

# THE STATE Of ALASKA

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	y Name:		Date:	
Owner Na	ame:			
Mailing A	ddress:			
Pharmacy Registrati	y License <i>or</i> ion:		Expiration:	
Date of Ir	nspection:		Hours of Operation:	
Telephon	e #:		Fax #:	
DEA Registration #:			DEA Expiration:	
the operat	ion of the pharm	rmacist-in-charge include complian lacy (12 AAC 52.200(b)(1)). Please well as other pharmacists working in	identify the pharmacist-in-c	
Pharmaci	ist-in-Charge:		License #:	
List addit	tional Pharmac	ists:	Attach a separa	te page if necessary
Name:			License #:	
Name:			License #:	
Name:			License #:	
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Please Check:			
	Initial Application		
	Renewal		
	Change in Ownership		
	Change in Location		
	Re-Inspection		
	Please Check:		
	Please Check:		
_	Retail		

Authority	Item	Yes	No	Comments
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	PHARMACY PERSONNEL (GENERAL	-)		
AS 08.80.330, 12 AAC 52.200	1) The pharmacy has designated a licensed pharmacist who practices in this location as the pharmacist-in-charge.			
AS 08.80.030, 12 AAC 52.210, 12 AAC 52.220	2) Only the pharmacist or intern, under direct supervision of the pharmacist receives oral prescription drug orders.			
	3) 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	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.	

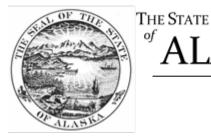
AS 08.80.030, 12	14) Except in the case of a pharmacy serving an institutional facility, drugs are not		
AAC 52.52	accepted for return or exchange after the drugs have been taken from the		
	premises.		
AS 08.80.030, 12	15) Patient records are reviewed for over or under utilization, therapeutic		
AAC 52.580	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	17) When a data processing system is used it has adequate safeguards to prevent		
AAC 52.585	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 A	APPLICABLE)	
AS 08.80.390, 12	1) The institutional pharmacy is managed by a licensed pharmacist, designated to		
AAC 52.700, 12 AAC 52.710	be the pharmacist-in-charge.		
32.710	2) 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	3) When the institutional pharmacy is closed, the designated person licensed to		
AAC 52.720	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.		
	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 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	1) A Schedule V record bound book is maintained which contains name and address	s
Substances Act of	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**

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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.