Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056	**INSPECTION:** **Medical Care Facility** Form I-02MCF

Clear Answers

INSPECTION INFORMATION

Facility Name: _____ Registration Number: _____

Inspector Name: _____ Date: _____

GENERAL INFORMATION

C-Compliant N/I-Needs Improvement N/C-Not Compliant
U-Unassessed N/A-Not Applicable
Asterisk * denotes Pharmacist in Charge responsibility

Pharmacist(s) on duty: _____

Pharmacist in Charge: _____

○C ○N/I ○N/C ○U ○N/A Registration displayed—K.S.A. 65-1645(e)

○C ○N/I ○N/C ○U ○N/A DEA number: _____—21 C.F.R. 1301.11

○C ○N/I ○N/C ○U ○N/A Pharmacist license(s) posted—K.S.A. 65-1641

Pharmacists: _____

○C ○N/I ○N/C ○U ○N/A Pharmacist intern registration(s) posted—K.S.A. 65-1676(h)

Interns: _____

○C ○N/I ○N/C ○U ○N/A Technician registration(s) posted—K.S.A. 65-1663(j)

Technicians: _____

○C ○N/I ○N/C ○U ○N/A All personnel registered or licensed—K.S.A. 65-1631 & K.S.A. 65-1663 *

○C ○N/I ○N/C ○U ○N/A Name tags—K.A.R. 68-2-15

PRACTICE SETTING

Facility type: _____

Is the facility accredited by a national accreditation organization: ☐Yes ☐No

If so, by whom: _____

Participates in 340B: ☐Yes ☐No

Facility compounds sterile product: ☐Yes ☐No

If yes: ☐see separate form ☐not inspected at this visit

Facility compounds nonsterile products: ☐Yes ☐No

If yes: ☐see separate form ☐not inspected at this visit

Emergency department on site? ☐Yes ☐No

Electronic supervision of pharmacy personnel: ☐Yes ☐No

Shared services: ☐Yes ☐No

Pharmacy(s) participating: _____

FACILITIES

○C ○N/I ○N/C ○U ○N/A Pharmacy clean, well-lit, etc.—K.S.A. 65-1642(a) & K.S.A. 65-668(a) & K.S.A. 65-656(m)

○C ○N/I ○N/C ○U ○N/A Drugs stored per manufacturer—K.A.R. 65-1634

Room temperature: _____

Refrigerator temperature: _____

Freezer temperature: _____

○C○N/I○N/C○U○N/A Outdated, mislabeled, or adulterated drugs have been removed from stock K.S.A. 65-1634 & K.S.A. 65-657(a)

○C○N/I○N/C○U○N/A Reference material available—K.S.A. 65-1642 & K.A.R. 68-7-11(i)*

○C○N/I○N/C○U○N/A Access to current KS Pharmacy Laws/Regulations—K.S.A. 65-1642 & K.A.R. 68-7-11(i)*

○C○N/I○N/C○U○N/A P&T approved policy and procedures—K.A.R. 68-7-11(b)*

○C○N/I○N/C○U○N/A Drug recall procedure—K.A.R. 68-7-11(g)*

○C○N/I○N/C○U○N/A Necessary equipment and supplies—K.S.A. 65-1642 & K.A.R. 68-2-12a(b)

SECURITY

○C○N/I○N/C○U○N/A Secure when pharmacist is not on the premises—K.A.R. 68-7-11(n)*

○C○N/I○N/C○U○N/A Controlled drugs locked or dispersed—21 C.F.R. 1301.75

RECORDS

○C○N/I○N/C○U○N/A Initial notification and DEA 106 loss or theft reported to Board—K.A.R. 68-20-15b

○C○N/I○N/C○U○N/A Duration of record keeping—K.S.A. 65-1642(b)(c)(3) & K.A.R. 68-20-16(a)

○C○N/I○N/C○U○N/A Central record keeping—21 C.F.R. 1304.04(b)(3)

Location: _____

○C○N/I○N/C○U○N/A Records readily retrievable—21 C.F.R. 1300.01(b)(38) & K.S.A 65-1626(iii) & 65-4101(oo)

REVIEW OF INVENTORY AND INVOICE RECORDS

○C○N/I○N/C○U○N/A Annual inventory of controlled substances—K.A.R. 68-20-16

Date: _____

○C○N/I○N/C○U○N/A Change of PIC controlled substances inventory—K.A.R. 68-7-11(o)&(p)*

Date(s): _____

○C○N/I○N/C○U○N/A C-II inventory filed separately—K.A.R. 68-20-16

○C○N/I○N/C○U○N/A C-II invoices filed separately—K.A.R. 68-20-16

○C○N/I○N/C○U○N/A CIII-V invoices filed separately or readily retrievable—K.A.R. 68-20-16

○C○N/I○N/C○U○N/A Drugs received from registered sources—K.S.A. 65-1643(c)

○C○N/I○N/C○U○N/A DEA 222 forms completed—21 C.F.R. 1305.12 & 21 C.F.R. 1305.13

○C○N/I○N/C○U○N/A 222 forms for C-II transfers—K.A.R. 68-20-17

○C○N/I○N/C○U○N/A Controlled substance ordering system—21 C.F.R. 1305.21

○C○N/I○N/C○U○N/A Power of attorney—21 C.F.R. 1305.05

PHARMACY PROCESSES

○C ○N/I ○N/C ○U ○N/A Pharmacist to interpret order—K.A.R. 68-7-11(l)

○C ○N/I ○N/C ○U ○N/A Documentation of pharmacist performing medication order verification—K.A.R. 68-2-20(b)(7)

○C ○N/I ○N/C ○U ○N/A Medication order is filled in strict conformity
—K.S.A. 65-1637(g)&(h) & K.S.A. 65-657(n) & K.A.R. 68-7-11(l)

○C ○N/I ○N/C ○U ○N/A "After the fact" review within 7 days of the date order was written—K.A.R. 68-7-11(l)

○C ○N/I ○N/C ○U ○N/A Maintenance of emergency kits—K.A.R. 68-7-11(c)*

○C ○N/I ○N/C ○U ○N/A Quarterly check of drug records—K.A.R. 68-7-11(e)*

○C ○N/I ○N/C ○U ○N/A Quarterly check of drug storage conditions —K.A.R. 68-7-11(e)*

○C ○N/I ○N/C ○U ○N/A Tech check Tech—K.A.R. 68-7-11(q)

TECHNICIANS

○C ○N/I ○N/C ○U ○N/A Ratio of pharmacy technicians to pharmacists—K.A.R. 68-5-16

Ratio during inspection**:** _____

○C ○N/I ○N/C ○U ○N/A Maintain a list of the names of pharmacy technicians—K.S.A. 65-1663(i)

○C ○N/I ○N/C ○U ○N/A Technician training—K.A.R. 68-5-15(d)(2) *

○C ○N/I ○N/C ○U ○N/A Annual review of technician training course—K.A.R. 68-5-15(d)(1) *

○C ○N/I ○N/C ○U ○N/A Supervision of technicians—K.S.A. 65-1626(n) & K.A.R. 68-7-11(j)

PHARMACIST NOT ON DUTY

○C ○N/I ○N/C ○U ○N/A Access to pharmacy only by designated RN/PA(s)—K.S.A. 65-1648 & K.A.R. 68-7-11(d)

○C ○N/I ○N/C ○U ○N/A Log of inpatient drug withdrawal—K.A.R. 68-7-11(d)(1)

○C ○N/I ○N/C ○U ○N/A Single dose transfer from stock bottle—K.A.R. 68-7-11(d)(3)

○C ○N/I ○N/C ○U ○N/A Limited outpatient supply—K.S.A. 65-1648(a) & K.A.R. 68-7-11(d)(2)(B)

○C ○N/I ○N/C ○U ○N/A Prescription order maintained on file—K.A.R. 68-7-11(d)(2)(B)(i)

○C ○N/I ○N/C ○U ○N/A Records of the distribution of interim supplies of prepackaged drugs —K.A.R. 68-7-11(d)(2)(B)

○C ○N/I ○N/C ○U ○N/A Emergency and outpatient drug supplies labeled appropriately—K.A.R. 68-7-11(d)(2)(A) & K.A.R. 68-7-14

○C ○N/I ○N/C ○U ○N/A Child proof packaging—FDA Poison Prevention Packaging Act *

○C ○N/I ○N/C ○U ○N/A Report to K-TRACS when providing over a 48-hour supply of a controlled substance—K.A.R. 68-21-3(c)

PREPACKAGING/REPACKAGING—K.A.R. 68-7-11(h)

Type of packaging used: _____

○C ○N/I ○N/C ○U ○N/A Stored according to manufacturer's recommendation

○C ○N/I ○N/C ○U ○N/A Proper control system for recall purposes

○C ○N/I ○N/C ○U ○N/A Expiration date not to exceed the shorter of 12 months, manufacturer's exp. date, or packaging limitations

PREPACKAGING/REPACKAGING LABELS—K.A.R. 68-7-11(h)

○C ○N/I ○N/C ○U ○N/A Brand or generic name

○C ○N/I ○N/C ○U ○N/A Name of manufacturer or distributor for generic drugs (may be kept in a repackaging log)

○C ○N/I ○N/C ○U ○N/A Strength and quantity

○C ○N/I ○N/C ○U ○N/A Lot number (may be kept in a repackaging log)

○C ○N/I ○N/C ○U ○N/A Date repackaged (may be kept in a repackaging log)

○C ○N/I ○N/C ○U ○N/A Person responsible for packaging (may be kept in a repackaging log)

○C ○N/I ○N/C ○U ○N/A Expiration date

○C ○N/I ○N/C ○U ○N/A Auxiliary labels if necessary

AUTOMATED DRUG DELIVERY SYSTEMS—K.A.R. 68-9-2 & 68-9-3*

Type of automated drug delivery system: _____

○C ○N/I ○N/C ○U ○N/A Good working order with accuracy in selection

○C ○N/I ○N/C ○U ○N/A All drugs removed and returned are secure and accounted for

○C ○N/I ○N/C ○U ○N/A All wasted/discarded drugs are secure and accounted for

○C ○N/I ○N/C ○U ○N/A Loaded accurately

○C ○N/I ○N/C ○U ○N/A Medications stored per manufacturers storage requirements

○C ○N/I ○N/C ○U ○N/A Loading and unloading limited to R. Ph, Pharm. Intern, Pharm. Tech or Licensed Nurse

○C ○N/I ○N/C ○U ○N/A Maintain a current list of approved individuals to unload any drug

○C ○N/I ○N/C ○U ○N/A All drugs are compliantly packaged

○C ○N/I ○N/C ○U ○N/A Track lot numbers and expiration date of containers

○C ○N/I ○N/C ○U ○N/A Preventive maintenance and sanitation

○C ○N/I ○N/C ○U ○N/A Discrepancy report and reconciliation

○C ○N/I ○N/C ○U ○N/A Inspections are conducted and documented at least monthly—K.A.R. 68-9-3(f)(9)

COMMENTS