

HOSPITAL PHARMACY QUALITY ASSURANCE REPORT NOTICE

DHHS
 DIVISION OF PUBLIC HEALTH
 LICENSURE UNIT
 TELEPHONE # (402) 471-4363

Your Hospital Pharmacy Quality Assurance Report (PQAR) is due on December 31 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 regulatory requirements.

NOTE: If you have a current Community Pharmacy license, you will still need to complete that PQAR and submit it to the Department.

Hospital Name: _____

Hospital DEA Registration Number: _____ Exp. Date: _____

Hospital Street Address: _____

Hospital City, State, Zip Code: _____

Pharmacy Telephone #: _____ Pharmacy Fax #: _____

Pharmacy/PIC Email: _____

Pharmacist – In – Charge name: _____ PIC License #: _____

Pharmacy Hours: _____

List Pharmacy Personnel:

Staff Pharmacists Name & NE License #	Pharmacist Interns Name & NE Registration #	Pharmacy Technicians Name & NE Registration #

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

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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 of Pharmacist-in-Charge)

(Date)

C = In Compliance

NC = Not in Compliance

NA = Not Applicable

Section cited	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 Hospitals: 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 principles.			
175 NAC 8-007.02 175 NAC 9-007	3. The pharmacy is maintained in a clean, orderly and sanitary manner.			
175 NAC 8-007.03 175 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 Hospitals: 42 CFR 482.25(b) (NOTE: after December 31, 2016, Neb. Rev. Stat. 38-2867.02 will require this.)	6. Prior to the 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 1 st 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 485.635(a)(3) Acute Hospitals: 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) ACUTE HOSPITALS: 42 CFR 482.25(a)(3) CAHs 42 CFR 85.635(a)(3)(iv)	11. Complete and accurate records are maintained of all controlled substances received and added to the inventory.			
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.			

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<p>Neb. Rev. Stats. §28-414.04 and §28-414.05 <u>ACUTE HOSPITALS</u> - 42 CFR 482.25(a)(3) <u>CAHs</u> - 42 CFR 485.635(a)(3)(iv) – 21 CFR Ch. II- 1307.11 21 CFR Ch. II- 1317</p>	<p>13. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.</p>			
<p>175 NAC 9-006.09G7 175 NAC 8-006.02D Neb Rev Stat §71-2461 Neb Rev Stat §71-2470 Neb. Rev. Stat. §71-2481</p>	<p>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.</p>			
<p>175 NAC 9-006.09G7 175 NAC-8-006.04G</p>	<p>15. All requirements pertaining to multi-drug containers are met, including proper labeling.</p>			
<p>175 NAC 9-006.09G3 Neb. Rev. Stat. - §28-410 21 CFR Ch. II- 1305.11 21 CFR 1304</p>	<p>16. All requirements pertaining to the inventory of controlled substances are met. Date of Current Inventory: _____</p> <ul style="list-style-type: none"> • A copy of the annual inventory has been sent to the Department of Health & Human Services, 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 CIII-CV invoices are properly completed and maintained. 			
<p>175 NAC 9-006.09G(3) 175 NAC 8-006.05A Neb. Rev. Stat. §28-410 <u>CAHs</u>: 42 CFR 485.635(a)(3) <u>ACUTE CARE HOSPITALs</u>: 42 CFR 482.25(B)</p>	<p>17. All controlled substances are properly stored.</p>			
<p>Neb. Rev. Stat §38-28,108 thru §38-28,116</p>	<p>18. The pharmacy is in compliance with the requirement for Drug Product Selection Act.</p>			
<p>175 NAC 9-006.06B(4)(1) Neb. Rev. Stat. §71-470 <u>ACUTE HOSPITALS</u>: 42 CFR 482.25 <u>CAHs</u>: 42 CFR 85.635(a)(3)(iv)</p>	<p>19. The Pharmacist in Charge maintains documented policies and procedures for the practice of pharmacy and use of medication in the hospital.</p>			
<p>Neb. Rev. Stat. §38-2867.01 <u>ACUTE HOSPITALS</u>: 42 CFR 482.25(b)(1) <u>CAHs</u>: 42 CFR 485.635(a)(3)(iv)</p>	<p>20. The pharmacy is in compliance with USP Chapters 795 and 797.</p>			
<p>Neb. Rev. Stats. §71-2444 through §71-2452</p>	<p>21. The pharmacy is in compliance with the use of an automated medication system.</p>			
<p>Neb. Rev. Stats. § 71-7427 through §71-7463 DQSA-Title II</p>	<p>22. The pharmacy is in compliance with state and federal wholesale drug distribution statutes or regulations.</p>			
<p>175 NAC 9-006.09G7 Neb Rev Stats. §28-410, §28-414.05, and §71-2481</p>	<p>23. Expired, mislabeled, unlabeled or unusable drugs and medical devices are not available for patient use and are disposed of in compliance with state and federal law.</p>			
<p>175 NAC 8-006.01D 172 NAC 128-012.04 Neb Rev Stat §38-2892 <u>ACUTE CARE HOSPITALs</u>: 42 CFR 482.25 (a) <u>CAHs</u>: 42 CFR 85.635(a)(3)(iv)</p>	<p>25. All requirements are met for the utilization of Pharmacy Technicians and documentation is maintained, including:</p> <ul style="list-style-type: none"> • Pharmacy Technicians are registered with DHHS • Pharmacy Technicians are identified as technicians • Pharmacy Technician training is completed 			

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Check Pharmacy Tech registration status at: https://www.nebraska.gov/LISSearch/search.cgi	<ul style="list-style-type: none">• 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	26. 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: http://www.sos.ne.gov/rules-and-regs/regsearch/Rules/Health_and_Human_Services_System/Title-175/Chapter-09.pdf

Nebraska Pharmacy Act: http://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: <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>

Nebraska Legislature Bill Search: <http://www.nebraskalegislature.gov/bills/>

Please forward your completed Hospital Pharmacy Quality Assurance Report (PQAR) to the Office of Acute Care Facilities at:

DHHS.acutecarefacilities@nebraska.gov

OR

fax: 402-742-8319.

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STATEMENT OF COMPLIANCE PAGE

For each item not in compliance, please list below (you 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

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

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

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

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

Hospital Name: _____ City: _____ PQAR Date _____

For Office Use Only:

In Compliance _____ **Not In Compliance** _____

Comments:
