

REMOTE PHARMACY QUALITY ASSURANCE REPORT

Remote Pharmacy License Number: # _____ Exp. Date: _____
 DEA registration Number: # _____ Exp. Date: _____
 Supervising Pharmacy Name: _____
 Supervising Pharmacy License Number: # _____
 Remote Pharmacy Name: _____
 Remote Pharmacy Street Address: _____
 Remote Pharmacy City, State, Zip Code _____
 Remote Pharmacy Telephone #: _____ Remote Pharmacy Fax #: _____
 Remote Pharmacy PIC E-mail: _____
 Remote Pharmacy Hours: _____
 List Remote Pharmacy Personnel:
Name of Pharmacist-In-Charge: _____ License #: _____

| Supervising Pharmacists Name and License # | Pharmacy Technicians at Remote Pharmacy Name & NE Registration # | Technician Certifying Body, Certification # if applicable, & Certification Expiration Date |
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SOFTWARE: _____
 REAL TIME AUDIOVISUAL EQUIPMENT USED: _____ RX'S PER DAY: _____

Choose an item. _____
 (Pharmacy Inspector) (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 name of facility, ownership, address, and name of pharmacist in charge. If non-compliant, contact the Department at: dhhs.medicaloffice@nebraska.gov | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 175 NAC 8-006.02C NRS 28-410, CFR 1301.71 | 2. Adequate security at the remote pharmacy is maintained for the prescription inventory and prescription records. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 175 NAC 8-006.02A | 3. Drugs, devices and biologicals are stored under proper conditions within the remote pharmacy. Storage conditions shall be monitored regularly. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 175 NAC 8-007.02 NRS 38-2866 | 4. The remote pharmacy is: a. maintained in a clean, orderly, and sanitary manner; b. open for the practice of pharmacy only when a pharmacist is physically present at the remote pharmacy or at the supervising pharmacy via real time audio-visual. | <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 175 NAC 8-007.03 | 5. The remote pharmacy maintains in printed or electronic form appropriate reference material for the practice of pharmacy. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 175 NAC 8-007.01 USP 795 USP 797 | 6. The remote pharmacy provides the pharmacist and the pharmacy technician 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 type="checkbox"/> |
| NRS 71-436.02 (4) | 7. Patient counseling is being attempted via real-time audiovisual communication as required. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NRS 38-2869 (2)(a) | 8. The supervising pharmacy maintains documentation of a patient's refusal of counseling. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NRS 71-436.02 | 9. Patient counseling is being done by only by PIC or Supervising Pharmacist | <input 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 is conducting a prospective drug utilization review. | <input 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 at the remote pharmacy location including requirements for electronic prescriptions for controlled substances. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 175 NAC- 8-005.03A5 | 12. The poison control phone number is posted in the remote pharmacy. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Remote Pharmacy License# _____ Date of Inspection _____

| Section Cited | Requirement | C | NC | NA |
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| 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 type="checkbox"/> |
| NRS 28-411(4) CFR 1304.21 CFR 1304.22(c) | 14. The remote pharmacy maintains complete and accurate records of all controlled substances received and/or distributed. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NRS 28-414.05 CFR 1304.22 CFR 1317 | 15. The remote pharmacy complies with all transfer and/or destruction requirements for controlled substances. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21 U.S. Code 351 21 U.S. Code 352 NRS 71-2461 NRS 71-2470 | 16. The remote pharmacy does not have in its saleable inventory any drug, device or biological which is misbranded or adulterated, as defined in statute. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 175 NAC- 8-006.04C, .04D, .04E NRS 38-28,107 | 17. The supervising pharmacy assures that all requirements pertaining to unit dose packaging and returned product labeling are met. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NRS 71-2479 | 18. The supervising pharmacy assures that all requirements pertaining to multi-drug containers are met, including proper labeling. | <input type="checkbox"/> | <input type="checkbox"/> | <input 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. 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. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NRS 28-410(4) | 20. All controlled substances are properly stored within the remote pharmacy location. | <input type="checkbox"/> | <input type="checkbox"/> | <input 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 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 type="checkbox"/> |
| CFR 1306.13 CFR 1306.23 NRS 28-414, 28- 414.01 | 23. Partial fillings of controlled substances are recorded and dispensed appropriately. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| CFR 1306.05(f) NRS 38-179(13) | 24. The pharmacy is correctly utilizing pre-populated refill request forms for controlled substances | <input type="checkbox"/> | <input type="checkbox"/> | <input 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 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 type="checkbox"/> |
| NRS 28-414.03 NRS 28-415 NRS 38-2867.01 NRS 71-2451, 2479 | 27. All prescription containers within the remote pharmacy are properly labeled. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Neb. Rev. Stat. 38-2055 | 28. All prescriptions are properly labeled. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NRS 38-28,108 to NRS 38-28,116 | 30. The pharmacy is in compliance with the Drug Product Selection Act | <input 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 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 or his/her designee 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 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 type="checkbox"/> |

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| 175 NAC 8-006.07 | 34. Supervising pharmacy has written disaster preparedness policies and Procedures at the remote pharmacy location. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NRS 71-436.02 (3) | 35. Pharmacist is onsite at least once each calendar month (Documentation) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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 type="checkbox"/> |
| USP 797 NRS 38-2867.01 | 37. The pharmacy is compliant with USP 797 (sterile compounding). | <input type="checkbox"/> | <input type="checkbox"/> | <input 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 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 type="checkbox"/> |
| NRS 71-7444 (2)(a-h); NRS 71-7454 | 40. All prescription drugs purchased or received for the remote pharmacy are from entities licensed under the Nebraska Wholesale Drug Distributor Licensing Act, with exceptions in 71-7444 or 71-7454. | <input 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

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