#1

	2013	2014	Sep-14
Administrative Filings	37	43	4
Criminal Filing/Felony	3	0	0
Letter of Concern	60	98	5
Referred to Diversion	1	1	1
PR/Outreach	3	4	0
Cases Received	710	330	24
Case Assigned	676	318	24
Closed Cases	731	342	45
Citations Issued	103	26	8
Pharmacy Inspections	225	201	18
Pharmacy Alerts	191	196	12
Dr. Shopper/Law Enforcement Letters	209	426	37

NOTES: Pharmacy Group	**Sep-14**
Administrative Action	Pharmacist-In-Charge, Mark Harward, entered into a Stipulation and Order where his license was suspended for 6 months and placed on Probation for 3 years, for disciplinary actions taken by the Office of Inspector General for the U.S. Department of Health and Human Services.
Administrative Action	Pharmacist-In-Charge, Richard Perry, entered into a Stipulation and Order and was fined $500. $250 was suspended and Mr. Perry was fined $250 and placed on Probation for Pharmacy Violations.
Administrative Action	Reams Pharmacy entered into a Stipulation and Order and was fined $5,000. $2,500 was suspended. Reams Pharmacy was fined $2,500 and their license was placed on Probation for Pharmacy Violations.
Citation	Rite Aide Pharmacy was issued a Citation with a fine of $1,250 for Pharmacy Violations found during a Random Inspection.
Citation	Winegars Pharmacy was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Roe RX Inc was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Taylor Drug was issued a Citation with a $2,000 fine for Pharmacy Violations found during a Random Inspection.
Citation	Lee's Market Place was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Spence's North Pharmacy was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.
Citation	Spence's North Pharmacy was issued a Citation with a $2,000 fine for Pharmacy Violations found during a Random Inspection.
Citation	Orchard Drug was issued a Citation with a $1,050 fine for Pharmacy Violations found during a Random Inspection.

3

WV pharmacy board reporting 'doctor shoppers' to authorities

Mark Lowery, Content Editor
Publish Date: SEP 18,2014

The West Virginia Board of Pharmacy has created a list of suspected "doctor shoppers" and given it to law enforcement officials, according to a report in the *Charleston Gazette*.

The list includes 90 people who sought an excessive number of painkiller scripts over the past year. It was provided to the West Virginia State Police and U.S. Drug Enforcement Administration. West Virginia has the highest drug overdose rate in the country.

Pill-mill crackdown cut Florida's overdose deaths

One person on the list received painkiller scripts from 34 doctors, according to the report. Others obtained prescriptions from different doctors in different areas of the state. The list was created by analyzing the state's controlled-substances database. No arrests have been made yet.

"You have someone on a 30-day supply, and then they're getting two or three other prescriptions in the same month," Mike Goff, a pharmacy board administrator, told the newspaper. "Those are the ones who are the clear problems, the ones law enforcement will look at further."

David Potters, the pharmacy board's executive director, said some of the people on the list might have legitimate reasons for securing painkiller scripts from more than one doctor. He said law enforcement officials will interview pharmacists and medical professionals before making any arrests.

"The doctor-shopping crime happens when a patient tells a doctor, 'my back is hurting, and I need this medication, and, no I haven't seen any other doctors but you,'" Goff said. "The patient is misleading the doctor in trying to get pills. They're hitting up multiple doctors and lying to them to get prescriptions."

The board has also sent 2,800 letters to medical professionals across West Virginia that warn them of specific patients have obtained multiple prescriptions from various medical professionals.

"We said, 'Here's your patient. You wrote them a prescription, and so did 11 other people,'" Goff told the newspaper. "We're telling them they need to register [for the state's controlled-substances database], and there's been a big influx of sign-ups after the letters went out. The letters have prompted a lot of them to comply."

58-17b-803. Qualifications for licensure as a dispensing medical practitioner -- Scope of practice.

(4) A dispensing medical practitioner:

(a) shall inform the patient:

(i) that the drug dispensed by the practitioner may be obtained from a pharmacy unaffiliated with the practitioner;

(ii) of the directions for appropriate use of the dispensed drug;

(iii) of potential side effects to the use of the dispensed drug; and

(iv) how to contact the dispensing medical practitioner if the patient has questions or concerns regarding the drug;

(b) shall report to the controlled substance database in the same manner as required in Section 58-37f-203; and

(c) may delegate the dispensing of the drug if the individual to whom the dispensing was delegated is:

(i) employed by the dispensing medical practitioner or the outpatient clinic setting in which the dispensing medical practitioner works; and

(ii) acting under the direction of a dispensing medical practitioner who is immediately available on site for any necessary consultation.

(4b)

Recommendation for Process Change Relating to Candidate Examination Eligibility
10/23/14

The following is a recommendation for the National Association of Boards of Pharmacy (NABP) to initiate and manage a pre-approval process through the pharmacist e-Profiles for candidates to take the North American Pharmacist Licensure Examination (NAPLEX) and Multistate Pharmacy Jurisprudence Examination (MPJE) in instances where a state requests this service.

Background:
In recent discussions with Rich Oborn, Bureau Manager at the Utah Division of Occupational and Professional Licensing (DOPL), he explained his charge to streamline DOPL licensure processes, and asked that NABP provide assistance. More specifically, he has requested that NABP take over the task of confirming examination eligibility of candidates wishing to sit for the NAPLEX and MPJE. This would allow DOPL to focus more closely on essential licensure responsibilities while providing NABP with ownership of responsibilities relating directly to the Association's examinations.

DOPL shared its view that determining eligibility distracts DOPL staff from its core licensing responsibilities. Currently all Utah pharmacist applicants have six months to complete the NAPLEX and MPJE. This means that an individual may apply for licensure with DOPL in January and then wait until May or June to sit for his or her examination, making it appear as if DOPL has taken nearly six months to process an application and license. Mr. Oborn expressed concerns that if legislators were to review the average time from when an individual first applies for licensure and when the license is issued, they may misinterpret the data to be slow processing times on DOPL's end rather than the fact that these timelines are primarily driven by the candidates themselves.

Recommendation:
To assist DOPL and other states that may potentially be faced with similar issues, Competency Assessment and Member Relations and Government Affairs propose that NABP implement a service to allow NABP to determine candidate examination eligibility on behalf of the jurisdiction. The verified candidate data and final exam scores would be made available to the jurisdiction via the e-Profile Connect. It is suggested that this service be piloted through Utah with the intent of rolling it out to additional states that may request this type of service in the future. In terms of timing, Utah is hoping to have this service up and running prior to the April 2015 graduation.

Initial Updates Necessary:
Prior to implementing this new eligibility process, the NAPLEX and MPJE memorandum of understanding between NABP and Utah would first need to be amended or an addendum would need to be put in place. The e-Profile Connect interface would also need to be updated to allow for the applicable verified candidate data to be made available to the state. Additionally, DOPL indicated that changes to agency rule would be necessary, but no statutes would need to be changed. The concept will be presented by DOPL to the Utah Board of Pharmacy for recommendation, but it does not require Board approval.

Process:
By initiating this process, documentation and notification pertaining to the NAPLEX/MPJE sent to a jurisdiction ahead of the examination would be eliminated. Instead, candidates would complete a pre-approval application directly with NABP prior to registering for the examination (should their board wish to participate in this service). This pre-approval application would also be accompanied by any necessary supplemental documentation and an administrative fee would also be collected in addition to the examination fee.

Should there be any questions of eligibility when NABP reviews a candidate's application, NABP would have the ability to consult with the jurisdiction.

Regarding collection of supplemental documentation, in order to avoid the candidate submitting duplicate documentation to both NABP and the jurisdiction, it is recommended that NABP collect this documentation up front and include in the candidate's e-Profile for the jurisdiction to view electronically. It is also suggested that NABP set a uniform standard for the type of documentation necessary based on existing state requirements. Should a jurisdiction require additional items they may then collect these documents directly from the candidate.

Recommended information and documents to collect from candidates at time of pre-approval includes:

- Educational History –
  - Official transcript documenting completion of an ACPE-accredited program
  - Copy of FPGEC certificate
- If New License: Internship Hours –
  - Official transcript documenting completion of ACPE-accredited program
  - Verification of internship license and hours from another state.
- If Previously Licensed –
  - Official NABP License Transfer Application
  - Verification of licensure as a pharmacist in good standing from another state
  - Letter from employer on company letterhead attesting the number of hours worked
- Criminal History –
  - All police reports, court records, or probation/parole officer reports

Official educational data submitted would ideally be validated by schools and colleges of pharmacy through a linked database to NABP, while professional data would be verified through the jurisdiction. Upon review and verification of all documentation, NABP staff will approve eligibility for the candidate to test. After the candidate sits for the NAPLEX and/or MPJE, the examination score would be provided directly to the jurisdiction and the supplemental documentation would be made available in the applicant's e-Profile. It is at that time, that the individual would apply for licensure with the jurisdiction.

Outcome:
It is estimated that by eliminating this examination-related task from DOPL's responsibilities, DOPL will be better prepared to focus on essential licensure responsibilities and, in some cases,

application processing times may reduce by nearly 6 months. For reference, in 2013, 248 examinees sat for the Utah MPJE and 150 NAPLEX examinees specifically named Utah as their primary jurisdiction.

R156-17b-303c. Qualifications for Licensure - Examinations.

(1) In accordance with Subsection 58-17b-303(1)(h), the examinations that shall be successfully passed by an applicant for licensure as a pharmacist are:

(a) the NAPLEX with a passing score as established by NABP; and

(b) the Multistate Pharmacy Jurisprudence Examination(MPJE) with a minimum passing score as established by NABP.

[~~(2) An individual who has failed either examination twice shall meet with the Board to request an additional authorization to test. The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.~~]

(3) In accordance with Subsection 58-17b-303(3)(j), an applicant applying by endorsement is required to pass the MPJE.

[~~(4) Applicants taking the NAPLEX or MPJE examination shall pass the exams within six months from the date of the Division's approval for the applicant to take the exam. If the applicant does not pass the required exam within six months, the pending license application shall be denied.~~]

(5) In accordance with Subsection 58-17b-305(1)(g), an applicant applying for licensure as a pharmacy technician shall pass the PTCB or ExCPT with a passing score as established by the certifying body. The certificate shall exhibit a valid date and that the certification is active.

(6) A graduate of a foreign pharmacy school shall obtain a passing score on the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.

4c

R156-17b-303a. Qualifications for Licensure - Education Requirements.

(1) In accordance with Subsections 58-17b-303(2) and 58-17b-304(7)(b), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy Foundation.

(2) In accordance with Subsection 58-17b-304(7), an applicant for a pharmacy intern license shall demonstrate that he meets one of the following education criteria:

(a) current admission in a College of Pharmacy accredited by the ACPE by written verification from the Dean of the College;

(b) a graduate degree from a school or college of pharmacy which is accredited by the ACPE; or

(c) a graduate degree from a foreign pharmacy school as established by a certificate of equivalency from an approved credentialing agency defined in Subsection (1).

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician shall complete a training program that is:

(a) accredited by ASHP; or

(b) conducted by:

(i) the National Pharmacy Technician Association;

(ii) Pharmacy Technicians University; or

(iii) a branch of the Armed Forces of the United States, and

(c) meets the following standards:

(i) completion of at least 180 hours of directly supervised practical training in a licensed pharmacy as determined appropriate by a licensed pharmacist in good standing; and

(ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technician[~~s in training~~] trainees that address:

(A) the specific manner in which supervision will be completed; and

(B) an evaluative procedure to verify the accuracy and completeness of all acts, tasks and functions performed by the pharmacy technician [~~in training~~]trainee.

(4) An individual shall complete a pharmacy technician training program and successfully pass the required examination[~~s~~] as listed in Subsection R156-17b-303c(4) within two years [~~from the date of the first day of the training program~~]of obtaining a pharmacy technician trainee license, unless otherwise approved by the Division for good cause showing exceptional circumstances in collaboration with the Board.

(a) Unless otherwise approved under Subsection (4), [A]an individual who fails to apply for and obtain a pharmacy technician license within the two-year time frame[~~ or within six months after completion of a pharmacy technician training program, whichever comes first:~~

[~~(i) is no longer eligible for employment as a technician-in-training and shall work in the pharmacy only as supportive personnel; and~~

~~(ii)~~]shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

(5)(a) Pharmacy technician training programs that received Division approval on or before April 30, 2014 are exempt from satisfying standards established in Subsection R156-17b-303a(3) for students enrolled on or before December 31, 2018.

(b) A student in a program described in Subsection (5)(a) shall comply with the program completion deadline and testing requirements in Subsection (4), except that the license application shall be submitted to the Division no later than December 31, 2021.

(c) A program in ASHP candidate status shall notify a student prior to enrollment that if the program is denied accreditation status while the student is enrolled in the program, the student will be required to complete education in another program with no assurance of how many credits will transfer to the new program.

(d) A program in ASHP candidate status that is denied accreditation shall immediately notify the Division, enrolled students and student practice sites, of the denial. The notice shall instruct each student and practice site that:

(i) the program no longer satisfies the pharmacy technician license education requirement in the State of Utah; and

(ii) enrollment in a different program meeting requirements established in Subsection R156-17b-303a(3) is necessary for the student to complete training and to satisfy the pharmacy technician license education requirement in the State of Utah.

(6) An applicant for licensure as a pharmacy technician is deemed to have met the qualifications for licensure in Subsection 58-17b-305(1)(f) and 58-17b-305(1)(g) if the applicant:

[~~(a) is currently licensed and in good standing in another state and has not had any adverse action taken on that license;~~]

([~~b~~]a) has engaged in the practice as a pharmacy technician for a minimum of 1,000 hours in that state within the past two years or equivalent experience as approved by the Division in collaboration with the Board; and

([~~c~~]b) has passed and maintained current PTCB or ExCPT certification.

4d

R156-17b-617c. Class E Pharmacy Operating Standards – Animal Control or Narcotic Detection Training.

(1) In accordance with Section 58-17b-302 and Subsection 58-17b-601(1), an animal control or narcotic detection training facility shall:

(a) maintain for immediate retrieval a perpetual inventory of all drugs including controlled substances that are purchased, stored, processed and administered;

(b) maintain for immediate retrieval a current list of authorized employees and their training with regards to the handling and use of legend drugs and/or controlled substances in relation to euthanasia, [~~or~~]immobilization, or narcotic detection training of animals;

(c) maintain, for immediate retrieval documentation of all required materials pertaining to legitimate animal scientific drug research, guidance policy and other relevant documentation from the agency's Institutional Review Board, if applicable;

(d) maintain stocks of legend drugs and controlled substances to the smallest quantity needed for efficient operation to conduct animal euthanasia, [~~or~~]immobilization, or narcotic detection training purposes;

(e) maintain all legend drugs and controlled substances in an area within a building having perimeter security which limits access during working hours, provides adequate security after working hours, and has the following security controls:

(i) a permanently secured safe or steel cabinet substantially constructed with self-closing and self-locking doors employing either multiple position combination or key lock type locking mechanisms; and

(ii) requisite key control, combination limitations, and change procedures;

(f) have a responsible party who is the only person authorized to purchase and reconcile legend drugs and controlled substances and is responsible for the inventory of the animal control or narcotic detection training facility pharmacy;

(g) ensure that only defined and approved individuals pursuant to the written facility protocol have access to legend drugs and controlled substances; and

(h) develop and maintain written policies and procedures for immediate retrieval which include the following:

(i) the type of activity conducted with regards to legend drugs and/or controlled substances;

(ii) how medications are purchased, inventoried, prepared and used in relation to euthanasia, [~~or~~]immobilization, or narcotic detection training of animals;

(iii) the type, form and quantity of legend drugs and/or controlled substances handled;

(iv) the type of safe or equally secure enclosures or other storage system used for the storage and retrieval of legend drugs and/or controlled substances;

(v) security measures in place to protect against theft or loss of legend drugs and controlled substances;

(vi) adequate supervision of employees having access to manufacturing and storage areas;

(vii) maintenance of records documenting the initial and ongoing training of authorized employees with regard to all applicable protocols;

(viii) maintenance of records documenting all approved and trained authorized employees who may have access to the legend drugs and controlled substances; and

(ix) procedures for allowing the presence of business guests, visitors, maintenance personnel, and non-employee service personnel.

[~~(2) In accordance with Section 58-37-6 and Subsection R156-37-305(1), individuals employed by an agency of the State or any of its political subdivisions who are specifically authorized in writing by their employer to possess specified controlled substances in specified reasonable and necessary quantities for the purpose of euthanasia, or immobilization, or narcotic detection training upon of animals, shall be exempt from having a controlled substance license if the employing agency or jurisdiction has obtained a controlled substance license and a DEA registration number, and uses the controlled substances according to a written protocol in performing animal euthanasia, or]immobilization or narcotic detection training.~~]

4e

R156-37f. Controlled Substance Database Act Rule.

R156-37f-102. Definitions.

In addition to the definitions in Sections 58-17b-102, 58-37-2 and 58-37f-102, as used in this chapter:

(1) "ASAP" means the American Society for Automation in Pharmacy system.

(2) "DEA" means Drug Enforcement Administration.

(3) "NABP" means the National Association of Boards of Pharmacy.

(4) "NCPDP" means National Council for Prescription Drug Programs.

(5) "NDC" means National Drug Code.

(6) "Positive identification" means:

(a) one of following photo identifications issued by a foreign or domestic government:

(i) driver's license;

(ii) non-driver identification card;

(iii) passport;

(iv) military identification; or

(v) concealed weapons permit; or

(b) in rare cases when the individual does not have government-issued identification ~~and the pharmacist determines that harm to a patient would result if the prescription is not filled,~~ the pharmacist may request alternative evidence of the individual's identity as deemed appropriate by the pharmacist as long as the pharmacist documents in a prescription record a description of how the individual was positively identified.

58-37f-203. Submission, collection, and maintenance of data.

(1) (a) The pharmacist in charge of the drug outlet where a controlled substance is dispensed shall submit the data described in this section to the division:

(i) in accordance with the requirements of this section;

(ii) in accordance with the procedures established by the division; and

(iii) in the format established by the division.

(b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with the provisions of this section and the dispensing medical practitioner shall assume the duties of the pharmacist under this chapter.

(2) The pharmacist described in Subsection (1) shall, for each controlled substance dispensed by a pharmacist under the pharmacist's supervision other than those dispensed for an inpatient at a health care facility, submit to the division the following information:

(a) the name of the prescribing practitioner;

(b) the date of the prescription;

(c) the date the prescription was filled;

(d) the name of the individual for whom the prescription was written;

(e) positive identification of the individual receiving the prescription, including the type of identification and any identifying numbers on the identification;

(f) the name of the controlled substance;

(g) the quantity of the controlled substance prescribed;

(h) the strength of the controlled substance;

(i) the quantity of the controlled substance dispensed;

(j) the dosage quantity and frequency as prescribed;

(k) the name of the drug outlet dispensing the controlled substance;

(l) the name of the pharmacist dispensing the controlled substance; and

(m) other relevant information as required by division rule.

R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer[~~ in Utah~~].

In accordance with Subsections 58-17b-102(44) and 58-17b-601(1), the operating standards for Class C pharmacies designated as pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensees includes the following:

(1) Every pharmaceutical wholesaler or manufacturer that engages in the wholesale distribution and manufacturing of drugs or medical devices [~~located in this state~~]shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah.

(2) Manufacturers distributing only their own FDA-approved prescription drugs or co-licensed product shall satisfy this requirement by registering their establishment with the Federal Food and Drug Administration pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205, including any amendments thereto, to the Division.

(3) An applicant for licensure as a pharmaceutical wholesale distributor shall provide the following minimum information:

(a) All trade or business names used by the licensee (including "doing business as" and "formerly known as");

(b) Name of the owner and operator of the license as follows:

(i) if a person, the name, business address, social security number and date of birth;

(ii) if a partnership, the name, business address, and social security number and date of birth of each partner, and the partnership's federal employer identification number;

(iii) if a corporation, the name, business address, social security number and date of birth, and title of each corporate officer and director, the corporate names, the name of the state of incorporation, federal employer identification number, and the name of the parent company, if any, but if a publicly traded corporation, the social security number and date of birth for each corporate officer shall not be required;

(iv) if a sole proprietorship, the full name, business address, social security number and date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(v) if a limited liability company, the name of each member, social security number of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

(c) any other relevant information required by the Division.

(4) The licensed facility need not be under the supervision of a licensed pharmacist, but shall be under the supervision of a designated representative who meets the following criteria:

(a) is at least 21 years of age;

(b) has been employed full time for at least three years in a pharmacy or with a pharmaceutical wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to prescription drugs;

(c) is employed by the applicant full time in a managerial level position;

(d) is actively involved in and aware of the actual daily operation of the pharmaceutical wholesale distribution;

(e) is physically present at the facility during regular business hours, except when the absence of the designated representative is authorized, including but not limited to, sick leave and vacation leave; and

(f) is serving in the capacity of a designated representative for only one licensee at a time.

(5) The licensee shall provide the name, business address, and telephone number of a person to serve as the designated representative for each facility of the pharmaceutical wholesaler that engages in the distribution of drugs or devices.

[~~(6) Each facility that engages in pharmaceutical wholesale distribution and manufacturing facilities shall undergo an inspection by the Division for the purposes of inspecting the pharmaceutical wholesale distribution or manufacturing operation prior to initial licensure and periodically thereafter with a schedule to be determined by the Division.~~]

(7) All pharmaceutical wholesalers and manufacturer shall publicly display or have readily available all licenses and the most recent inspection report administered by the Division.

(8) All Class C pharmacies shall:

(a) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

(b) have storage areas designed to provide adequate lighting, ventilation, sanitation, space, equipment and security conditions;

(c) have the ability to control temperature and humidity within tolerances required by all prescription drugs and prescription drug precursors handled or used in the distribution or manufacturing activities of the applicant or licensee;

(d) provide for a quarantine area for storage of prescription drugs and prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, opened or unsealed containers that have once been appropriately sealed or closed or in any other way unsuitable for use or entry into distribution or manufacturing;

(e) be maintained in a clean and orderly condition; and

(f) be free from infestation by insects, rodents, birds or vermin of any kind.

(9) Each facility used for wholesale drug distribution or manufacturing of prescription drugs shall:

(a) be secure from unauthorized entry;

(b) limit access from the outside to a minimum in conformance with local building codes, life and safety codes and control access to persons to ensure unauthorized entry is not made;

(c) limit entry into areas where prescription drugs, prescription drug precursors, or prescription drug devices are held to authorized persons who have

a need to be in those areas;

(d) be well lighted on the outside perimeter;

(e) be equipped with an alarm system to permit detection of entry and notification of appropriate authorities at all times when the facility is not occupied for the purpose of engaging in distribution or manufacturing of prescription drugs; and

(f) be equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.

(10) Each facility shall provide the storage of prescription drugs, prescription drug precursors, and prescription drug devices in accordance with the following:

(a) all prescription drugs and prescription drug precursors shall be stored at appropriate temperature, humidity and other conditions in accordance with labeling of such prescription drugs or prescription drug precursors or with requirements in the USP-NF;

(b) if no storage requirements are established for a specific prescription drug, prescription drug precursor, or prescription drug devices, the products shall be held in a condition of controlled temperature and humidity as defined in the USP-NF to ensure that its identity, strength, quality and purity are not adversely affected; and

(c) there shall be established a system of manual, electromechanical or electronic recording of temperature and humidity in the areas in which prescription drugs, prescription drug precursors, and prescription drug devices are held to permit review of the record and ensure that the products have not been subjected to conditions which are outside of established limits.

(11) Each person who is engaged in pharmaceutical wholesale distribution of prescription drugs for human use that leave, or have ever left, the normal distribution channel shall, before each pharmaceutical wholesale distribution of such drug, provide a pedigree to the person who receives such drug. A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy engages in pharmaceutical wholesale distribution of prescription drugs. The pedigree shall:

(a) include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any pharmaceutical wholesaler, until sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the necessary chain of distribution information shall include:

(i) name, address, telephone number, and if available, the email address of each owner of the prescription drug, and each pharmaceutical wholesaler of the prescription drug;

(ii) name and address of each location from which the product was shipped, if different from the owner's;

(iii) transaction dates;

(iv) name of the prescription drug;

(v) dosage form and strength of the prescription drug;

(vi) size of the container;

(vii) number of containers;

(viii) lot number of the prescription drug;

(ix) name of the manufacturer of the finished dose form; and

(x) National Drug Code (NDC) number.

(b) be maintained by the purchaser and the pharmaceutical wholesaler for five years from the date of sale or transfer and be available for inspection or use upon a request of an authorized officer of the law.

(12) Each facility shall comply with the following requirements:

(a) in general, each person who is engaged in pharmaceutical wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel;

(b) upon receipt, each outside shipping container containing prescription drugs, prescription drug precursors, or prescription drug devices shall be visibly examined for identity and to prevent the acceptance of prescription drugs, prescription drug precursors, or prescription drug devices that are contaminated, reveal damage to the containers or are otherwise unfit for distribution:

(i) prescription drugs, prescription drug precursors, or prescription drug devices that are outdated, damaged, deteriorated, misbranded, adulterated or in any other way unfit for distribution or use in manufacturing shall be quarantined and physically separated from other prescription drugs, prescription drug precursors or prescription drug devices until they are appropriately destroyed or returned to their supplier; and

(ii) any prescription drug or prescription drug precursor whose immediate sealed or outer secondary sealed container has been opened or in any other way breached shall be identified as such and shall be quarantined and physically separated from other prescription drugs and prescription drug precursors until they are appropriately destroyed or returned to their supplier;

(c) each outgoing shipment shall be carefully inspected for identity of the prescription drug products or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions:

(i) if the conditions or circumstances surrounding the return of any prescription drug or prescription drug precursor cast any doubt on the product's safety, identity, strength, quality or purity, then the drug shall be appropriately destroyed or returned to the supplier, unless examination, testing or other investigation proves that the product meets appropriate and applicable standards related to the product's safety, identity, strength, quality and purity;

(ii) returns of expired, damaged, recalled, or otherwise non-saleable prescription drugs shall be distributed by the receiving pharmaceutical wholesale distributor only to the original manufacturer or a third party returns processor that is licensed as a pharmaceutical wholesale distributor under this chapter;

(iii) returns or exchanges of prescription drugs (saleable or otherwise),

including any redistribution by a receiving pharmaceutical wholesaler, shall not be subject to the pedigree requirements, so long as they are exempt from the pedigree requirement under the FDA's Prescription Drug Marketing Act guidance or regulations; and

(d) licensee under this Act and pharmacies or other persons authorized by law to dispense or administer prescription drugs for use by a patient shall be accountable for administering their returns process and ensuring that all aspects of their operation are secure and do not permit the entry of adulterated and counterfeit prescription drugs.

(13) A manufacturer or pharmaceutical wholesaler shall furnish prescription drugs only to a person licensed by the Division or to another appropriate state licensing authority to possess, dispense or administer such drugs for use by a patient.

(14) Prescription drugs furnished by a manufacturer or pharmaceutical wholesaler shall be delivered only to the business address of a person described in Subsections R156-17b-102(16)(c) and R156-17b-615(13), or to the premises listed on the license, or to an authorized person or agent of the licensee at the premises of the manufacturer or pharmaceutical wholesaler if the identity and authority of the authorized agent is properly established.

(15) Each facility shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following:

(a) there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

(b) there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped or otherwise disposed of by specific product and strength;

(c) there shall be a record of the dates of receipt and distribution or other disposal of any product;

(d) there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver and the address of the location to which the products were shipped;

(e) inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities;

(f) required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities and such records shall be maintained for a period of two years following disposition of the products; and

(g) records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for

authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

(16) Each facility shall establish, maintain and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, manufacturing, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following:

(a) a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first with a provision for deviation from the requirement if such deviation is temporary and appropriate;

(b) a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the FDA or other federal, state or local law enforcement or other authorized administrative or regulatory agency;

(ii) any voluntary action to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health, safety or welfare by replacement of existing product with an improved product or new package design;

(c) a procedure to prepare for, protect against or handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster or other situations of local, state or national emergency;

(d) a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed;

(e) a procedure for providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state or local authorities for a period of five years after disposition of the product;

(f) a procedure for identifying, investigating and reporting significant drug inventory discrepancies (involving counterfeit drugs suspected of being counterfeit, contraband, or suspect of being contraband) and reporting of such discrepancies within three (3) business days to the Division and/or appropriate federal or state agency upon discovery of such discrepancies; and

(g) a procedure for reporting criminal or suspected criminal activities involving the inventory of drugs and devices to the Division, FDA and if applicable, Drug Enforcement Administration (DEA), within three (3) business days.

(17) Each facility shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors, managers and other persons in charge which lists shall

include a description of their duties and a summary of their background and qualifications.

(18) Each facility shall comply with laws including:

(a) operating within applicable federal, state and local laws and regulations;

(b) permitting the state licensing authority and authorized federal, state and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and

(c) obtaining a controlled substance license from the Division and registering with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacturing of controlled substances and shall comply with all federal, state and local regulations applicable to the distribution or manufacturing of controlled substances.

(19) Each facility shall be subject to and shall abide by applicable federal, state and local laws that relate to the salvaging or reprocessing of prescription drug products.

[~~(20) A person who is engaged in the wholesale distribution or manufacturing of prescription drugs but does not have a facility located within Utah in which prescription drugs are located, stored, distributed or manufactured is exempt from Utah licensure as a Class C pharmacy, if said person is currently licensed and in good standing in each state of the United States in which that person has a facility engaged in distribution or manufacturing of prescription drugs entered into interstate commerce.~~]

(21) [~~No facility located at the same address shall be dually licensed as both a Class C pharmacy and any other classification of Class A or B pharmacy~~] A Class C pharmacy shall not be located in the same building as a separately licensed Class A, B, D, or E pharmacy unless the two pharmacies are located in different suites as recognized by the United States Postal Service. Two Class C pharmacies may be located at the same address without separate suites if the pharmacies:

(a) are under the same ownership;

(b) have processes and systems for separating and securing all aspects of the operation;

(c) have traceability with a clear audit trail that distinguishes a pharmacy's purchases and distributions.[~~Nothing within this section prevents a facility from obtaining licensure for a secondary address which operates separate and apart from any other facility upon obtaining proper licensure.~~]