

State of Utah DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

160 East 300 South, P.O. Box 146741 Salt Lake City, Utah 84114-6741 Telephone (801) 530-6628 www.dopl.utah.gov

PHARMACY SELF-INSPECTION REPORT CLASS "A" PHARMACY

(Retail)

Instruction: This document is provided to reporting pharmacies in two different formats:

- The MS Word version is provided as a "fill in the blanks" document where pharmacies can complete the document using MS Word and then email the document directly to DOPL at DOPLInvestigations@utah.gov without printing it. DOPL highly recommends this approach as it allows the pharmacy to quickly and legibly enter the required data and for DOPL to receive your report electronically and to better serve you. For those pharmacies without email capability the document can also be printed and submitted by FAX at (801) 530-6301.
- The Adobe Acrobat version is provided to allow those pharmacies without MS Word to print the document and complete it in a more manual format and send it to DOPL by FAX or by mail.

Both versions of the Pharmacy Self-Inspection Report can be found on DOPL's web site at dopt-utah.gov/licensing/pharmacy.html

If you need information on how to complete the report or how to use either the MS Word or the Adobe Acrobat version please contact us at (801) 530-6630 or by email at DOPLInvestigations@utah.gov

at (601) 330-0030	of by chian at <u>bot</u>	Linvestigations(a, atan.g)	<u>0 v</u>				
Pharmacy Name:			Rep		Report Date:	port Date:	
Mailing Address:							
City:				S	State:	ZIP:	
Phone #:	Pharmacy FAX #:		E-Mail:				
Pharmacy Hours of Operation:	" I Monday Hriday:		Saturday:		Sunday:		
DOPL Pharmacy License Number:				Expiration Date:			
DOPL Controlled Substance License Number:				Expiration Date:			
DEA Registration	Number:			Expiration Date:			
List ALL Pharmac	ists, Interns and Pha	armacy Technicians. (A	ttach a separate sheet, if nec	cessary.)			
Pharmacist-in-Charge:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		
Name:		License Number:		Expirati	Expiration Date:		

List ALL Technicians-in-Training. (Attach a separate sheet, if necessary.)	
Name:	Program Start Date:

SELF ASSESSMENT QUESTIONNAIRE						
Read thoroughly, and answer the questions as "Yes", "No" or "N/A". Only answer "N/A" if the question does not apply to your						
pharmacy. <u>Do not leave any question blank.</u>						
For each "No" answer, provide an explanation on an attached sheet.						
☐ Yes ☐ No ☐ N/A	1. Pharmacy technicians, including no more than one pharmacy technician-in-training, shall be supervised on-site by a pharmacist. <i>Pharmacy Practice Act Rule, R156-17b-601</i>					
☐ Yes ☐ No ☐ N/A	2. The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy technician/pharmacy intern/supportive personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. <a href="https://pharmacy.new.new.new.new.new.new.new.new.new.new</td></tr><tr><td>☐ Yes ☐ No ☐ N/A</td><td>3. If the facility has a pharmacy technician training program, the program has been granted approval by the Division in collaboration with the Board. <i>Pharmacy Practice Act Rule, R156-17b-304</i></td></tr><tr><td>☐ Yes ☐ No ☐ N/A</td><td>4. All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility shall wear on their person a clearly visible and readable identification showing the individual's name and position. <i>Pharmacy Practice Act</i>, 58-17b-603</td></tr><tr><td>☐ Yes ☐ No ☐ N/A</td><td>5. Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. <i>Pharmacy Practice Act Rule, R156-17b-603</i></td></tr><tr><td>☐ Yes ☐ No ☐ N/A</td><td>6. When communicating by any means, written, verbal, or electronic, pharmacy personnel must identify themselves as to licensure classification. <i>Pharmacy Practice Act, 58-17b-603</i></td></tr><tr><td>☐ Yes ☐ No ☐ N/A</td><td>7. Every pharmacy facility shall orally offer to counsel a patient or a patient's agent in a personal face-to-face discussion with respect to each prescription drug dispensed A pharmacist or pharmacy intern shall provide counseling to each patient. <a href=" https:="" pharmacy.new.new.new.new.new.new.new.new.new.new<="" td="">					
☐ Yes ☐ No ☐ N/A	8. The offer to counsel shall be documented and said documentation shall be available to the Division. **Pharmacy Practice Act Rule, R156-17b-610** 8. The offer to counsel shall be documented and said documentation shall be available to the Division.					
☐ Yes ☐ No ☐ N/A	9. Facilities shall have a counseling area to allow for confidential patient counseling, where applicable. <u>Pharmacy Practice Act Rule, R156-17b-614a</u>					
☐ Yes ☐ No ☐ N/A	10. The facility shall be well lighted, ventilated, clean and sanitary. <u>Pharmacy Practice Act Rule, R156-17b-614a</u>					
☐ Yes ☐ No ☐ N/A	11. The dispensing area shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. <i>Pharmacy Practice Act Rule, R156-17b-614a</i>					
☐ Yes ☐ No ☐ N/A	12. The facility shall be equipped to permit the orderly storage of prescription drugs and devices in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. <i>Pharmacy Practice Act Rule, R156-17b-614a</i>					
☐ Yes ☐ No ☐ N/A	13. The facility shall be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare. Pharmacy Practice Act Rule, R156-17b-614a					
☐ Yes ☐ No ☐ N/A	14. The facility shall be equipped with a security system to permit detection of entry at all times when the facility is closed. <i>Pharmacy Practice Act Rule, R156-17b-614a</i>					
☐ Yes ☐ No ☐ N/A	15. The facility is engaged in extensive compounding activities. If you answer "yes" to this question, a compounding questionnaire must be completed. <i>Pharmacy Practice Act Rule, R156-17b-614a</i>					
☐ Yes ☐ No ☐ N/A	16. The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of the drugs. Documentation verifying temperature compliance shall be available to the Division upon request. <i>Pharmacy Practice Act Rule, R156-17b-614a</i>					
☐ Yes ☐ No ☐ N/A	17. The temperature of the refrigerator and freezer shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. Documentation verifying temperature compliance shall be available to the Division upon request. Pharmacy Practice Act Rule, R156-17b-614a					

☐ Yes ☐ No ☐ N/A	18. The facility shall post the license of the facility and the license or a copy of the license of each pharmacist, pharmacy intern and pharmacy technician who is employed in the facility, but may <i>not</i> post the license of any just stated employee not actually employed in the facility. <i>Pharmacy Practice Act Rule</i> ,				
	<u>R156-17b-614a</u>				
	19. The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel: Pharmacy Practice Act Rule , R156-17b-614a				
	• DOPL Licensing Act, 58-1 • General Rule for DOPL, R156-1				
☐ Yes ☐ No ☐ N/A	• <u>Pharmacy Practice Act, 58-17b</u> • <u>Pharmacy Practice Act Rule, R156-17b</u>				
	• <u>Utah Controlled Substances Act, 58-37</u> • <u>Utah Controlled Substance Act Rule, R156-37</u>				
	• Code of Federal Regulations – CRF Title 21 • FDA – Orange Book: Approved Drug Products				
	General Drug References				
☐ Yes ☐ No ☐ N/A	20. If the pharmacy is located within a larger facility such as a grocery or department store, and a licensed Utah pharmacist is not immediately available in the facility, the pharmacy shall not remain open to pharmacy patients and shall be locked in such a way as to bar entry to the public or any non-pharmacy personnel. All pharmacies located within a larger facility shall be locked and enclosed in such as way as to bar entry by the public or any non-pharmacy personnel when the pharmacy is closed. <i>Pharmacy</i>				
	Practice Act Rule, R156-17b-614a				
☐ Yes ☐ No ☐ N/A	21. Only a licensed Utah pharmacist or authorized pharmacy personnel shall have access to the pharmacy when the pharmacy is closed. <i>Pharmacy Practice Act Rule, R156-17b-614a</i>				
	22. The facility shall maintain a permanent log of the initials or identification codes which identify each				
☐ Yes ☐ No ☐ N/A	dispensing pharmacist by name. The initials or identification codes shall be unique to ensure that each				
	pharmacist can be identified. <u>Pharmacy Practice Act Rule, R156-17b-614a</u>				
☐ Yes ☐ No ☐ N/A	23. Prescription files, including refill information, shall be maintained for a minimum of five years and				
	should be immediately retrievable in written or electronic format. <u>Pharmacy Practice Act Rule, R156-17b-612</u> 24. An annual inventory shall be conducted every 12 months, following the inventory date of each year and				
	may be taken within four days of the specified inventory date. The PIC is responsible for meeting all				
☐ Yes ☐ No ☐ N/A	inventory requirements. Inventory records shall be filed separately from all other records and must be				
	maintained for a period of five years and be readily available for inspection. <u>Pharmacy Practice Act Rule</u> ,				
	<u>R156-17b-605</u>				
☐ Yes ☐ No ☐ N/A	25. Unless otherwise requested, child-resistant containers are used for dispensing medications to patients. 16 CFR 1700 – Poison Prevention Packaging				
	26. Each drug dispensed from the pharmacy shall have a label securely affixed to the container indicating				
	the required minimum information, including: <u>Pharmacy Practice Act, 58-17b-602</u>				
	Name, Address, & Phone Number of Pharmacy Serial Number of Prescription Name, Address, & Phone Number of Pharmacy Name, Address, & Phone Number of Pharmacy				
☐ Yes ☐ No ☐ N/A	• Filling Date or Last Dispensing Date • Name of the Patient or Animal Owner / Species • Name of the Patient or Animal Owner / Species				
	 Name of the Prescriber Trade, Generic or Chemical Name Directions For Use & Cautionary Statements Amount Dispensed & Strength of Dosage Form 				
	 Trade, Generic or Chemical Name (Unless Otherwise Indicated by Prescriber) Amount Dispensed & Strength of Dosage Form Beyond Use Date 				
	27. Prescription records may be maintained electronically so long as the original of each prescription,				
	including telephone prescriptions, is maintained in a physical file and contains all of the information				
☐ Yes ☐ No ☐ N/A	required by federal and state law; and an automated data processing system is used for the storage and				
	immediate retrieval of refill information for prescription orders. <u>Utah Controlled Substance Act Rule, R156-37-</u>				
	602				
	28. Prescription forms and records of all controlled substances listed in Schedule II are maintained separately from Schedules III through V, which are maintained separately from all other facility				
☐ Yes ☐ No ☐ N/A	records. Records must be maintained by licensee for a period of five (5) years. <i>Utah Controlled Substance</i>				
	<u>Act Rule, R156-37-602</u>				
	29. The registered pharmacy only processes electronically signed prescriptions for controlled substances				
	under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable				
☐ Yes ☐ No ☐ N/A	requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal				
	Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the				
	prescription be converted to another form (i.e. facsimile) for transmission. 21 CFR 1311 – Requirement for				
	Electronic Orders and Prescriptions				
	30. The PIC shall, for each controlled substance dispensed by a pharmacist under the PIC's				
☐ Yes ☐ No ☐ N/A	supervisionsubmit to the divisionpositive identification of the individual receiving the				
	prescription, including the type of identification and any identifying numbers on the identification. Controlled Substance Database Act, 58-37f-203				

☐ Yes ☐ No ☐ N/A	31. Controlled substance data collection is submitted to the least once a week. <i>Utah Controlled Substance Act Rule, R156-3</i>	
☐ Yes ☐ No ☐ N/A	32. Any facility who experiences a shortage or theft of comappropriate forms with the Drug Enforcement Administ the attention of the Investigation Bureau. <i>Utah Controlled</i>	rolled substances shall immediately file the tration, with a copy to the Division directed to
☐ Yes ☐ No ☐ N/A	33. The pharmacy does not dispense legend drugs or contro online prescriber as part of an Internet facilitator arrang to Utah Code Annotated, Title 58, Chapter 83. <u>Online Pr 83-501 and 503</u>	olled substances that have been issued by an gement, unless as otherwise allowed for pursuant
☐ Yes ☐ No ☐ N/A	34. Except when delivered to the ultimate user via the Unit carrier, or supportive personnel, prescription drugs are directly from the pharmacy. <i>Pharmacy Practice Act, 58-17b-</i>	only dispensed to the ultimate user or his agent
☐ Yes ☐ No ☐ N/A	35. The pharmacy does not accept back and redistribute an allowed for pursuant to Section 58-17b-503. <i>Pharmacy Pharmacy Pharmacy</i>	
Comments:		
I understand that it is ur	tion contained in this "Pharmacy Self-Inspection Renlawful and punishable as a Class A Misdemeanor to fraud, forgery, or intentional deception, misrepres	o deal with DOPL or the Licensing
I understand that it is un Board through the use of Signature of Pharmacist	nlawful and punishable as a Class A Misdemeanor to fraud, forgery, or intentional deception, misrepres	o deal with DOPL or the Licensing