

REMOTE DISPENSING PHARMACY

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INSPECTION

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Random

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		INFORMATION			
Pharmacy Name:			_ Date:		· · · · · · · · · · · · · · · · · · ·
License Number:			_ Exp Date:		
C.S. License Number:			_ Exp Date:		
DEA Registration:			_ Exp Date:		
Pharmacy FEIN # (Tax I	D):				
Pharmacy Email:					
Pharmacy Phone Numb	er:		Fax:		
Pharmacy Toll Free Nur	mber:				
Affiliated Websites:					
Pharmacy Hours: Mond	ay-Friday:	Saturday:	S	unday:	
Pharmacy Address:		•			
		State:		Zip:	
Supervising Pharmacy:			License Numbe	r:	
Remote Dispensing Pharm					· · · · · · · · · · · · · · · · · · ·
RDPIC License Num <u>ber:</u>			_Expiration Date:		
		Personnel			
List ALL pharmacists, into		ans and techs-in-trai			ecessary):
Name:	License #		Title:	Exp:	
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INSPECTION

CLASS A PHARMACY

CLASS B PHARMACY

,	YES	NO	The facility shall maintain a surrent list of licensed applicates involved in the surely of the
1			The facility shall maintain a current list of licensed employees involved in the practice of the pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)(a)(i-iv)(b)]
2			Notification has been provided to the Division in regards to the unique email address used for self audits or pharmacy alerts. The pharmacy will notify the Division of any change in the email address within seven days of the change. [UAC R156-17b-603 (2) and (3) (t) (i-ii)]
3			Notification has been provided to the Division in regards to the assignment of the RDPIC at the above stated pharmacy. The Division is notified of a change in RDPIC within 30 days of the change. $[UAC\ R156-17b-603\ (3)\ (s)]$
4			A remote dispensing pharmacy shall display a sign easily visible to the public that informs patients of the following: that the pharmacy is a remote dispensing pharmacy; the location of the supervising pharmacy; and that at the patient's request, a pharmacist will counsel the patient using audio and video communication systems. [UAC R156-17b-614g (9)(b)(i-iii)]
5			Unless a pharmacist is physically present, a remote dispensing pharmacy shall be staffed by no more than two licensed pharmacy technicians. $[UAC\ R156-17b-614g(5)(c)]$
6			At any time that a remote dispensing pharmacy is open and available to serve patients, its pharmacy technicians shall remain under the physical or electronic supervision of a supervising pharmacist from the supervising pharmacy. [UAC R156-17b-614g(5)(a)]
7			The supervising pharmacy shall maintain a surveillance system and telepharmacy system that provides for effective video and audio communication between supervising pharmacy personnel and remote dispensing pharmacy personnel and patients, that includes the following features: [UAC R156-17b-614g(6)(a-d)]
			provides an adequate number of views of the entire site; facilitates adequate pharmacist supervision; allows the appropriate exchanges of visual, verbal, and written communication for patient counseling and other matters involved in the lawful transaction or dispensing of drugs;
			confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and the prescription; and is secure and HIPAA compliant as defined in R156-17b-102(64).
8			Adequate supervision by a supervising pharmacist of a remote dispensing pharmacy shall include maintaining uninterrupted visual supervision and auditory communication with the site, and full supervisory control of the automated system, if applicable. This supervision may not be delegated to any other person. [UAC R156-17b-614g(5)(e)(i-ii)]
9			Each component of the telepharmacy system shall be in good working order. If any component of the system is malfunctioning the remote dispensing pharmacy shall immediately close to the public and remain closed until system corrections or repairs are completed, unless a pharmacist is present onsite. [UAC R156-17b-614g(7)(a)(b)]
10			The supervising pharmacy shall develop and include in both the supervising pharmacy's and the remote dispensing pharmacy's policies and procedures a plan for continuation of pharmaceutical services by the remote dispensing pharmacy in case of an emergency interruption: [UAC R156-17b-614g (8) (a-c)]

		☐ The plan shall address the timely arrival at the personnel, and the delivery to the remote dispensir reasonable period of time following the identification pharmacist shall be available onsite at the remote emergency, and shall notify the Division in writing it	ng pharmacy of necessary supplies, within a on of an emergency need. A supervising dispensing pharmacy as soon as possible after an				
		☐ The plan may provide for alternate met remote dispensing pharmacy, including persor alternate pharmacy location or on-site pharmacists					
11		receiving services from that pharmacy facility doe	ndividuals employed in a pharmacy facility having any contact with the public or patients eiving services from that pharmacy facility does wear on their person a clearly visible readable identification showing the individual's name and position. [UAC 58-17b-603 (1)]				
12		with the the following time frames: within 30 days of DMPIC, or RDPIC; within 30 days of the opening of the end of each license renewal cycle. The facility m	the facility conducts a pharmacy self-audit on a form provided by the Division, in accordance the the following time frames: within 30 days of a change of consulting pharmacist, PIC, MPIC, or RDPIC; within 30 days of the opening of a new facility; and at least 90 days before e end of each license renewal cycle. The facility maintains each pharmacy self-audit form for o years from the date of the self-audit. [UCA R156-17b-603 (3)(u)(i-iv)]				
		Date of last self inspection:					
13		or identification codes that identify each dispensing production identification code shall be unique to ensure that ea	ne facility or parent company shall maintain a record for not less than five years of the initials identification codes that identify each dispensing pharmacist by name. The initials or entification code shall be unique to ensure that each pharmacist can be identified; therefore entical initials or identification codes shall not be used. [UCA R156-17b-614a (8)]				
14		The facility does have current and retrievable editions of the following reference publications print or electronic format and readily available and retrievable to facility personnel: [UAC R156-17b-614a (4) (a-k)]					
		UCA 58-1 (DOPL Licensing Act)	UAC R156-1 (General Rules of DOPL)				
		UCA 58-17b (Pharmacy Practice Act)	UAC R156-17b(Pharmacy Practice Act Rules)				
		UCA 58-37 (Controlled Substance Act)	UAC R156-37(Controlled Substance Act Rules)				
		UCA 58-37f (Controlled Substance Database Act)	UAC R156-37f (Controlled Substance				
		Code of Federal Regulations Title 21 parts 1300 to end General Drug References	Database Act Rule) FDA Approved Drug Product(Orange Book)				
15		The facility is well lighted, ventilated, clean and sani	tary . [UAC R156-17b-614a (1) (a)]				
16		If transferring a drug from a manufacturer's or distribution container, the dispensing area, shall have a sink with apart from restroom facilities. [UAC R156-17b-614a (1) (b)]					
17		The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1) (d)]					
18		The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (e)]					
19		All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605(1)]					
20	П	The facility is 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. [UAC R156-17b-614a (1) (f)]					

REMOTE DISPENSING PHARMACY If dispensing controlled substances, the facility is equipped with a security system to permit 21 detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1)(q)(i-ii)(h)(i-ii)] If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the 22 pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (15)] N/A Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (7)] The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (3)] The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log for three years. [UAC R156-17b-614a (3)] For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such **as**: [UAC R156-17b-611 (2) (a-g)] ☐ Therapeutic duplications ☐ Inappropriate drug utilization ☐ Drug-drug interactions □ Drug-disease contraindications ☐ Incorrect duration of drug treatment ☐ Incorrect drug dosage ☐ Drug-allergy interactions Clinical abuse or misuse Facility does have a counseling area to allow for confidential patient counseling. [UAC R156-17b-614a (1)(i)] Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-28 to-face discussion regarding each prescription drug dispensed. If the patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)] The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)] Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5)(a)(i-viii)] ☐ name, address, & phone number of pharmacy ☐ serial number of prescription name of the patient or animal owner/species filling date or last dispensing date directions for use & cautionary statements name of the prescriber amount dispensed & strength of dosage form trade, generic or chemical name beyond use date (Unless Otherwise Indicated by Prescriber) Centralized prescription processing services may be performed if the parties: [UCA R156-17b-614f (1) (a-c)]

have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract; and share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription order.

have common ownership or common administrative control;

or

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32	The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual, and documentation of implementation, which shall be made available to the Division upon inspection and which includes the following: [UCA R156-17b-614f(2)(a-e)]
	a description of how the parties will comply with federal and state laws and regulations;
	appropriate records to identity the responsible pharmacists and the dispensing and counseling process;
	$\hfill \square$ a mechanism for tracking the prescription drug order during each step in the dispensing process;
	$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $
	a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
33	The remote dispensing pharmacy shall retain a recording of surveillance, excluding patient communications, for at least 45 days. [UAC R156-17b-614g (10) (b)]
34	Unless otherwise requested, child-resistant containers are used for dispensing medications to patients. [16 CFR 1700.15]
35	Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.22]
36	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 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. [UAC R156-17b-613(1) & 21 CFR 1311]
37	Prescription files, including refill information, is maintained for a minimum of five years and shall be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]
38	Electronic records shall be available to and accessible from both the remote dispensing pharmacy and the supervising pharmacy [UAC R156-17b-614g (10)(a)(ii)]
39	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 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. [UAC R156-37-602 (4) (a-b)]
40	The original records of the controlled substance prescriptions dispensed from the remote dispensing pharmacy shall be maintained at the remote dispensing pharmacy. [UAC R156-17b-614g (10)(a)(iii)]
41	The RDPIC shall oversee documented monthly inspections of the remote dispensing pharmacy. Documentation of such inspections shall be kept for five years, and shall includes: [UAC R156-17b-614g (10)(c)(i-ii)(A-D)] maintenance and reconciliation of all controlled substances;

temperature logs of the refrigerator and freezer that hold medications; and

the RDPIC's periodic review of the record of entries into the remote dispensing pharmacy.

- All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years.

 [UAC R156-37-602(3, 5)]
- All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 6)]
- Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]
- Requirements for taking the initial controlled substances inventory shall include the following: pharmacies having stock of controlled substances shall take an inventory, including out-of-date drugs and drugs in automated pharmacy systems, on the opening day of business; if a pharmacy commences business with no Schedule I or II controlled substances, the pharmacy shall record this fact as the initial inventory and shall document Schedule I and II controlled substance inventory separately from an inventory reporting no Schedule III, IV, and V controlled substances; the initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section. [UAC R156-17b-605 (3) (a-c)]

the PIC shall be responsible for taking all required inventories; but may delegate the performance of the inventory to another person or persons;

the inventory records shall be maintained for a period of five years and be readily available for inspection

the inventory records shall be filed separately from all other records

the inventory may be taken either at the opening of business or the close of business on the inventory date;

the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory

the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances

if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventoried, the perpetual inventory shall be reconciled on the date of the inventory

- All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances that shall be reconciled according to facility policy. [UAC R156-17b-605(6)]
- The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603(3)(j) & R156-37-502(4)]
- Any facility who experiences a shortage or theft of controlled substances will immediately notify law enforcement and file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau of the Division. [UAC R156-37-602 (2)]
- Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (11)]

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- The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]
- The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614a(9)]
- The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a) (i,ii)]
- In accordance with 58-37f-203(6) the pharmacist in charge and the pharmacist identified in subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division; the state that issued identification, type of identification used, identification number used and first and last name of the individual picking up dispensed drug. [UCA R156-37f-203(4)(bb-ff)]
- The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.
- The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]

COMMENTS

REMOTE DISPENSING PHARMACY

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By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."				
Signature of Responsible Party:	Date:			
Name of Responsible Party (Print):				
Signature of Division Investigator:	Date:			
Name of Division Investigator (Print):	Revised 3/2025			