PHARMACY QUALITY ASSURANCE REPORT NOTICE

DHHS
DIVISION OF PUBLIC HEALTH
LICENSURE UNIT
TELEPHONE # (402) 471-2118

Your Pharmacy Quality Assurance Report (PQAR) is due on the same date annually. The Department will accept your PQAR THIRTY (30) days before the due date. You will be notified by the Department whether your PQAR is determined to be in full compliance with the Health Care Facilities Licensure Act and 175 NAC 8 Nebraska Regulations Governing Licensure of Pharmacies. (Revised as of 10/17/19)

Pharmacy License Number: _____ Exp. Date: _____

DEA registration Number: _____ Exp. Date: _____

Owner's Name: _____

Pharmacy Name: _____

Pharmacy Street Address: _____

Pharmacy City, State, Zip Code: _____

Pharmacy Telephone #: _____ Pharmacy Fax #: _____

Pharmacy Web Page/E-mail: _____

Pharmacy Hours: _____

List Pharmacy Personnel:

Name of PIC: _____ License #: _____

Staff Pharmacists & Interns Name & NE RPh. License # Or NE Intern Registration #	**Pharmacy Technicians Name & NE Registration #**	**Technician Certifying Body, Certification #, if applicable & Certification Expiration Date**		
#	#		#	
#	#		#	
#	#		#	
#	#		#	
#	#		#	
#	#		#	
#	#		#	
#	#		#	
#	#		#	

SOFTWARE: _____ RX'S PER DAY: _____

I, the pharmacist in charge, state that all of the statements herein contained are each and strictly true in every respect. I have read the applicable Nebraska State Statutes and Rules and Regulations concerning the practice of pharmacy, am familiar with its provisions, and agree to abide by all said provisions. I understand that false or forged statements made in connection with this Quality Assurance Report may be grounds for action against my pharmacist license and/or the pharmacy license.

_____ _____

(Signature of Pharmacist in Charge) (Date of Inspection)

C = In Compliance ***NC = Not in Compliance*** ***NA = Not Applicable***

Section cited **CFR=21 CFR Ch 11; NAC=Nebraska Administrative Code; NRS=Nebraska Revised Statute; USC=United States Code; USP=United States Pharmacopeia**	**Requirement**	**C**	**NC**	***NA***
175 NAC 8-003.01A	1. All information provided on the current pharmacy license document is correct, including name of facility, ownership, address, and name of pharmacist in charge. If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov			
175 NAC 8-006.02C NRS 28-410, CFR 1301.71	2. Adequate security is maintained for the prescription inventory and prescription records.			
175 NAC 8-006.02A	3. Drugs, devices and biologicals are stored under proper conditions. Storage conditions shall be monitored regularly.			
	4. The pharmacy:			
175 NAC 8-007.02	4a. is maintained in a clean, orderly, and sanitary manner.			
NRS 38-2866	4b. is open for the practice of pharmacy only when a pharmacist is physically present.			
175 NAC 8-007.03	5. The pharmacy maintains in printed or electronic form appropriate reference material for the practice of pharmacy.			
175 NAC 8-007.01 USP 795 USP 797	6. The pharmacy provides the pharmacist access to all utilities/equipment needed to practice pharmacy. Water used for compounding is at USP standards. When Applicable, water purification systems are maintained.			
175 NAC 8-006.04H NRS 38-2869 (2)(a)	7. Patient counseling is being provided as required.			
NRS 38-2869 (2)(a)	8. The pharmacy maintains documentation of a patient's refusal of counseling.			
175 NAC 8-006.04H	9. Patient counseling is being done by only a pharmacist or pharmacist intern.			
NRS 38-2869	10. Prior to the dispensing or the delivery of each new or refill prescription, a pharmacist is conducting a prospective drug utilization review.			
NRS 28-414.02 CFR 1304, 1306 CFR 1311.305	11. All computer or electronic record keeping requirements are met including requirements for electronic prescriptions for controlled substances.			
175 NAC- 8-005.03A5	12. The poison control phone number is posted in the pharmacy.			
CFR 1305 CFR 1311.45 CFR 1311.60	13. Acquisition and distribution requirements for Schedule II controlled substances are met regarding the use of an official order form or the electronic equivalent. Power of Attorney forms completed and filed when applicable.			
NRS 28-411(4) CFR 1304.21 CFR 1304.22(c)	14. The pharmacy maintains complete and accurate records of all controlled substances received and/or distributed.			
NRS 28-414.05 CFR 1304.22 CFR 1317	15. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.			
21 U.S. Code 351 21 U.S. Code 352 NRS 71-2461 NRS 71-2470	16. The pharmacy does not have in its saleable inventory any drug, device or biological which is misbranded or adulterated as defined in statute.			
175 NAC- 8-006.04C, .04D, .04E NRS 38-28,107	17. The pharmacy assures that all requirements pertaining to unit dose packaging and returned product labeling are met.			
175 NAC- 8-006.04G	18. The pharmacy assures that all requirements pertaining to multi-drug containers are met, including proper labeling.			

Section Cited	Requirement	C	NC	NA
NRS 28-410 CFR 1304.11	19. All requirements pertaining to the inventory of controlled substances are met. **Date of Current Inventory: _____** Controlled substance inventories require the following Information: 1. **Name** of your facility. 2. **Address** of your facility. 3. **Date and time of day** the inventory was taken. 4. Indicate **open or close** of business. 5. Facility's **DEA#**. 6. **Signature of the Pharmacist-In-Charge**, who is responsible for the inventory. 7. **Schedule II** inventory pages **must be separate** from the **Schedule III, IV, V** inventory pages.	☐	☐	☐
NRS 28-410(4)	20. All controlled substances are properly stored.	☐	☐	☐
CFR 1306.05 NRS 28-414 NRS 28-414.01 NRS 71-2478	21. All prescriptions contain the required information prior to being filled.	☐	☐	☐
175 NAC- 8-006.04B.9a, 172 NAC- 128-014.01(9a), CFR 1306.22	22. All refill requirements for prescriptions are in compliance.	☐	☐	☐
CFR 1306.13 CFR 1306.23 NRS 28-414 NRS 28-414.01	23. Partial fillings of controlled substances are recorded and dispensed appropriately.	☐	☐	☐
CFR 1306.05(f) NRS 38-179(13)	24. The pharmacy is not utilizing pre-populated request forms for controlled substance prescriptions.	☐	☐	☐
175 NAC 8-006.05D CFR-1306.11(d)(1,2,3,4) NRS 28-414	25. All emergency Schedule II prescription procedures are followed. Only direct verbal authorization from the prescribing practitioner is allowed.	☐	☐	☐
NRS 28-414 NRS 28-1437 NRS 38-2870	26. All requirements for filling electronic prescriptions (e-prescribing) and faxed prescriptions are followed. A manual "wet" signature is required for all written or faxed controlled substance prescriptions.	☐	☐	☐
NRS 28-414.03 NRS 28-415 NRS 38-2867.01 NRS 71-2451, 2479	27. All prescription containers are properly labeled.	☐	☐	☐
Neb. Rev. Stat. 38-2055	28. All prescriptions are properly labeled.	☐	☐	☐
Neb. Rev. Stat. 28-414, 175 NAC 8-006.03A1, 21 CFR Ch. II 1306.11	29. Hardcopy requirements for Schedule II prescriptions are met.	☐	☐	☐
NRS 71-5401 to NRS 71-5409	30. The pharmacy is in compliance with the Drug Product Selection Act.	☐	☐	☐
175 NAC- 8-006.03A1, NRS 28-414(3a)(3c)	31. A two or three file system for prescriptions is used and maintained.	☐	☐	☐
NRS 71-2413(1) CFR 1306.11 CFR 1306.21	32. Proper records are maintained for Emergency Drug Box use including: a. receipt upon delivery signed by the Director of Nursing b. proof of use forms. c. a list of emergency box drugs identical to the list on the exterior of the emergency box. Controlled substance drugs cannot be removed from the Emergency Drug Box until the pharmacy receives a valid oral, faxed, or written prescription from the practitioner.	☐	☐	☐

Section Cited	Requirement	C	NC	NA
NRS 38-2847 NRS 38-2866.01 NRS 38-2890 thru NRS 38-2896 172 NAC 128-012.04	33. All requirements and documentation are met for the utilization of Pharmacy Technicians, including: a. documentation of training by the pharmacist in charge. b. pharmacy technicians are identified as technicians. c. a pharmacist's supervision of pharmacy technicians and/or pharmacist interns does not exceed three people. d. verification confirmation of a pharmacy technician's acts, tasks, or functions undertaken to assist the pharmacist in the practice of pharmacy. e. all technicians are registered with NE DHHS. f. all technicians are certified (as required). Check credential status at: http://www.nebraska.gov/LISSearch/search.cgi If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov	☐	☐	☐
175 NAC 8-006.07	34. Pharmacy has written disaster preparedness policies and procedures.	☐	☐	☐
175 NAC 128-013	35. The pharmacy is compliant with "Pharmaceutical Care Agreement" requirements: a. a copy of the agreement with written protocols is available for review by the Department. b. practice agreements and written protocols must be signed by the physician and participating pharmacists. c. practice agreements and written protocols must be reviewed, signed and dated every 24 months.	☐	☐	☐
NRS 38-2867.01 USP 795	36. The pharmacy is compliant with USP 795 (non-sterile compounding) including Master Formulation and Compounding Records. The preparation labeling shall include the beyond use date and storage conditions.	☐	☐	☐
USP 797	37. The pharmacy is compliant with USP 797 (sterile compounding).	☐	☐	☐
NRS 28-456 NRS 28-457 NRS 28-458 NRS 28-459 CFR 1314	38. The pharmacy is compliant with all State and federal regulations pertaining to the retail sale of scheduled listed chemical products/methamphetamine precursors, including: a. a purchaser signature logbook that displays the warning listed under Section 1001 Title 18, US Code. b. records of training and annual self-certification. c. the name or initials of the seller who sold the product is submitted to the exchange.	☐	☐	☐
NRS 71-7444(2)(d) NRS 71-7454(1)	39. The sale, purchase or trade of a prescription drug for emergency medical reasons or for a practitioner to use for routine office procedures does not exceed five percent of sales as provided in section 71-7454.	☐	☐	☐
NRS 71-7444 (2)(a-h); NRS 71-7454	40. All prescription drugs purchased or received are from entities licensed under the Nebraska Wholesale Drug Distributor Licensing Act, with exceptions in 71-7444 or 71-7454.	☐	☐	☐

Please forward your completed Pharmacy Quality Assurance Report (PQAR) to your Pharmacy Inspector. Use this link (http://dhhs.ne.gov/publichealth/Licensure/Documents/PharmInspectorsByCountyList.pdf) to determine which Inspector covers your geographic location.

STATEMENT OF COMPLIANCE PAGE

For each item not in compliance, please list below (may continue on a separate page if needed):

a) The item number that is not in compliance;
b) Why it is not in compliance;
c) How the deficiency will be corrected; and
d) How long it will take to do so