

STATE OF NEBRASKA
DEPARTMENT OF HEALTH & HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
Licensure Unit
P. O. Box 94986
Lincoln, NE 68509-4986

PHARMACY QUALITY ASSURANCE REPORT

Pharmacy (Dispensing Practitioner) License Number: #140

Exp. Date: 11/15/24

DEA Registration Number: # _____

Exp. Date: _____

Owner's Name: Aaron Campbell, MD

Pharmacy (Dispensing Practitioner) Name: _____ Aaron Campbell, MD

Pharmacy (Dispensing Practitioner) Street Address: _____ 1002 W Mission Ave

Pharmacy (Dispensing Practitioner) City, State, Zip: _____ Bellevue, NE 68805

Pharmacy (Dispensing Practitioner) Telephone #: _____ (402) 291-4797

Pharmacy (Dispensing Practitioner) Fax #: _____ (402) 291-4643

Pharmacy (Dispensing Practitioner) E-mail: _____ careclinics.J9@gmail.com

Pharmacy (Dispensing Practitioner) Hours: _____ Thur/Fri every other week alternating with
Fri/Sat - Thur and Fri 9 am - 5:30 pm; Sat 9 am - 3 pm

List Pharmacy (Dispensing Practitioner) Personnel:

Name of Practitioner responsible for compliance: _____ Aaron Campbell

Practitioner Medical License Number: _____ #35888

Name & NE License # of other practitioners [pursuant §38-2850(1)] that are dispensing under this license
<u>Jill Meadows / #25740</u>
<u>Tamer Middleton / #CP278</u>
____ / # _____
____ / # _____
____ / # _____
____ / # _____
____ / # _____
____ / # _____
____ / # _____
____ / # _____
____ / # _____
____ / # _____

SOFTWARE: Manual

RX'S PER DAY: 0-10

Melissa Pollard, RP
(Pharmacy Inspector)

12/1/23
(Date of Inspection)

Section Cited	Requirement	C	NC	NA
<u>CFR</u> = 21 CFR Ch.II <u>NAC</u> = Nebraska Administrative Code <u>NRS</u> = Nebraska Revised Statute <u>USC</u> = United States Code <u>USP</u> = United States Pharmacopeia	<u>C</u> = In Compliance <u>NC</u> = Not in Compliance <u>NA</u> = Not Applicable			
175 NAC 8-003.01A	1. All information provided on the current pharmacy license document is correct, including the physical address where dispensing occurs and the name of the responsible Dispensing Practitioner (DP). If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.02C NRS 28-410, CFR 1301.71	2. Adequate security is maintained for the prescription inventory and prescription records.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.02A	3. Drugs, devices and biologicals are stored under proper conditions. Storage conditions shall be monitored regularly.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-007.02 NRS 38-2866	4. The pharmacy is: a. maintained in a clean, orderly, and sanitary manner; b. open for the practice of pharmacy only when a pharmacist (or dispensing practitioner) is physically present.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
175 NAC 8-007.03	5. The pharmacy maintains in printed or electronic form appropriate reference material for the practice of pharmacy.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-007.01 USP 795 USP 797	6. The pharmacy provides access to all utilities/equipment needed to practice pharmacy. Water used for compounding is at USP standards. When applicable, water purification systems are maintained.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC 8-006.04H NRS 38-2869 (2)(a)	7. Patient counseling is being provided as required.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NRS 38-2869 (2)(a)	8. The pharmacy maintains documentation of a patient's refusal of counseling.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC 8-006.04H	9. Patient counseling is being done by only a pharmacist or pharmacist intern. [or Dispensing Practitioner (DP)]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NRS 38-2869	10. Prior to the dispensing or the delivery of each new or refill prescription, a pharmacist (or DP) is conducting a prospective drug utilization review.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC- 8-005.03A5	12. The poison control phone number is posted in the pharmacy.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

<u>Section Cited</u>	<u>Requirement</u>	<u>C</u>	<u>NC</u>	<u>NA</u>
NRS 28-414.05 CFR 1304.22 CFR 1317	15. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC- 8-006.04G	18. The pharmacy assures that all requirements pertaining to multi-drug containers are met, including proper labeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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 (or of the DP) . 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 (or DP's) DEA# . 6. Signature of the Pharmacist-In-Charge (or DP) , who is responsible for the inventory. 7. Schedule II inventory pages must be separate from the Schedule III, IV, V inventory pages.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
NRS 28-410(4)	20. All controlled substances are properly stored.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CFR 1306.05 NRS 28-414 NRS 28-414.01 NRS 71-2478	21. All prescriptions contain the required information prior to being filled.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC- 8-006.04B.9a, 172 NAC- 128-014.01(9a), CFR 1306.22	22. All refill requirements for prescriptions are in compliance.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CFR 1306.13 CFR 1306.23 NRS 28-414 NRS 28-414.01	23. Partial fillings of controlled substances are recorded and dispensed appropriately.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CFR 1306.05(f) NRS 38-179(13)	24. The pharmacy is not utilizing pre-populated request forms for controlled substance prescriptions.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Section Cited	Requirement	C	NC	NA
NRS 28-414.03 NRS 28-415 NRS 38-2867.01 NRS 71-2451, 2479	27. All prescription containers are properly labeled.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NRS 71-5401 to NRS 71-5409	30. The pharmacy is in compliance with the Drug Product Selection Act.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
175 NAC- 8-006.03A1, NRS 28-414(3a)(3c)	31. A two or three file system for prescriptions is used and maintained.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
175 NAC 8-006.07	34. Pharmacy has written disaster preparedness policies and procedures.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 12 months.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Section Cited	Requirement	C	NC	NA
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
USP 797	37. The pharmacy is compliant with USP 797 (sterile compounding).	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

2023 Initial On-Site Inspection

- a)
- b)
- c)
- d)

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- a)
 - b)
 - c)
 - d)

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- a)
 - b)
 - c)
 - d)

Inspector's Note: Practitioner does not dispense any controlled substances and every patient is counseled.