

ALASKA Department of Commerce, Community, and Economic Development Division of Corporations, Business and Professional Licensing

> Board of Pharmacy PO Box 110806, Juneau, AK 99811-0806 (907) 465-2550 Email: BoardofPharmacy@Alaska.Gov Website: Pharmacy.Alaska.Gov

Pharmacy Self-Inspection Report

Pharmacy Name:	Date:	
Owner Name:		Please Check:
Mailing Address:		Initial Application
Pharmacy License <i>or</i> Registration:	Expiration:	Renewal
Date of Inspection:	Hours of Operation:	Change in Ownership
Telephone #:	Fax #:	Change in Location
DEA Registration #:	DEA Expiration:	Re-Inspection
the operation of the pharmacy (12	in-charge include compliance with all laws and regulations governing AAC 52.200(b)(1)). Please identify the pharmacist-in-charge of the ther pharmacists working in the pharmacy.	🗆 Retail
Pharmacist-in-Charge:	License #:	□ Institutional
List additional Pharmacists:	Attach a separate page if necessary	□ Sterile Compounding
Name:	License #:	Non-Sterile Compounding
Name:	License #:	Compounding
Name:	License #:	
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Authority	Item	Yes	No	Comments			
	PHARMACY PERSONNEL (GENERAL)						
AS 08.80.330, 12 AAC 52.200 AS 08.80.030, 12 AAC 52.210, 12 AAC 52.220	 The pharmacy has designated a licensed pharmacist who practices in this location as the pharmacist-in-charge. Only the pharmacist or intern, under direct supervision of the pharmacist receives oral prescription drug orders. Only the pharmacist or intern, under direct supervision of the pharmacist interprets the prescription drug order and determines the product required. 						
	4) Only the pharmacist does the final check on all aspects of the completed prescription.						
AS 08.80.030, AS 08.80.480, 12 AAC 52.220	5) ALL interns, graduate or undergraduate, paid or unpaid, are currently licensed by the Alaska Board of Pharmacy.6) Interns do not represent themselves to be pharmacists.						
	7) Interns perform the duties of a pharmacist only under the direct supervision of a licensed pharmacist.						
	8) Interns do not solely sign or initial any document required to be done by the pharmacist.						
AS 08.80.030, 12 AAC 52.230	9) Interns do not dispense prescriptions before a final check is made by the supervising pharmacist.						
AS 08.80.030, AS 08.80.480, 12 AAC	10) ALL pharmacy technicians are currently licensed by the Alaska Board of Pharmacy.						
52.140	11) All pharmacy technicians are under direct supervision of the pharmacist.						

	FACILITY STANDARDS (GENERAL)	
AS 08.80.157, 12 AAC 52.400	1) The pharmacy department has a sink with hot and cold running water and is maintained in a sanitary condition.	
	2) The temperature of the pharmacy is maintained within a range compatible with the proper storage of drugs.	
	3) The pharmacy has refrigeration facilities with a thermometer and the temperature is maintained within 36 to 46 degrees Fahrenheit.	
AS 08.80.157, 12 AAC 52.410	4) The pharmacy has the equipment, supplies, and reference materials necessary to compound, dispense, label, administer, and distribute drugs and devices.	
AS 08.80.157, 12 AAC 52.420	5) All drugs and devices that have exceeded their expiration date are removed from stock, and quarantined until properly disposed of.	
	6) All drug, devices, and poisons restricted to sale by a pharmacist are kept in the prescription department.	
	7) The pharmacy department is always locked when the pharmacist is not on site.	
	8) The pharmacy has a separate telephone number if its hours differ from the remainder of the store.	
	9) Filled prescriptions are stored in the prescription department only and are not removed unless a pharmacist is present.	

PRACTICE STANDARDS					
AS 08.80.030, 12 AAC 52.470	1) The pharmacy maintains its prescriptions in legible form for the required two year period.				
	2) No prescriptions are refilled after one year from the date of issue.				
AS 08.80.030, 12 AAC 52.480	3) All refills are recorded electronically or on the back of the prescription drug order.				
	4) All schedule II - V controlled substances dispensed have the label "Caution: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."				
AS 08.80.030, 12 AAC 52.490	5) All Prescriptions are labeled with the name, address, and telephone number of pharmacy, Rx number, date and pharmacist's initials.				
	6) All Prescriptions are labeled with patient name, prescribing practitioner, patient instructions, appropriate cautions, name, strength, and quantity of drug.				
AS 08.80.030, 12 AAC 52.490	7) Electronically transmitted prescriptions are only being received directly from the prescribing practitioner or the prescribing practitioner's agent.				
	8) All transferred prescriptions for controlled substances in Schedule III, IV, and V are transferred only once from the pharmacy which has the original prescription drug order.				
	9) Unless the two pharmacies share a common database, transfers of non-control prescriptions may be transferred verbally, electronically or by facsimile.				
	10) All transfer information is recorded can keep prescriptions, unless an automated data processing system is able to do so.				
AS 08.80.030, 12 AAC 52.510	11) Prescription orders transferred to another pharmacy are no longer refilled by the original pharmacy.				
AS 08.80.030, 12 AAC 52.520	12) When dispensing an equivalent drug product instead of the prescribed drug, the pharmacist notes on the prescription drug order either the manufacturer, distributor, NDC #, short name code, or trade name.				
AS 08.80.030, 12 AAC 52.530	13) If customized patient medication packages (med-paks) are prepared by the pharmacy, records are made and filed for each med-pak.				

AS 08.80.030, 12 AAC 52.52	14) Except in the case of a pharmacy serving an institutional facility, drugs are not accepted for return or exchange after the drugs have been taken from the premises.	
AS 08.80.030, 12 AAC 52.580	15) Patient records are reviewed for over or under utilization, therapeutic duplication, drug-disease, drug-food, and drug-drug interactions, reasonable dose, known allergies, and adverse drug reactions.	
	16) When a data processing system is used it is capable of producing an audit trail printout for all dispensing.	
AS 08.80.030, 12 AAC 52.585	17) When a data processing system is used it has adequate safeguards to prevent loss of data and reasonable security.	
	18) The pharmacist verbally provides counseling to the patient or the patient's agent with each new patient of the pharmacy, new medication for an existing patient, or a change in dose, strength, route of administration, or directions for use of an existing prescription previously dispensed.	

	INSTITUTIONAL PHARMACY STANDARDS (IF APPLICABLE)					
AS 08.80.390, 12 AAC 52.700, 12 AAC 52.710	 The institutional pharmacy is managed by a licensed pharmacist, designated to be the pharmacist-in-charge. When the institutional pharmacy is closed, no access is permitted unless a person licensed to handle drugs is designated by the pharmacist-in-charge to enter the institutional pharmacy. 					
AS 08.80.030, 12 AAC 52.720	 3) When the institutional pharmacy is closed, the designated person licensed to handle drugs records the removal of any drug. 4) All E.R. outpatient prepackaged medications bear a label with the name, address, and telephone number of hospital; name, strength, quantity, lot number, and expiration of drug; appropriate cautions; and initials of pharmacist 5) Only one prepackaged container of a drug is delivered to emergency room patients unless more than one is required to sustain the patient until a retail pharmacy is open in the community. 					

	STERILE PHARMACEUTICALS (IF APPLIC	ABLE)	
	1) A policy and procedure manual is present for the compounding, dispensing, and delivery of sterile pharmaceuticals.		
	2) The pharmacy has a functionally separate area used only for the preparation of sterile pharmaceuticals.		
	3) The pharmacy has appropriate environmental control devices capable of maintaining at least a Class 100 environment condition for preparing sterile pharmaceuticals.		
AS 08.80.030, 12 AAC 52.430	4) Cytotoxic sterile pharmaceuticals are prepared in appropriate biological safety cabinets.		
	5) The pharmacy uses temperature controlled delivery containers, if appropriate, for delivery of sterile pharmaceuticals to the patient.		
	6) The pharmacy has its laminar airflow hoods or clean rooms re-certified at least every six months.		
	7) The pharmacy has its laminar flow hood or clean room pre-filters replaced and documented on a regular basis.		
	8) The pharmacy has current copy of reference material related to sterile pharmaceutical preparation in the pharmacy.		
	9) All personnel participating in the preparation of sterile pharmaceuticals are trained in this specialized function.		
	10) The pharmacy has a licensed pharmacist accessible 24 hours a day if providing parenteral pharmaceuticals to non-hospitalized patients.		
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	5) The pharmacy uses temperature controlled delivery containers, if appropriate, for delivery of sterile pharmaceuticals to the patient.		
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8) The pharmacy has current copy of reference material related to sterile pharmaceutical preparation in the pharmacy.	
9) All personnel participating in the preparation of sterile pharmaceuticals are trained in this specialized function.	
10) The pharmacy has a licensed pharmacist accessible 24 hours a day if providing parenteral pharmaceuticals to nonhospitalized patients.	
11) All sterile pharmaceuticals dispensed bear the expiration date of the preparation.	
12) All cytotoxic waste is disposed of in compliance with all applicable local, state, and federal requirements.	
13) A licensed pharmacist is involved in patient training that relates to sterile pharmaceuticals.	
14) The pharmacy has a quality control and quality assurance program that is utilized for sterile pharmaceutical preparation and dispensing.	

	CONTROLLED SUBSTANCES					
Controlled Substances Act of	1) A Schedule V record bound book is maintained which contains name and address of purchaser, name and quantity of drug, date, and initials of pharmacist. Record					
1970	book is maintained two years from date of last transaction.					
	2) Prescriptions are not used to supply office stock or "medical bag" for physicians.					
	3) All prescriptions for controlled substances are dated, contain the full name and address of the patient, and the name, address, and DEA number of the physician.					
	4) Schedule II prescriptions are manually signed by the physician, and Schedule II prescriptions are not refilled.					
	5) Schedule III, IV and V prescriptions are refilled only if authorized. Refills are not dispensed more than six months after the issue date or refilled more than five times after the issue date.					
	6) Controlled substances are securely locked or dispersed throughout the non- controlled inventory.					



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Pharmacy Self-Inspection Report Signature Page

Attestation

I, the pharmacist-in-charge, state that all the statements herein contained are each and all strictly true in every respect. I understand that false or forged statements made in connection with this self-inspection report may be grounds for denial or revocation of the drug room license.

Notary Stamp	Pharmacist-In-Charge Printed Name:		
	Pharmacist-In-Charge Signature:		
	Notary Public for State of:	Subscribed and Sworn to Before me on this Day:	
	Notary's Signature:	My Commission Expires:	

NOTE: If any areas on the self-inspection report were checked off as not being in compliance, you must still send in the report. You then have 90 days to bring those areas into compliance. A new report will be sent to you to fill out.