May 13, 2014. The law expands access to naloxone in several ways. First, it permits certain medical professionals to prescribe and dispense naloxone to an individual at risk of opioid overdose, or to a family member, friend, or other person who may be in a position to assist such a person. It also permits those people to administer naloxone. Finally, the law provides for various types of immunity for those who engage in the activities authorized by the law.⁹

Limited Protections for Certain Controlled Substance Offenses

In many cases, overdose bystanders may fail to summon medical assistance because they are afraid that doing so may put them at risk of arrest and prosecution for drug-related or other crimes.¹⁰ The Overdose Good Samaritan law attempts to address this problem by providing an affirmative defense to the possession of a controlled substance for both a person who seeks medical assistance in good faith for an individual experiencing a drug-related overdose, and the person suffering from the overdose, as long as the alleged offense is committed in the same course of events giving rise to the

reported overdose and the person who sought medical assistance can prove that he fulfilled all the requirements of the law.¹¹

To avail himself or herself of the protections afforded by the law, the person who sought medical assistance must show that (1) he or she reasonably believed that an overdose was in process; (2) that he or she reported the overdose, including a location, in good faith to a medical professional, law enforcement officer, or the 911 system; (3) he or she remained at the scene of the overdose until help arrived; and (4) he or she “cooperate[d]” with the responding provider, including providing any available information about the substance(s) used by the person experiencing the overdose. Under the law, this affirmative defense can be raised for charges including: (1) the possession and use of less than 16 ounces of marijuana; (2) the possession or use of a controlled substance other than marijuana; and (3) violations of the Utah Drug Paraphernalia Act or Imitation Controlled Substances Act.¹² Although the Overdose Good Samaritan law does not provide any limit on the amount of a controlled substance other than marijuana for which an affirmative defense is provided, in practice the possession of a large amount of drugs can be and often is charged as possession with intent to distribute, which is not covered by the law.¹³

Similarly, the Overdose Good Samaritan law permits the fact that a defendant made a good faith effort to obtain medical assistance for an individual experiencing a drug-related overdose to be used as a mitigating factor at sentencing after conviction for a controlled substance offense for which an affirmative defense is not provided.¹⁴ The defendant must comply with the same requirements for establishing an affirmative defense. This protection applies to the person experiencing the overdose as well, although, as with the affirmative defense provisions, the victim is only covered by the law if the person who sought assistance fulfilled all the requirements to be granted protection. These restrictions apply even when the victim seeks assistance for him or herself.

Increased Access to Naloxone

The Emergency Administration of Opiate Antagonist Act takes several steps to make it more likely that naloxone will be available when and where it is needed. First, it authorizes physicians, physician assistants, and advanced practice registered nurses who are otherwise authorized to prescribe or dispense an opiate antagonist to do so without establishing a prescriber-patient relationship.¹⁵ This means that these health care providers may prescribe and dispense naloxone to any individual, regardless of whether they are a patient of the provider, including those at risk of overdose and family members, friends, or other persons who may be in a position to assist such a person.¹⁶ The prescriber or dispenser must provide education to the individual receiving the naloxone, including instructions to take the person to whom the naloxone is administered to an emergency care facility for medical evaluation.¹⁷ Further, the law explicitly states that it is not unprofessional or unlawful conduct for a pharmacist to dispense naloxone to any person receiving a prescription that is authorized under the law, including where the naloxone is intended for use by a third-party.¹⁸

The law also provides both the prescriber and dispenser with protection from criminal and civil liability as well as professional disciplinary action, so long as they act in good faith, for either prescribing or dispensing naloxone.¹⁹ The protection from civil liability applies to any outcomes resulting from the eventual administration of the medication as well.

The law also provides protection from civil liability for individuals, other than health care facilities and providers, who administer naloxone to another person that the individual believes is suffering an opioid-related overdose, so long as the individual acts in good faith.²⁰ Health care providers such as physicians, physician assistants, and advanced practice registered nurses are provided protection from civil liability for administering naloxone in good faith when they are not acting under a legal duty or within the scope of their professional responsibilities.²¹ This means, for example, that a health care provider *would* receive protection from civil liability when administering naloxone if he or she simply happens to come across an individual they believe are experiencing an overdose, but would *not* receive such protection when treating a patient in the course of their usual medical practice.

Conclusion

With the passage of the Overdose Good Samaritan law and the Emergency Administration of Opiate Antagonist Act, Utah joins the majority of states that have taken legislative action to increase access to emergency medical care for drug overdose.²² While it is too early to tell whether these laws will reduce overdose deaths, initial data from other states are encouraging. A recent evaluation of a naloxone distribution program in Massachusetts, which trained over 2,900 potential overdose bystanders, reported that opioid overdose death rates were significantly reduced in communities in which the program was implemented compared to those in which it was not.²³

Although Utah's Good Samaritan law may encourage some overdose witnesses to summon emergency responders when they otherwise would not, its protections are not as broad as those provided in most states that have passed similar laws. It is possible that more comprehensive protections, such as protection from prosecution for minor drug crimes, would encourage more overdose witnesses to call 911. To date, approximately 30 states have passed laws providing this protection, with promising initial results. For example, in Washington State, which passed such a law in 2010, 88 percent of people who use drugs surveyed indicated that they would be more likely to summon emergency personnel during an overdose as a result of the legal change.²⁴

SUPPORTERS



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References

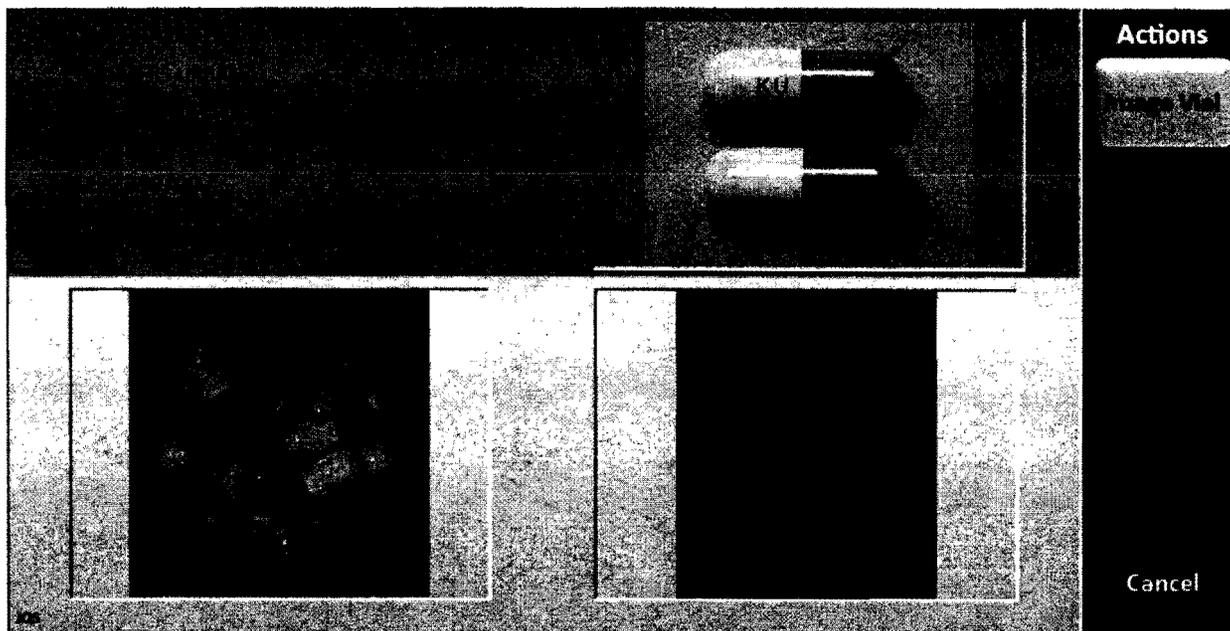
- ¹ Chen LH, Hedegaard H, Warner M. QuickStats: Rates of deaths from drug poisoning and drug poisoning involving opioid analgesics—United States, 1999–2013, 64 MORBIDITY AND MORTALITY WEEKLY REPORT 32 (2015), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a10.htm>.
- ² Utah Dep't of Health, *Utah Health Status Update: Prescription Opioid Deaths* (Sept. 2014), http://health.utah.gov/opha/publications/hsu/1409_RxOpioidDth.pdf.
- ³ Chris Stock & Melissa Brewster, *Op-ed: We have the tools to reduce Utah's high number of overdose deaths*, THE SALT LAKE TRIB. (July 7, 2015), available at <http://www.sltrib.com/opinion/2666555-155/op-ed-we-have-the-tools-to>.
- ⁴ *Utah Health Status Update: Prescription Opioid Deaths*, *supra* note 2.
 - ⁵ See C. Baca, et al., *Take-home Naloxone to Reduce Heroin Death*, 100 ADDICTION 1823 (2005); Ctrs. for Disease Control and Prevention, *Community-Based Opioid Overdose Prevention Programs Providing Naloxone – United States, 2010*, 61 MORBIDITY AND MORTALITY WEEKLY REPORT 101 (2012).
 - ⁶ See Davis CS, Webb D, Burris S. *Changing Law from Barrier to Facilitator of Opioid Overdose Prevention*, 41 JOURNAL OF LAW, MEDICINE AND ETHICS 33 (2013).

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- ⁷ For a comprehensive list of other state efforts, see NETWORK FOR PUBLIC HEALTH LAW, LEGAL INTERVENTIONS TO REDUCE OVERDOSE MORTALITY: NALOXONE ACCESS AND GOOD SAMARITAN LAWS (2015), available at https://www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf.
- ⁸ UTAH CODE ANN. §§ 58-37-8(16); 76-3-203.11. The full text of the law is available at <http://le.utah.gov/~2014/bills/static/HB0011.html>.
- ⁹ The full text of the law is available at <http://le.utah.gov/~2014/bills/static/HB0119.html>.
- ¹⁰ Karin Tobin, et al., *Calling emergency medical services during drug overdose: an examination of individual, social and setting correlates*, 100 ADDICTION 397 (2005); Robin A. Pollini, et al., *Response to Overdose Among Injection Drug Users*, 31 AMERICAN JOURNAL OF PREVENTIVE MEDICINE 261 (2006).
- ¹¹ UTAH CODE ANN. § 58-37-8(16)(a).
- ¹² UTAH CODE ANN. § 58-37-8(16)(b).
- ¹³ UTAH CODE ANN. § 58-37-8(1)(a)(iii).
- ¹⁴ UTAH CODE ANN. § 76-3-203.11.
- ¹⁵ UTAH CODE ANN. § 26-55-104(2).
- ¹⁶ UTAH CODE ANN. § 26-55-104(2)(a)-(b).
- ¹⁷ UTAH CODE ANN. § 26-55-104(3).
- ¹⁸ UTAH CODE ANN. § 58-17b-507(3).
- ¹⁹ UTAH CODE ANN. §§ 26-55-104(2); 58-17b-507, 58-31b-703, 58-67-702, 58-68-702, 58-70a-505.
- ²⁰ UTAH CODE ANN. § 26-55-104(1)(a).
- ²¹ UTAH CODE ANN. § 26-55-104(1)(b)(ii).
- ²² For a comprehensive list of other state efforts, see NETWORK FOR PUBLIC HEALTH LAW, LEGAL INTERVENTIONS TO REDUCE OVERDOSE MORTALITY: NALOXONE ACCESS AND GOOD SAMARITAN LAWS (2015), available at https://www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf.
- ²³ Alex Walley, et al., *Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis*, 346 BMJ f174 (2013).

Digital Image Capture Vial Screen



Place the vial on the tray so both the contents and label are visible.
Then press "Image Vial".





Dispensing of Naloxone by Pharmacists and Pharmacy Interns without a Prescription

Updated 8-31-2015

Section 4729.44 of the Ohio Revised Code and rule 4729-5-39 of the Ohio Administrative Code authorizes a pharmacist or pharmacy intern under the direct supervision of a pharmacist to dispense naloxone without a prescription to the following in accordance with a physician-approved protocol:

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- (2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose; or
- (3) A peace officer as defined in section 2921.51 of the Revised Code.

Section 3707.56 of the Ohio Revised Code permits a local board of health, through a physician serving as the board's health commissioner or medical director, to authorize the protocol for pharmacists and pharmacy interns working in that board of health's jurisdiction.

For questions regarding these changes, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

More information about these recent law changes can also be accessed here:
<https://www.legislature.ohio.gov/legislation/legislation-documents?id=GA131-HB-4>

Q1) What are the requirements for an approved protocol in rule 4729-5-39?

According to the rule, a physician approved protocol for dispensing naloxone without a prescription must include all of the following:

- (1) A description of the clinical pharmacology of naloxone.
- (2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.
- (3) Precautions and contraindications concerning dispensing naloxone.
- (4) Assessment and follow-up actions by the pharmacist or pharmacy intern.
- (5) Naloxone products authorized to be dispensed, including: name of product, dose, route of administration, required delivery device and directions for use.
- (6) Any patient instructions in addition to the counseling requirements in the rule.



Full text of the rule is available at the end of this document and can also be accessed here: www.pharmacy.ohio.gov/naloxone

Q2) Is there a sample protocol available?

Yes. The Board has developed a sample protocol that can be used by physicians and pharmacies as their official protocol. The sample protocol can be accessed here: www.pharmacy.ohio.gov/naloxone

Q3) What type of naloxone can be dispensed pursuant to a physician approved protocol?

The type of naloxone that may be dispensed includes all of the following formulations:

Intramuscular naloxone:

- Naloxone 0.4 mg/ml single dose vial, 2 vials
- NDC No. 00409-1215-01
- SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat x1.

- Syringe 3 ml 25G x1 inch No. 2
- SIG: Use as directed for naloxone administration

Intranasal naloxone:

- Naloxone 2 mg/2 ml prefilled syringe, 2 syringes
- NDC No. 76329-3369-01
- SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x1.

- Two mucosal atomization devices (MAD300)
- SIG: Use as directed for naloxone administration

Auto-injector (intramuscular naloxone):

- Naloxone 0.4 mg/0.4 ml
- NDC No. 60842-030-01
- No. 1 twin pack
- SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x1.

Please note: The type of naloxone that may be dispensed is subject to the formulations specified in the physician protocol. If new formulations are developed, they may be added to the protocol.

Q4) Where do I obtain the naloxone and the required delivery devices?

The single-dose vial, prefilled syringe, auto-injector and IM syringes are available from wholesale distributors with a valid Ohio license. The atomizers (MAD300) for nasal administration are available from medical supply vendors and, in some cases, can be purchased directly from the pharmacy wholesaler, or obtained from point persons within the pharmacy corporation.

Q5) Can I bill a patient's insurance for the naloxone?

Medicaid, Medicare, and many private insurance companies may cover the cost of naloxone. To assist with billing, the law permits a pharmacist to document the dispensing of naloxone by the pharmacist or a pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.

According to the Ohio Department of Medicaid, all plans, except Buckeye Health Plan, pay for all formulations of naloxone (intranasal, intramuscular and auto-injector) when dispensed to a plan member. Buckeye Health Plan will cover the intranasal formulation as part of their pharmacy benefit.

Please be advised that the auto-injector for all plans requires prior authorization.

Please note: The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy. Therefore, it must also be billed in the name of that person (if billing insurance).

Q6) Can I bill a patient's insurance for the atomizer needed for intranasal use?

It may be difficult securing reimbursement for the atomizer needed for intranasal use. Currently, the atomizer lacks a National Drug Code or UPN, which are universal product identifiers typically used in insurance billing systems. Most likely, the pharmacy will have to charge the patient the cost of the atomizer if not covered by insurance.

Q7) Why do I need to submit notification to the Board if my pharmacy initiates a protocol to dispense naloxone without a prescription?

Rule 4729-5-39 of the Ohio Administrative Code requires a pharmacy to submit notification to the Board within 30 days of establishing an approved protocol. The Board will use this documentation to create a list on its web site of all pharmacies that offer naloxone pursuant to a physician protocol in an effort to facilitate access to the medication. Please be advised, that a pharmacy that discontinues their protocol will also be required to notify the Board. The Naloxone Notification Form can be accessed here: www.pharmacy.ohio.gov/naloxone

NOTE: If you are a chain pharmacy that is planning to offer this service in a particular region or state-wide, please submit a signed notification on company letterhead that includes a spreadsheet of all participating pharmacies to: contact@pharmacy.ohio.gov.

Q8) How do I submit this required documentation?

Step 1: The pharmacy's responsible person completes the notification form, which can be accessed here: www.pharmacy.ohio.gov/naloxone

Step 2: Go to the general document submission page:
<http://www.pharmacy.ohio.gov/TDDD/GeneralDocumentUpload.aspx>

Step 3: When at the page, enter the following information:

- The pharmacy's TDDD license number.
- Select "Naloxone Notification Form" from the drop down menu.
- Include your e-mail address or addresses for confirmation of your submission.

- Indicate whether you are dispensing naloxone pursuant to OAC 4729-5-39 or you are no longer dispensing naloxone in accordance with the rule.
- Upload the form (.PDF only).

Step 4: Once all the information is entered and the Click the submit button.

This process is also used for notifying the Board that your pharmacy has discontinued the protocol.

NOTE: If you are a chain pharmacy that is planning to offer this service in a particular region or state-wide, please submit a signed notification on company letterhead that includes a spreadsheet of all participating pharmacies to: contact@pharmacy.ohio.gov.

Q9) What are the counseling requirements for a pharmacist or pharmacy intern prior to dispensing naloxone pursuant to a protocol?

In addition to requirements specified in the protocol, OAC 4729-5-39 requires a pharmacist or pharmacy intern to provide written and verbal counseling on the following topics:

- (1) Instructing the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone;
- (2) Risk factors of opioid overdose;
- (3) Strategies to prevent opioid overdose;
- (4) Signs of opioid overdose;
- (5) Steps in responding to an overdose;
- (6) Information on naloxone;
- (7) Procedures for administering naloxone; and
- (8) Proper storage and expiration of naloxone product dispensed.

All patient counseling shall be documented in accordance with rule [4729-5-27 of the Ohio Administrative Code](#).

Q10) Is there written information available to assist pharmacists and pharmacy interns with meeting the counseling requirements?

Yes. The Board has developed a brochure that covers all of the required counseling listed in OAC 4729-5-39. The Board has a printed supply of these brochures that can be requested by a pharmacy free-of-charge by sending a request with all of the following information to contact@pharmacy.ohio.gov:

- Name of Requestor
- Pharmacy Name
- Mailing Address
- Phone Number
- Quantity Requested (there is a 250 pamphlet limit but additional requests can be made if the pharmacy is running low)

Please allow 7-10 days for delivery from the date of the request.

The pamphlet is also available electronically by visiting: www.pharmacy.ohio.gov/naloxone

Q11) The law allows me to dispense naloxone to "a person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose". How do I go about making this determination?

Many individuals work in environments where they may assist an individual experiencing an overdose including, but not limited, to the following:

- Colleges (residence life staff) and schools (school nurses, administrators, teachers, etc.)
- Substance abuse treatment programs (residential and nonresidential)
- Halfway houses
- Homeless shelters
- Home healthcare agencies

The pharmacist or pharmacy intern should use their professional judgement to determine if the person meets the requirement of the law.

Please note: The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy. Therefore, it must also be billed in the name of that person (if billing insurance).

Q12) What type of prescribers are able to authorize the protocol?

Ohio licensed physicians must authorize the protocol. The law does not limit the number of protocols a physician may authorize therefore a physician may authorize a protocol for a number of pharmacy locations.

The law also permits a local board of health, through a physician serving as the board's health commissioner or medical director, to authorize the protocol for pharmacists and pharmacy interns working in that board of health's jurisdiction.

Q13) Are there any protections for pharmacists, physicians and boards of health in the law?

Yes. A pharmacist, physician or board of health, acting in good faith, is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Q14) When does the protocol expire?

Pursuant to rule 4729-5-39 of the Ohio Administrative Code, the protocol must be renewed annually. A pharmacy may discontinue a protocol at any time as long as proper notice is provided to the Board within 30 days (see Q7).

Q15) Is there a limit to the amount of naloxone that can be dispensed pursuant to a protocol?

The pharmacist or pharmacy intern should refer back to their protocol to determine if there are any established limits. If no such limitations exist, they should exercise their professional judgement to determine if additional doses may be supplied.

Q16) Are there recordkeeping and other requirements for pharmacists and pharmacy interns dispensing naloxone pursuant to a protocol?

All laws and regulations regarding the dispensing of drugs by a pharmacy would apply to naloxone dispensed pursuant to a protocol.

Q17) Are there any substance abuse resources available to patients and their families?

For anyone seeking substance abuse treatment, please refer them to the Ohio Department of Mental Health and Addiction Services' treatment referral line at 1.877.275.6364.

Q18) Are there any training resources available for pharmacists that dispense naloxone?

Yes. A no-cost ACPE approved pharmacist continuing education course is available from Prescribe to Prevent and Boston University. It can be accessed here:
http://www.opioidprescribing.com/naloxone_module_1-landing

Q19) I am a pharmacy dispensing naloxone pursuant to a prescription? Do I need to comply with the requirements of OAC 4729-5-39?

No. The requirements for OAC 4729-5-39 are only required for pharmacies that dispense naloxone pursuant to a physician approved protocol. It does not apply to pharmacies that provide naloxone pursuant to a prescription or an order by a licensed prescriber.

Q20) Are there any age restrictions for dispensing naloxone pursuant to a protocol?

Unless specified in the signed protocol, there are no restrictions on age for dispensing naloxone. A pharmacist must use their professional judgement to determine if a minor is sufficiently mature with respect to intellect and emotions to carry out all the responsibilities to effectively respond to a suspected overdose, including the administration of naloxone.

Q21) I am a physician that will be authorizing a number of pharmacies to dispense naloxone pursuant to a protocol. Do I need to have a signed protocol for every pharmacy?

No. The protocol issued by the physician can be signed once and include a list of all the authorized pharmacies. That protocol should then be copied and provided to all of the participating pharmacies to be signed by the responsible person.

4729-5-39 Dispensing of Naloxone

(A) A pharmacist or pharmacy intern under the direct supervision of a pharmacist may dispense naloxone without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of this rule:

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- (2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose; or
- (3) A peace officer as defined in section 2921.51 of the Revised Code.

(B) To be considered an approved protocol pursuant to section 4729.44 of the Revised Code, the physician-established protocol for the dispensing of naloxone by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

- (1) A description of the clinical pharmacology of naloxone.
- (2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.
- (3) Precautions and contraindications concerning dispensing naloxone.
- (4) Assessment and follow-up actions by the pharmacist or pharmacy intern.
- (5) Naloxone products authorized to be dispensed, including all of the following information:
 - (a) Name of product;
 - (b) Dose;
 - (c) Route of administration and required delivery device; and
 - (d) Directions for use.
- (6) Any patient instructions in addition to the counseling specified in paragraphs (C) and (D) of this rule.

(C) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who dispenses naloxone pursuant to this rule shall instruct the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone.

(D) A pharmacist or pharmacy intern under the direct supervision of a pharmacist shall personally provide the service of verbal counseling and written educational materials to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed, including, but not limited to, all of the following:

- (1) Risk factors of opioid overdose;
- (2) Strategies to prevent opioid overdose;
- (3) Signs of opioid overdose;
- (4) Steps in responding to an overdose;
- (5) Information on naloxone;
- (6) Procedures for administering naloxone; and
- (7) Proper storage and expiration of naloxone product dispensed.

(E) The pharmacy's responsible person shall ensure that all pharmacists and pharmacy interns that dispense naloxone pursuant to this rule are appropriately trained on the use of naloxone and can meet the counseling requirements listed in paragraphs (C) and (D) of this rule.

(F) A pharmacist may document the dispensing of naloxone by the pharmacist or a pharmacy intern supervised by the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

(G) All physician-established protocols shall be signed and dated by the physician prior to implementation and maintained by the pharmacy's responsible person. The protocol shall be made readily available to the dispensing pharmacist or pharmacy intern under the direct supervision of a pharmacist. The pharmacy's responsible person shall renew the protocol annually with the physician.

(H) Any pharmacy that dispenses naloxone pursuant to this rule, shall notify the board, in a manner prescribed by the board, within 30 days of establishing an approved protocol. A pharmacy that no longer dispenses naloxone pursuant to this rule shall notify the board, in a manner prescribed by the board, within 30 days of discontinuation.

Effective 7.16.2015