

Summary of Amendments to Pharmacy Practice Act Rule, Effective November 29, 2012

During the 2012 General Session, H.B. 109 was passed allowing the Division to grant licenses, under specified terms, to conduct research using Schedule I controlled substances. Amendments to this rule implement H.B. 109. Other rule amendments are made at the request of the Board of Pharmacy to clarify issues related to definitions, supervision, emergency room dispensing of a short course of necessary medications, and the administration of vaccines by properly trained pharmacists. All amendments listed below became effective on November 29, 2012.

The following rule amendments are made throughout Rule R156-17b:

- Minor grammatical changes, updating of references, and renumbering of subsections.
- Subsections R156-17b-102(5), (6), (13), (17), and (26) are added to define the terms: "centralized prescription filling;" "centralized prescription processing;" "medical device;" "durable medical equipment," as used in proposed amendments to Subsection R156-17b-617(e); and "medical supplies," reflecting current operational definitions.
- Subsection R156-17b-617(41) clarifies that a supervisor is a pharmacist in good standing with the Division.
- Subsection R156-17b-617(46) is updated to reflect the current edition of the United States Pharmacopeia-National Formulary (USP-NF) books. Subsection R156-17b-105(4) is added to require the pharmacist-in-charge (PIC) and responsible party to establish an email address for use in self-audits and Division pharmacy alerts dissemination. Subsection R156-17b-302(5) updates and alphabetizes Class E Pharmacy designations, adding animal euthanasia and human clinical investigational drug research facility, reflective of H.B. 109 allowing the conduct of research with Schedule 1 controlled substances. "Animal euthanasia agency" is defined in Subsection 58-17b-102(4) and the recommended amendment will enable the Division to issue the appropriate license.
- Subsection R156-17b-303a(3) clarifies pharmacy technician training program content and practical training hours requirements.
- Subsections R156-17b-303a(3)(d), (3)(e)(i), and (3)(e)(ii) clarify pharmacy technician training and licensing time frames to eliminate confusion and ensure practice competency. Subsection R156-17b-303a(4)(d) provides the correct name of the examination currently in use.

- Section R156-17b-303b is renumbered for easier reference. Subsection R156-17b-303c(2) provides a remedy for pharmacy interns who fail either the North American Pharmacy Licensing Examination (NAPLEX) or Multistate Jurisprudence Examination (MPJE) twice.
- Subsection R156-17b-303c(4)(a) clarifies the format and reflects current scoring for the Utah Pharmacy Technician Law and Rule Examination. Section R156-17b-303d is renumbered for easier reference. Subsection R156-17b-304(2)(b) corrects the name of one of the required examinations.
- Subsection R156-17b-304(3) clarifies the action to be taken when a temporary license expires due to an applicant's failure to pass either the NAPLEX or MPJE twice as noted in Subsection R156-17b-304(2)(b). Section R156-17b-305 is renumbered for easier reference.
- Section R156-17b-307 was added.
- Subsection R156-17b-307(1) requires documentation of the owners and management of the pharmacy and the facility in which the pharmacy is located.
- Subsection R156-17b-307(2) identifies the key personnel involved in the operation of the applicant pharmacy for which background checks are required.
- In Section R156-17b-402, many of the administrative penalties were added or renumbered to properly organize and reflect by description and citation all added or renumbered rules and statutes identified in
- Subsection 58-17b-504(5) and in Subsection R156-37-502(50) is added to reflect an administrative penalty for failing to update the Division of an email address change that would be used for self-audits and pharmacy alerts as required in Section R156-17b-105 and defined as unprofessional conduct in Subsection R156-17b-502(20).
- Subsection R156-17b-502(12) updates the referenced rule to the correct rule. Subsection R156-17b-502(22) defines an additional form of unprofessional conduct, failing to update the division of an email address change.
- Subsection R156-17b-601(1)(k) clarifies prescription drug orders that a pharmacy technician may accept, removing the ambiguity of the phrase "telephonically or electronically submitted".

- Subsection R156-17b-601(3) clarifies supervisory requirements for pharmacy technicians and pharmacy technicians-in-training.
- Subsection R156-17b-603(1) clarifies the responsibilities of the PIC. Subsection R156-17b-603(2) adds the requirement of a secure email address for self-audits and Division pharmacy alerts, and creates a time frame wherein establishment of an email address needs to be accomplished.
- Subsection R156-17b-603(3) specifically delineates the duties of the PIC.
- Subsection R156-17b-603(3)(u) adds Division notification of any change in the email address used for self-audits and pharmacy alerts as a duty of the pharmacist-in-charge.
- Subsection R156-17b-612(13) clarifies that an actual physical address is needed for a valid prescription, not a post office box.
- Subsection R156-17b-612(14) reflects statutory changes allowing the conduct of research with Schedule I controlled substances, pursuant to H.B. 109, Use of Controlled Substances in Research.
- In Section R156-17B-613, the referenced statutes in the introductory paragraph to issuing prescriptions by electronic means are updated to reflect the correct references.
- In Subsection R156-17b-614a(1)(c), the term "durable medical equipment" (DME) is added to reflect the real possibility that Class A and B pharmacies may provide DME with Class A and B pharmacy licenses. There has been confusion in the industry, with many Class A and B pharmacies thinking they needed an additional Class E pharmacy license to dispense DME.
- Subsection R156-17b-614(4)(g) updates the references that must be available to facility personnel to include the Controlled Substance Database Act and Controlled Substance Database Act Rule.
- Subsection R156-17b-614(16) clarifies pharmacy structural security requirements to prevent unauthorized entry into the pharmacy. Also updated the Trissel's Handbook on Injectable Drugs to the 16th edition, dated 10/27/2010.
- Section R156-17b-614e is added to update, streamline, and formalize a 1999 document, "Guidelines for Hospital Pharmacies" utilized by rural hospitals dispensing a short course of necessary medications to patients when a pharmacy was not open to fill their prescriptions. The course of

medication is changed from a three-day course to a seven-day course at the request of the Utah Coalition Against Sexual Assault and emergency department providers so that critical treatment for sexually transmitted infections could be started immediately and not interrupted over a long holiday weekend if pharmacies were not open and/or the medication was not immediately available for dispensing. A patient receiving prescription medication during the critical treatment window is the most significant issue addressed in this section.

- Subsection R156-17b-615(8) is deleted because the issue of background checks for key personnel is addressed in Section R156-17b-307.
- Subsection R156-17b-615(21) is added to clarify that a Class C pharmacy and any other classification of pharmacy may not be located at the same address. This is included, in part, in an attempt to prohibit the purchasing of critical, short-supply, in-demand emergency medications by one pharmacy and that same pharmacy selling those medications at a greatly increased cost to an affiliated pharmacy for further distribution, e.g., the gray market or parallel market. Emergency Departments and EMS in the state of Utah are now resorting to using emergency medications beyond the expiration date because they simply cannot purchase new medications due to lack of availability, a nationwide problem. The gray market fuels this shortage of critical medications. This section also has significant renumbering of subsections.
- Section R156-17b-617 is changed to Section R156-17b-617a because the category of Class E pharmacy was broadened to include specific types of Class E pharmacies and their operating standards, all under Section R156-17b-617. Section R156-17b-617a became the introductory paragraph requiring a written pharmacy care protocol for all Class E pharmacies. Section R156-17b-617b is added to define basic operating standards for the analytical laboratory, a Class E pharmacy.
- Section R156-17b-617c is added to define basic operating standards for an animal euthanasia facility, a Class E pharmacy.
- Section R156-17b-617d is added to define basic operating standards for a durable medical equipment facility. This designation is helpful for pharmacies engaged in the competitive bidding process for Medicare contracts.
- Subsection R156-17b-617d(2) clarifies that a licensed practitioner is exempt from licensure as a Class E pharmacy when administering DME to a patient or animal.

- Section R156-17b-617e is added to define basic operating standards for a human clinical investigational drug research facility and pursuant to H.B. 109. This designation was requested by the industry to facilitate research activities and acquisition of a Drug Enforcement Administration (DEA) license for Schedule I controlled substances.
- Section R156-17b-617f is added to define basic operating standards for the medical gas facility, a Class E pharmacy.
- Subsection R156-17b-618(1)(a) adds a change in "name" to the list of changes requiring a pharmacy to make application for a new license and receive approval from the Division prior to the proposed change. This requirement will prevent the licensing of multiple pharmacies with the same name and allow the Division to monitor pharmacies undergoing frequent name changes in short periods of time.
- Subsection R156-17b-618(1)(b) includes a change in "name" to the list of changes that must be approved prior to issuance of a new license and surrender of the old license.
- In Subsection R156-17b-618(2)(a), dealing with a name change without application for a new license, is deleted.
- Subsection R156-17b-621(4) adds the "Vaccine Administration Protocol: Standing Order to Administer Immunizations and Emergency Medications" as the guideline or standard for pharmacist administration of vaccines and emergency medications.