HOSPITAL PHARMACY QUALITY ASSURANCE REPORT

Hospital Name/City:

The Hospital Pharmacy Quality Assurance Report is required to be submitted by each hospital pharmacy along with an annual inventory on May 1 every year. However, the Department will accept your HPQAR between March 15 and June 15th annually. Your report will be reviewed by the Department and you will be notified after the review whether your HPQAR is determined to be in compliance or if deficiencies were noted.

NOTE: If you have a current Community Pharmacy license, you will still need to complete the PQAR and submit that to your Pharmacy Inspector on the date of the anniversary of that license.

HOSPITAL/PHARMACIST IN CHARGE INFORMATION

Hospital Name:

Hospital DEA Registration Number: **Expiration Date:**

Hospital City:

Pharmacy telephone number: **Pharmacy fax number:**

Pharmacist-In-Charge (PIC) name:

PIC license number:

Pharmacy/PIC email:

Pharmacy hours:

PHARMACY PERSONNEL **(Please use Page 6 for additional names/license numbers)**

Staff Pharmacist(s) Name and Nebraska License #

Pharmacist Intern(s) Name and Nebraska License #

Pharmacy Technician(s) Name and Nebraska Registration #

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Software Used **# RXs per day**

I, the Pharmacist in Charge, state that all of the statements contained herein 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 hospital license.

Signature **Date**

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

Regulation	Requirement	C	NC	NA
175 NAC 8-006.02C 175 NAC 9-006.09G Neb Rev Stat 28-411	1. Adequate security is maintained for the medications and for patient records.	☐	☐	☐
175 NAC 8-006.02A 175 NAC 9-006.09G5 Neb Rev Stat 28-410 CAHs: 42 CFR 485.635(a)(3)(iv) Acute Hosp: 42 CFR 482.25	2. Drugs, devices, and biologicals are stored at the proper temperature, in locked areas, and in accordance with manufacturer's instructions and accepted professional standards of practice.	☐	☐	☐
175 NAC 8-007.02 175 NAC 9-007	3. The pharmacy is maintained in a clean, orderly and sanitary manner.	☐	☐	☐
175 NAC 8-007.02 175 NAC 9-006.09 175 NAC 9-006.09G8	4. The pharmacy maintains in printed or electronic form, appropriate reference material for the practice of pharmacy.	☐	☐	☐
175 NAC 8-007.01	5. The pharmacy provides the pharmacist access to necessary utilities and equipment.	☐	☐	☐
CAHs: 42 CFR 485.635(a)(3) Acute Hosp: 42 CFR 482.25(b) Neb Rev Stat 38-2867.02	6. Prior to dispensing or the delivery of a drug or device pursuant to a medical order to a patient or caregiver, a pharmacist shall conduct a review of all orders prior to the 1st dose being administered (except in emergency situations).	☐	☐	☐
Neb Rev Stat 28-407 21 CFR Ch II – 1301	7. All registration requirements are met.	☐	☐	☐
Neb Rev Stats 28-401, 28-456.01 and 28-458-28.462 21 CFR Ch II – 1305/1311	8. All record keeping requirements are met.	☐	☐	☐
CAHs: 42 CFR 482.635(a)(3) Acute Hosp: 42 CFR 482.24(c) 21 CFR Ch II – 1305/1311	9. All requirements for ordering Schedule I and/or II controlled substances are met, including Power of Attorney forms.	☐	☐	☐
21 CFR Ch II – 1305/1311	10. All CSOS requirements are met.	☐	☐	☐
175 NAC 9-006.09G2 175 NAC 8-006.03A Neb Rev Stat 28-411(4) CAHs: 42 CFR 482.635(a)(3)(iv) Acute Hosp: 42 CFR 482.25(a)(3)	11. Complete and accurate records are maintained of all controlled substances received and added to the inventory.	☐	☐	☐

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175 NAC 8-06.04C,04D,04E 175 NAC 9-006.09G 175 NAC 9-006.09G7	12. All requirements pertaining to unit dose packaging and returned product labeling are met.	☐	☐	☐
Neb Rev Stats 28-414.04 and 28-414.05 CAHs: 42 CFR 482.635(a)(3)(iv) Acute Hosp: 42 CFR 482.25(a)(3) 21 CFR Ch II 1307.11 21 CFR Ch II 1317	13. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.	☐	☐	☐
175 NAC 9-006.09G7 175 NAC 8-006.02D Neb Rev Stats 71-2461 and 71-2470 and 71-2481	14. The pharmacy inventory does not have any drug, device or biological which is misbranded or adulterated. Finished drug forms are FDA approved. Compounds or bulk ingredients are purchased from FDA-registered facilities.	☐	☐	☐
175 NAC 9-006.09G7 175 NAC 8-006.04G	15. All requirements pertaining to multi-drug containers are met including proper labeling.	☐	☐	☐
175 NAC 9-006.09G3 Neb. Rev. Stat.- §28-410 21 CFR Ch. II- 1305.11 21 CFR 1304	16. All requirements pertaining to the inventory of controlled substances are met. DATE OF CURRENT INVENTORY: • A copy of the inventory has been sent to DHHS Licensure Unit • Active Power of Attorney and revocation of Power of Attorney records are maintained • All DEA Form 222s are properly completed • All CII invoices are properly maintained • All CII-CV invoices are properly completed and maintained	☐	☐	☐
175 NAC 9-006.09G(3) 175 NAC 8-006.05A Neb. Rev. Stat. §28-410 CAHs: 42 CFR 485.635(a)(3) ACUTE HOSP: 42 CFR 482.25(B)	17. All controlled substances are properly stored.	☐	☐	☐
Neb. Rev. Stat §38-28,108 thru §38-28,116	18. The pharmacy is in compliance with the requirement for Drug Product Selection Act.	☐	☐	☐
175 NAC 9-006.06B(4)(1) Neb. Rev. Stat. §71-470 ACUTE HOSP: 42 CFR 482.25 CAHs: 42 CFR 85.635(a)(3)(iv)	19. The Pharmacist in Charge maintains documented policies and procedures for the practice of pharmacy and use of medication in the hospital.	☐	☐	☐
Neb. Rev. Stat. §38-2867.01 ACUTE HOSPITALS: 42 CFR 482.25(b)(1) CAHs: 42 CFR 485.635(a)(3)(iv)	20. The Pharmacy is in compliance with USP Chapters 795 and 797.	☐	☐	☐
Neb. Rev. Stat §71-2444 through §71-2452	21. The Pharmacy is in compliance with the use of an automated medication system.	☐	☐	☐
Neb. Rev. Stats. § 71-7427 through §71-7463 DQSA-Title II	22. The Pharmacy is in compliance with state and federal whole-sale drug distribution statutes and regulations.	☐	☐	☐

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175 NAC 9-006.09G7 Neb Rev Stats. §28-410, §28-414.05, and §71-2481	23. Expired, mislabeled, unlabeled or unusable drugs and medical devices are not available for patient use and are disposed of in accordance with state and federal law.	☐	☐	☐
175 NAC 8-006.01D 172 NAC 128-012.04 Neb Rev Stat §38-2892 ACUTE CARE HOSPITALs: 42 CFR 482.25 (a) CAHs: 42 CFR 85.635(a)(3)(iv) Check Pharm Tech registration status at: **https://www.nebraska.gov/LISSearch/search.cgi**	24. All requirements are met for the utilization of Pharmacy Technicians and documentation is maintained, including: • Pharmacy Technicians are registered with DHHS • Pharmacy Technicians are identified as technicians • Pharmacy Technician training is completed • The ratio of supervising Pharmacist to Pharmacy Technician is compliant • All work performed by a Pharmacy Technician or intern is verified by a Pharmacist.	☐	☐	☐
See Raymond Declaratory Order. Neb. Rev. Stat.- §28-411, §28-14, §28-414.01, §28-414.03, §71-2479	25. Drugs are dispensed in accordance with the Raymond Declaratory Order. All requirements for record keeping and labeling of drugs are followed.	☐	☐	☐

Regulatory References:

Nebraska DEQ: http://deq.ne.gov/RuleAndR.nsf/Title_128.xsp

Nebraska Hospital Licensure Regulations: https://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-175/Chapter-09.pdf

Nebraska Pharmacy Act: https://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-172/Chapter-128.pdf

Acute Care Hospital and CAH federal regulations: https://www.ecfr.gov/cgi-bin/ECFR?page=browse

Nebraska Legislature Bill Search: https://www.nebraskalegislature.gov/bills/

Please forward your completed Hospital Pharmacy Quality Assurance Report (HPQAR) and Inventory to:

dhhs.acutecarefacilities@nebraska.gov

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STATEMENT OF COMPLIANCE

For any item marked “N” (Not in Compliance) please complete A – D below: (the fields are unlimited in characters)

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. WHEN the deficiency will be corrected.

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