



Verified Pharmacy Program (VPP)
 Utah Board of Pharmacy
 January 28, 2014



National Association of Boards of Pharmacy (NABP)

- 501(c)(3) Charitable and Educational Organization
 - since 1904
- Members are the state boards of pharmacy for 50 states, District of Columbia, and US territories
 - Boards regulate the practice of pharmacy-laws/regulations
 - Boards license pharmacists, pharmacy technicians, pharmacies, other facilities that handle prescription drugs (varies state to state)
 - Disciplinary actions for violations of law/regulation
- Mission to assist our members in public protection
 - License transfer program, examinations, and accreditations



Existing NABP Infrastructure

- License Verification Services
- Disciplinary Clearinghouse – HIPDB reporting
- License Transfer for Pharmacists
- Accreditation Programs
- Contracted State Inspection Services
 - Resident
 - Nonresident



Lessons learned post-NECC

- States needed to be able to better identify sterile compounding pharmacies
- States needed adequate resources
 - More robust inspection programs
 - Appropriate educational background and training for inspectors on sterile compounding
- Legislation/regulation changes to address needs
- **Current nonresident pharmacy system not working**

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Post NECC NABP Action Plan

- Collaborate/Communicate with FDA/Congress on behalf of Boards
- Training and Education
- Information Sharing Network
- State-specific inspection programs
 - Iowa
 - New Jersey

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From Action Plan to Now

- Continue to provide training opportunities to the boards and their compliance officers as needed
- Improving communication systems between states and federal agencies
- Recognized in the new federal law as having a consulting role with FDA in implementation
- Develop a system to continue to provide inspection assistance within our staffing resources

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Nonresident Pharmacy Licensure Process Prior to NECC:

- Submit application and fee to the board
- Provide proof of licensure from state of domicile
- Submit copy of inspection or proof of inspection in some, not all states
 - Some states require on initial application, but not renewals
- Nonresident state relied on resident states to provide adequate oversight, inspections, and investigations/complaint resolution

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System Not Working

- Many states lack resources to perform timely and/or robust inspections appropriate to the type practice
- States have differing (or no) standards for compounding
- Only requiring inspection on initial licensure gives no assurance for subsequent renewals
- Lack of communication protocols between the states and FDA related to problem pharmacies licensed in multiple states

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Solution: Verified Pharmacy Program (VPP)

- Develop a system to fill the gaps in the nonresident system and provide states complete information needed to make licensing decisions.
- Extrapolate the successes of the Electronic Licensure Transfer Program® for pharmacists and apply it to facilities that want to operate in multiple states
- Create an e-Profile for each pharmacy and link to e-Profiles for key pharmacy personnel
- Create inspection clearinghouse to facilitate sharing of inspection reports/results



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VPP – A Unified Resource for States

- Verify pharmacy licenses (resident/nonresident)
- Verify pharmacist-in-charge licenses (resident/nonresident)
- Verify that a qualified inspection has occurred, either by the resident state in accordance with the established uniform standards, or by NABP
- Report any disciplinary action by another state
- All information will be packaged through VPP, within the Board e-Profile Connect interface



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Need Assistance from Member Boards

In order to make this work, we need boards to:

- Review and provide any feedback on the uniform inspection standards and forms that have been developed at this point
- Identify any barriers to acceptance of these standards or forms for meeting your requirements for a qualified nonresident pharmacy inspection
- Share license status changes and disciplinary actions in real time
- Share inspection reports
- **PARTICIPATE**

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VPP – Benefit to Boards

- There will be agreement on uniform minimum standards that would be acceptable to all boards with ability to also add some customization if necessary to ensure that nonresident pharmacies are not afforded the opportunity to practice at a lower standard than the resident state
- Boards will be able to make informed licensing decisions on nonresident pharmacies
- Seamlessly integrated into Board portal
- No cost to Boards



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Benefits to nonresident pharmacies

- One inspection that meets the needs of multiple states
 - Resident state inspection is reviewed to determine if it meets VPP criteria-timeliness, inspection content, trained inspectors, and if not approved NABP will perform the inspection
- Uniform standards accepted by the states makes a level playing field for all pharmacies operating in multiple states
- Costs lower than if every state had to send their own inspectors and require the pharmacy to cover costs (CA model)



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Future Enhancements

- Fully automated system connected to board through the portal, and integrated with other NABP data services
- Assist boards with renewal/other notifications
- Assist nonresident pharmacies with pushing information to boards, such as PIC changes
- Criminal background checks for owners
- Other customizations that could provide value for boards or pharmacies – you tell us.



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Questions?

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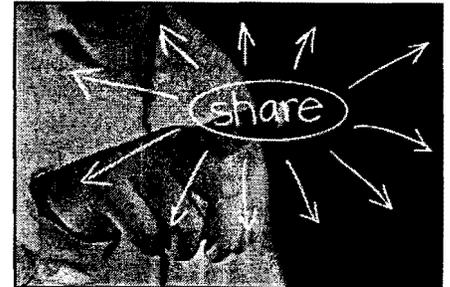
NABP Verified Pharmacy Program™

Providing a vital resource for the boards of pharmacy for use when making licensure and registration determinations.

In the wake of the New England Compounding Center (NECC) tragedy, member state boards of pharmacy spoke out very clearly about the need to build regulatory uniformity among the states and enhance the services offered by the National Association of Boards of Pharmacy® (NABP®). Due to the strength and leadership of its member boards, NABP had a strong foundation to rapidly build and deploy services to assist member boards in their charge to protect the public health. Building from a wide range of existing services – including license verification; the Electronic Licensure Transfer Program® ; NABP Clearinghouse, which includes disciplinary information; accreditation; and inspection services – NABP developed the Verified Pharmacy Program™ (VPP™) to assist member boards in enhancing the licensure processes they already have in place.

What Is VPP?

VPP, or the Verified Pharmacy Program, is an inspection service and information sharing network the boards of pharmacy may use to share critical inspection and licensing data with their fellow boards. Similar to the Electronic Licensure Transfer Program for pharmacists, VPP also facilitates what could be described as the nonresident pharmacy licensure transfer process.



What Is VPP Meant to Accomplish?

VPP creates e-Profiles for each pharmacy and links these facility e-Profiles to key personnel e-Profiles, including those of the pharmacist-in-charge (PIC) in the state of domicile as well as any nonresident PICs.

The program is meant to enhance what the state boards of pharmacy are already doing in terms of determining qualifications for pharmacy licensure and ensure that the boards have complete and accurate information for making licensure decisions on nonresident pharmacies.

What Does Recognizing and/or Requiring VPP Mean for the Boards?

The boards can recognize VPP and/or require that nonresident pharmacies apply through VPP when seeking to obtain or renew licensure. If an e-Profile for the applicant does not already exist, one will be created and applicable alerts pertaining to that facility's disciplinary and inspection history will automatically be pushed to the board of pharmacy. Additionally, participating boards will have access to the e-Profiles and will have the capability to search for facilities by a variety of categories. The boards also have the ability to attach their own inspection reports and other documentation to the e-Profiles.

Recognizing and/or requiring VPP does not necessarily mean that the board is requiring that an inspection be conducted by NABP. When a VPP application from a pharmacy is received, NABP reviews and verifies the data submitted by the pharmacy. This includes any recent inspection reports, if available. Should an applicant submit a "qualified" inspection report and/or already have a qualified inspection report attached to the pharmacy e-Profile through the Inspection Clearinghouse, that pharmacy will not require a new inspection and all qualifying information will be pushed directly to the state board of pharmacy where the pharmacy is seeking licensure. In addition, the information will be provided to any other states where the pharmacy holds a license in order to provide supplemental data for the states to utilize when making licensing decisions.

If the applicant is found to not have a "qualified" inspection, an inspection will be scheduled through NABP. All VPP inspections are conducted by licensed pharmacists.

NABP provides all data directly to the applicable state boards of pharmacy and does not render any judgment on an applicant, as this authority is left to the state boards.



What Is a “Qualified” Inspection and What Inspection Forms Are Available?

A qualified inspection is one that has been conducted within the past 18-24 months, if the facility provides routine retail pharmacy services, or within the past 12 months if it provides compounding services, and includes the appropriate modules of inspection standards depending on the services provided.

The simple presence of an inspection by the state of domicile does not necessarily mean the nonresident facility meets nonresident states' requirements. Further, if a facility has been performing sterile compounding, it is possible that it may not have been subjected to a thorough compliance inspection by a properly trained inspector in many years, if ever.



NABP recently convened a task force to compile licensure standards that are consistent across the states with the purpose of structuring a uniform inspection form. Drawing from the expertise provided during the task force meeting, this form is under development and will assist in further defining a qualified inspection. The form will continue to evolve to meet the states' needs. In addition, NABP has worked to develop uniform compounding inspection forms using elements of several different states' inspection forms that inspect to United States Pharmacopeia Chapter <795> and Chapter <797> as a minimum standard for compounding. These will also evolve to further meet the needs identified by the member boards of pharmacy.

NABP is also exploring the possibility of forming specialized working groups to develop inspection form modules based on the varying types of pharmacy services.

The uniform, qualified inspections can also be coupled with self-reported facility information in order to identify sterile compounding facilities.

What Are the Fees for VPP?

If recognizing and/or requiring VPP, and the board has the ability to pass the costs of an inspection along to the applicant/licensee, the board can direct nonresident pharmacies to NABP to begin the application process.

VPP applicants pay fees dependent on the type of pharmacy:

- Routine Retail: \$1,995
- Nonsterile Compounding or Large Mail Order: \$2,500
- Sterile Compounding or Institutional: \$3,000

If an applicant already has a resident state inspection deemed qualified through NABP processes, the applicant is refunded all but a \$500 processing fee. Pharmacies seeking licensure in multiple states will likely experience savings in inspection fees by avoiding costs associated with multiple state inspections.

For those states that must bear the costs of the inspections, NABP still recommends that states send their applicants through the VPP process and subsidize the inspection fee for the applicants. The Association may be able to work with the board on a discounted inspection fee.

The fees were developed based on estimates of NABP's costs of performing inspections and other processing functions and are not intended to generate excess revenue. Any excess revenue will be used to support member boards of pharmacy through programs and services including, but not limited to, additional compliance training, the development of uniform inspection forms, and the development of other technology and tools to perform inspections.

For more information or to apply for VPP, visit www.nabp.net/programs/licensure/verified-pharmacy-program.

Or contact VPP staff via phone at 847/391-4406 or via e-mail at vpp@nabp.net.



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USP <795> Guidelines
For Standard Operating Procedures
***DRAFT* 12/17/2013**

As defined in USP <795>, any pharmacy that engages in the practice of compounding is required to have Standard Operating Procedures (SOP) in place to state how different areas of practice are handled. The following document is designed to be a guideline to aid pharmacies in producing their own SOP to be compliant with state law. The items on this checklist should be included in the SOP. This is a guideline, not all inclusive. Pharmacies should write their SOP with their own practice in mind.

Patient Counseling of Compounded Medications:

- Procedure to educate patient and/or caregiver on how to use the compounded preparation.
- Includes storage, handling, and disposal of preparations; potential adverse effects and any other information deemed necessary
- Procedure in effect to report any changes in preparations, adverse side effects, etc. reported by patient. Includes investigation and reporting to proper authorities.
- Procedure for recall of compounded preparations

Quality Control

Compounding pharmacies must have a documented quality control plan that contains the following:

- Observation of the finished product, documenting any discrepancies and the corrective action taken
- The Master Formulation Record, the Compounding Record and associated written procedures shall be followed in execution of the compounding process. Any deviation shall be documented.
- Check and recheck each procedure at each stage of the process will be documented

- Have written procedures that describe the tests or examinations conducted on the compounded preparations,
- Control procedures shall be established to monitor the output and verify performance of compounding equipment

Compounding Documentation

There are specific documentation requirements for compounding. These are the Master Formulation Record and the Compounding Record. Both of these are required to be retained for the same length of time that a prescription hard copy would be required to be retained.

Master Formulation Record

- The Master Formulation Record (MFR) shall contain the following information:
 1. The name, strength and dosage form of the preparation
 2. Calculations required to determine and verify quantities of components and doses of active pharmaceutical ingredients.
 3. Description of all ingredients and their quantities
 4. Compatibility and stability information, including references if appropriate.
 5. Equipment required to prepare preparation
 6. Detailed mixing instructions
 7. Sample labeling information, including, generic name and quantity or concentration of each active ingredient, assigned BUD, storage conditions, and prescription or control number
 8. Container used in dispensing
 9. Packaging and storage requirements
 10. Description of final preparation
 11. Quality control measures and expected results

Compounding Record

- The Compounding Record (CR) shall contain the following information:
 1. The name, strength and dosage form of the preparation
 2. MFR reference for the preparation
 3. Names and quantities of all components
 4. Source, lot numbers, and expiration dates of components

5. Total quantity compounded
6. Name of person(s) who prepared the preparation, who performed the quality control procedures, and who approved the preparation
7. Date of preparation
8. Assigned control or RX number
9. Assigned BUD
10. Duplicate label as described in the MFR
11. Description of final preparation
12. Results of quality control procedures
13. Documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver.

Packaging and Drug Preparation Containers

Procedure that ensures the compounder understands the importance of containers used to package compounded medications:

- Utilize packaging that meets USP requirements and be familiar with the USP standards for containers used to package compounded preparations.
- The container used depends on the physical and chemical properties of the compounded preparation. Compounders should consider container drug interactions for substances that have absorptive or leaching properties.
- Containers and closures are stored off the floor
- Containers are rotated so that the oldest stock is used first.

Animal Patients

- Animal patient must be identified as either companion animal or food animal.
- Documentation of Withdrawal Time (WDT) if patient is a food animal. The WDT must be on the label of the preparation.
- Be knowledgeable about physiology, metabolic toxicity of medications for each species
- Document compliance with all state and federal laws regarding drug use in animals.

Component Selection, handling and Storage

- Documentation of sourcing for components that are USP, NF, FCC
- Component expiration dates may be honored if the following are met:
 - Stored in original container under recommended conditions
 - Minimal exposure from opening/closing container
 - Withdrawals performed by trained individuals
- Document expiration of components, using the following as guidelines
 - Components moved to new containers have the following documentation:
 - component name
 - Original supplier
 - Lot or control number
 - Transfer date
 - Expiration date
 - Components without expiration dates are given conservative dates no more than three years from the date received
 - Manufactured drugs must be from an FDA registered facility and have expiration/lot on the label
- Guidelines for component selection
 - When using manufactured drugs, consider all components of that product and not just the active ingredient to determine therapeutic appropriateness and stability

 - When preparing dietary or nutritional supplements, use USP, NF, or FCC products when available. If unavailable, products with a food grade standard and a proven record of safety in humans should be used

 - Components from ruminant animal require the supplier to provide written assurance the product is compliant with all regulations

 - Be aware of components that have been removed from the market by the FDA for efficacy reasons

- Store everything according to storage suggestions from the manufacturer
 - Clean area
 - Appropriate temperature and humidity
 - Off the floor
 - Rotated (old to new)
 - Labeled

Compounding Process

Pharmacy should have a designated compounding area.

- Pharmacy personnel authorized to be in compounding area
- Technique for working in the designated compounding area and behaviors to avoid.
- Personal hygiene

Beyond Use Date

Each preparation dispensed must have a Beyond Use Date (BUD) on the label.

- The following are the BUD guidelines from USP <795>
 - Non-aqueous formulation- 6 months
 - Water containing non-oral – 30 days
 - Water containing oral – 14 days, refrigerated
- All formulas need a source for BUD. If using one from above, site USP 795. Otherwise, the source must be cited
- BUD cannot be later than the earliest expiration date of the Active Pharmaceutical Ingredient (API)
- If a pharmacist feels that BUD for a particular product are inadequate, they may use professional judgment to assign a different BUD. However, they must be prepared to defend that judgment.

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R156-17b-303b. Licensure - Pharmacist - Pharmacy Internship Standards.

(1) In accordance with Subsection 58-17b-303(1)(g), the standards for the pharmacy internship required for licensure as a pharmacist is established as one of the following:

(a) for graduates of all U.S. [~~and foreign~~] pharmacy schools, include the following:

(~~[a]~~i) At least 1,740 hours of practice supervised by a pharmacy preceptor shall be obtained in Utah or another state or territory of the United States, or a combination of both according to the Accreditation Council for Pharmacy Education (ACPE), Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree Guidelines Version 2.0 Effective February 14, 2001, which is hereby incorporated by reference.

(ii) Introductory pharmacy practice experiences (IPPE) shall account for not less than 300 hours over the first three professional years.

(iii) A minimum of 150 hours shall be balanced between community pharmacy and institutional health system settings.

(~~[ii]~~v) Advanced pharmacy practice experiences (APPE) shall include at least 1440 hours (i.e., 36 weeks) during the last academic year and after all IPPE requirements are completed.

(~~[i]~~v) Required experiences shall:

(A) include primary, acute, chronic, and preventive care among patients of all ages; and

(B) develop pharmacist-delivered patient care competencies in the community pharmacy, hospital or health-system pharmacy, ambulatory care, inpatient/acute care, and general medicine settings.

(vi) Internship hours completed in another state or territory of the United States shall be accepted based on the approval of the hours by the pharmacy board in the jurisdiction where the hours were obtained.

(~~[b]~~vii) Evidence of completed internship hours shall be documented to the Division by the pharmacy intern at the time application is made for a Utah pharmacist license.

(~~[e]~~viii) Pharmacy interns participating in internships may be credited no more than 50 hours per week of internship experience.

(~~[d]~~viii) No credit will be awarded for didactic experience.

(~~[2]~~ix) If a pharmacy intern is suspended or dismissed from an approved College of Pharmacy, the intern shall notify the Division within 15 days of the suspension or dismissal.

(~~[3]~~x) If a pharmacy intern ceases to meet all requirements for intern licensure, the pharmacy intern shall surrender the pharmacy intern license to the Division within 60 days unless an extension is requested and granted by the Division in collaboration with the Board.

(b) for graduates of all foreign pharmacy schools, at least 1,440 hours of supervised pharmacy practice .

56

R156-17b-608. Common Carrier Delivery.

A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the pharmacist in charge or other responsible employee:

(1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication;

(2) use shipping containers that are sealed in a manner to detect evidence of opening or tampering;

(3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drugs; and

(4) provide for an electronic, telephonic, or written communication mechanism for a pharmacist, or a pharmacy intern working under the direct supervision of a pharmacist, to offer counseling to the patient and documentation of such counseling. The patient shall receive information indicating what the patient should do if the integrity of the packaging or medication was compromised during shipment.

R156-17b-612. Operating Standards - Prescriptions.

In accordance with Subsection 58-17b-601(1), the following shall apply to prescriptions:

(1) Prescription orders for controlled substances (including prescription transfers) shall be handled according to the rules of the Federal Drug Enforcement Administration.

(2) A prescription issued by an authorized licensed practitioner, if verbally communicated by an agent of that practitioner upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist or pharmacy intern.

(3) A prescription issued by a licensed prescribing practitioner, if electronically communicated by an agent of that practitioner, upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist, pharmacy intern and pharmacy technician.

(4) In accordance with Sections 58-17b-609 and 58-17b-611, prescription files, including refill information, shall be maintained for a minimum of five years and shall be immediately retrievable in written or electronic format.

(5) Prescriptions for legend drugs having a remaining authorization for refill may be transferred by the pharmacist or pharmacy intern at the pharmacy holding the prescription to a pharmacist or pharmacy intern at another pharmacy upon the authorization of the patient to whom the prescription was issued or electronically as authorized under Subsection R156-17b-613(9). The transferring pharmacist or pharmacy intern and receiving pharmacist or pharmacy intern shall act diligently to ensure that the total number of authorized refills is not exceeded. The following additional terms apply to such a transfer:

(a) the transfer shall be communicated directly between pharmacists or pharmacy interns or as authorized under Subsection R156-17b-613(9);

(b) both the original and the transferred prescription drug orders shall be maintained for a period of five years from the date of the last refill;

(c) the pharmacist or pharmacy intern transferring the prescription drug order shall void the prescription electronically or write void/transfer on the face of the invalidated prescription manually;

(d) the pharmacist or pharmacy intern receiving the transferred prescription drug order shall:

(i) indicate on the prescription record that the prescription was transferred electronically or manually; and

(ii) record on the transferred prescription drug order the following information:

(A) original date of issuance and date of dispensing or receipt, if different from date of issuance;

(B) original prescription number and the number of refills authorized on the original prescription drug order;

(C) number of valid refills remaining and the date of last refill, if applicable;

(D) the name and address of the pharmacy and the name of the pharmacist or pharmacy intern to which such prescription is transferred; and

(E) the name of the pharmacist or pharmacy intern transferring the prescription drug order information;

(e) the data processing system shall have a mechanism to prohibit the transfer or refilling of legend drugs or controlled substance prescription drug orders which have

been previously transferred; and

(f) a pharmacist or pharmacy intern may not refuse to transfer original prescription information to another pharmacist or pharmacy intern who is acting on behalf of a patient and who is making a request for this information as specified in Subsection (12) of this section.

(6) Prescriptions for terminal patients in licensed hospices, home health agencies or nursing homes may be partially filled if the patient has a medical diagnosis documenting a terminal illness and may not need the full prescription amount.

(7) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order;

(8) If there are no refill instructions on the original prescription drug order, or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills.

(9) Refills of prescription drug orders for legend drugs may not be refilled after one year from the date of issuance of the original prescription drug order without obtaining authorization from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(10) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsection 58-37-6(7)(f).

(11) A pharmacist may exercise his professional judgment in refilling a prescription drug order for a drug, other than a controlled substance listed in Schedule II, without the authorization of the prescribing practitioner, provided:

(a) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) either:

(i) a natural or manmade disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or

(ii) the pharmacist is unable to contact the practitioner after a reasonable effort, the effort should be documented and said documentation should be available to the Division;

(c) the quantity of prescription drug dispensed does not exceed a 72-hour supply, unless the packaging is in a greater quantity;

(d) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(e) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(f) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection; and

(g) the pharmacist affixes a label to the dispensing container as specified in Section 58-17b-602.

(12) If the prescription was originally filled at another pharmacy, the pharmacist may exercise his professional judgment in refilling the prescription provided:

(a) the patient has the prescription container label, receipt or other documentation

from the other pharmacy which contains the essential information;

(b) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(c) the pharmacist, in his professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of (a) and (b) of this subsection; and

(d) the pharmacist complies with the requirements of Subsections (11)(c) through (g) of this section.

(13) The address specified in Subsection 58-17b-602(1)(b) shall be a physical address, not a post office box.

(14) In accordance with Subsection 58-37-6(7)(e), a prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance unless:

(a) the person who writes the prescription is licensed to prescribe Schedule I controlled substances; and

(b) the prescribed controlled substance is to be used in research.

(15) Effective November 30, 2014, prescription container labels shall comply with standards established in USP-NF Chapter 17.

(16) Discharge prescriptions shall be dispensed and labeled in accordance with standards established in this section except that medications packaged in unit-of-dose containers, such as metered-dose inhalers, insulin pens, topical creams or ointments, or ophthalmic or otic preparation that are administered to the patient during the time patient was a patient in the hospital, may be provided to the patient upon discharge provided the pharmacy receives a discharge order and the product bears a label compliant with standards established in USP-NF Chapter 17.

R156-17b-302. Pharmacy Licensure Classifications - Pharmacist-in-Charge Requirements.

In accordance with Subsection 58-17b-302(4), the classification of pharmacies holding licenses are clarified as:

(1) Class A pharmacy includes all retail operations located in Utah and requires a PIC.

(2) Class B pharmacy includes an institutional pharmacy that provides services to a target population unique to the needs of the healthcare services required by the patient. All Class B pharmacies require a PIC except for pharmaceutical administration facilities and methadone clinics. Examples of Class B pharmacies include:

- (a) closed door;
- (b) hospital clinic pharmacy;
- (c) methadone clinics;
- (d) nuclear;
- (e) branch;
- (f) hospice facility pharmacy;
- (g) veterinarian pharmaceutical facility;
- (h) pharmaceutical administration facility; and
- (i) sterile product preparation facility.

(j) A retail pharmacy that prepares sterile products does not require a separate license as a Class B pharmacy.

(3) Class C pharmacy includes pharmacies located in Utah that are involved in:

- (a) manufacturing;
- (b) producing;
- (c) wholesaling;
- (d) distributing; and
- (e) reverse distributing.

(4) Class D pharmacy includes pharmacies located outside the state of Utah.

Class D pharmacies require a PIC licensed in ~~[the state where the pharmacy is located]~~ Utah and include ~~[Ø]~~ out-of-state mail order pharmacies. Facilities that have multiple locations must have licenses for each facility and every component part of a facility.

(5) Class E pharmacy includes those pharmacies that do not require a PIC and include:

- (a) analytical laboratory;
- (b) animal euthanasia;
- (c) durable medical equipment provider;
- (d) human clinical investigational drug research facility; and
- (e) medical gas provider.

(6) All pharmacy licenses will be converted to the appropriate classification by the Division as identified in Section 58-17b-302.

(7) Each Class A and each Class B pharmacy required to have a PIC shall have one PIC who is employed on a full-time basis as defined by the employer, who acts as a PIC for one pharmacy. However, the PIC may be the PIC of more than one Class A or Class B pharmacy, if the additional Class A or Class B pharmacies are not open to provide pharmacy services simultaneously.

(8) The PIC shall comply with the provisions of Section R156-17b-603.

R156-17b-616. Operating Standards - Class D Pharmacy - Out of State Mail Order Pharmacies.

(1) In accordance with Subsections 58-1-301(3) and 58-17b-306(2), an application for licensure as a Class D pharmacy shall include:

(a) a pharmacy care protocol that includes the operating standards established in Subsections R156-17b-610(1) and (8) and R156-17b-612(1) through (4); and

~~[(b) a copy of the pharmacist's license for the PIC; and]~~

(c) a copy of the most recent state inspection showing the status of compliance with the laws and regulations for physical facility, records and operations.

(2) An out of state mail order pharmacy that compounds must follow the USP-NF Chapter 795 Compounding of non-sterile preparations and Chapter 797 Compounding of sterile preparations.

CONTACT INFORMATION

Contact Person for Licensing Purposes: _____

Direct Phone Number: _____ Direct Email: _____

Address: _____

Street Address (including Apt/Unit/Ste #) and/or PO Box

City

State

ZIP Code

NOTE: The address of record for the license will be the **FACILITY** address listed on the first page of this application, and must be the address where the pharmacy is physically located.

PHARMACIST IN CHARGE

NOTE: In addition to completing this section, you must submit two completed fingerprint cards for the PIC; see the checklist at the end of this application for additional information regarding fingerprints.

Full Legal Name: _____

First

Middle

Last

Mailing Address: _____

Street/PO Box

City

State/Zip

License Number _____ State of Issue: _____

I authorize all persons, organizations, governmental agencies, or any others not specifically listed, which are set forth directly or by reference in this application, to release to the Division of Occupational and Professional Licensing, State of Utah, any files, records, or information of any type reasonably required for the Division to properly evaluate my qualifications for licensure/certification/registration by the State of Utah.

Signature of PIC: _____ Date: _____

PHARMACIST IN CHARGE SUPERVISOR

NOTE: In addition to completing this section, you must submit two completed fingerprint cards for the PIC's immediate supervisor; see the checklist at the end of this application for additional information regarding fingerprints.

Full Legal Name: _____

First

Middle

Last

SSN: _____ Date of Birth: _____ Gender: Male Female

I authorize all persons, organizations, governmental agencies, or any others not specifically listed, which are set forth directly or by reference in this application, to release to the Division of Occupational and Professional Licensing, State of Utah, any files, records, or information of any type reasonably required for the Division to properly evaluate my qualifications for licensure/certification/registration by the State of Utah.

Signature of Supervisor: _____ Date: _____

UTAH CONTROLLED SUBSTANCE AFFIDAVIT (OPTIONAL)

If you are applying for a controlled substance license, you must read and sign the affidavit below.

1. I have reviewed and understand that I must abide by the additional laws and rules that govern the practice of my profession as it pertains to controlled substances.
2. I understand that there may be additional continuing education requirements for those who hold a controlled substance license.
3. I understand it is required that I hold a valid Federal Drug Enforcement Administration (DEA) registration.

Signature of Applicant: _____ Date _____

Note: In addition to signing this affidavit, you must complete the items listed on the OPTIONAL CONTROLLED SUBSTANCE LICENSE checklist at the end of this application.

| State | Additional CS Requirements | | |
|----------------|---|--|--|
| | Medical | Mid Level Practitioners | Pharmacy |
| Alabama | Application with QQ, no exam | Application and collaborative agreement/CEUs: 12 hrs of Category 1 credits | Automatic with application unless waiver is completed. No Exam or Ed requirements. |
| Alaska | DEA Clearance Report for all MD/DO applicants, regardless of CS | DEA # Only | DEA # Only |
| Arizona | DEA # Only | DEA # Only | DEA # Only |
| Arkansas | DEA # Only | DEA # Only | DEA # Only |
| California | DEA # Only | DEA # Only | DEA # Only |
| Colorado | DEA # Only | DEA # Only once granted Prescribing Authority. | DEA # Only |
| Connecticut | Registration Only, some criminal convictions reviewed | Registration Only, some criminal convictions reviewed | Registration Only, some criminal convictions reviewed |
| Delaware | Application with QQ, no exam | Application and Collaborative Agreement, no exam | Application with QQ, no exam |
| DC | Registration Only, some criminal convictions reviewed | Registration Only, some criminal convictions reviewed | Registration Only, some criminal convictions reviewed |
| Florida | DEA # Only | DEA # Only | DEA # Only |
| Georgia | DEA # Only | DEA # Only | DEA # Only |
| Hawaii | Application with NDB background check | Application with NDB background check | Application with NDB background check |
| Idaho | After DEA # issued, apply to board of RX. QQ, no exam or ed. | After DEA # issued, apply to board of RX. QQ, no exam or ed. | After Pharmacist lic issued, separate application for CS. |
| Illinois | Application, qq, no exam | Application, qq, no exam | One Application, no exam |
| Iowa | Registration Only, some criminal convictions reviewed | Registration Only, some criminal convictions reviewed | Registration Only, some criminal convictions reviewed |
| Kansas | DEA # Only | DEA # Only | DEA # Only |
| Kentucky | DEA # Only | DEA # Only | DEA # Only |
| Louisiana | Application with QQ, no exam | Application with QQ, no exam | Application with QQ, no exam |
| Maine | DEA # Only | DEA # Only | DEA # Only |
| Maryland | Application with QQ, no exam | Application with QQ and deligation agreement, no exam | Application with QQ, no exam |
| Massachusetts | Application with QQ, no exam | Application with QQ and deligation agreement, no exam | Application with QQ and practice agreement if associated with clinic, no exam |
| Michigan | Application with QQ, no exam | Application with QQ and deligation agreement, no exam | Application with QQ, no exam |
| Minnesota | DEA # Only | DEA # Only | DEA # Only |
| Mississippi | DEA # Only | DEA # Only | DEA # Only |
| Missouri | Application with QQ and deligation agreement discloser, no exam | Application with QQ and deligation agreement, no exam | Application with QQ and practice agreement if associated with clinic, no exam |
| Montana | DEA # Only | DEA # Only | DEA # Only |
| Nebraska | DEA # Only | DEA # Only | DEA # Only |
| Nevada | Application with QQ, no exam | Application with QQ, no exam | DEA # Only |
| New Hampshire | DEA # Only | DEA # Only | DEA # Only |
| New Jersey | Application with QQ, no exam | Application with QQ, no exam | Application with QQ, no exam |
| New Mexico | Registration with QQ, no exam | Registration with QQ, no exam | Application with QQ, no exam |
| New York | DEA # Only | DEA # Only | DEA # Only |
| North Carolina | DEA # Only | DEA # Only | DEA # Only |
| North Dakota | DEA # Only | DEA # Only | DEA # Only |
| Ohio | DEA # Only | DEA # Only | DEA # Only |
| Oklahoma | Registration with QQ, no exam | Registration with QQ, no exam | Registration with QQ, no exam |
| Oregon | DEA # Only | DEA # Only | DEA # Only |
| Pennsylvania | DEA # Only | DEA # Only | DEA # Only |
| Rhode Island | Registration with QQ, no exam | Registration with QQ, no exam | Registration only |
| South Carolina | Registration with QQ, no exam | Registration with QQ, no exam | One Application, no exam |
| South Dakota | Registration with QQ, no exam | Registration w/ QQ and collaborative agreement | Registration with QQ, no exam |
| Tennessee | DEA # Only | DEA # Only | DEA # Only |
| Texas | Registration with QQ, no exam | Registration with QQ, no exam | Registration with QQ, no exam |
| Vermont | DEA # Only | DEA # Only | DEA # Only |
| Virginia | DEA # Only | DEA # Only | DEA # Only |
| Washington | DEA # Only | DEA # Only | DEA # Only |
| West Virginia | DEA # Only | DEA # Only | DEA # Only |
| Wisconsin | DEA # Only | DEA # Only | DEA # Only |
| Wyoming | Registration with QQ, no exam | Registration with QQ, no exam | Registration with QQ, no exam |



R156-17b-614b. Operating Standards - Class B pharmacy designated as a Branch Pharmacy.

In accordance with Subsections 58-17b-102(8) and 58-1-301(3), the qualifications for designation as a branch pharmacy include the following:

(1) The Division, in collaboration with the Board, shall approve the location of each branch pharmacy. The following shall be considered in granting such designation:

(a) the distance between or from nearby alternative pharmacies and all other factors affecting access of persons in the area to alternative pharmacy resources;

(b) the availability at the location of qualified persons to staff the pharmacy, including the physician, physician assistant or advanced practice registered nurse;

(c) the availability and willingness of a parent pharmacy and supervising pharmacist to assume responsibility for the branch pharmacy;

(d) the availability of satisfactory physical facilities in which the branch pharmacy may operate; and

(e) the totality of conditions and circumstances which surround the request for designation.

(2) A branch pharmacy shall be licensed as a pharmacy branch of an existing Class A or B pharmacy licensed by the Division.

(3) The application for designation of a branch pharmacy shall be submitted by the licensed parent pharmacy seeking such designation. In the event that more than one licensed pharmacy makes application for designation of a branch pharmacy location at a previously undesignated location, the Division in collaboration with the Board shall review all applications for designation of the branch pharmacy and, if the location is approved, shall approve for licensure the applicant determined best able to serve the public interest as identified in Subsection (1).

(4) The application shall include the following:

(a) complete identifying information concerning the applying parent pharmacy;

(b) complete identifying information concerning the designated supervising pharmacist employed at the parent pharmacy;

(c) address and description of the facility in which the branch pharmacy is to be located;

(d) specific formulary to be stocked indicating with respect to each prescription drug, the name, the dosage strength and dosage units in which the drug will be [REDACTED];

(e) complete identifying information concerning each person located at the branch pharmacy who will dispense prescription drugs in accordance with the approved protocol; and

(f) protocols under which the branch pharmacy will operate and its relationship with the parent pharmacy to include the following:

(i) the conditions under which prescription drugs will be stored, used and accounted for;

(ii) the method by which the drugs will be transported from parent pharmacy to the branch pharmacy and accounted for by the branch pharmacy; and

(iii) a description of how records will be kept with respect to:

- (A) formulary;
- (B) changes in formulary;
- (C) record of drugs sent by the parent pharmacy;
- (D) record of drugs received by the branch pharmacy;
- (E) record of drugs dispensed;
- (F) periodic inventories; and
- (G) any other record contributing to an effective audit trail with respect to prescription drugs provided to the branch pharmacy.

R156-17b-102. Definitions.

(37) "Prepackaged" or "Prepackaging" means the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to Dispense in the establishment in which the Prepackaging occurred.