| Kansas | **STATE BOARD OF PHARMACY**<br>800 SW Jackson, Suite 1414<br>Topeka, Kansas 66612-1244<br>www.pharmacy.ks.gov (785)296-4056 | **INSPECTION:**<br>**Medical Care Facility**<br>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

Self-Inspection

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C N/I N/C U N/A Outdated, mislabeled, or adulterated drugs have been removed from stock K.S.A. 65-1634 & K.S.A. 65-657(a)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. 1305.13

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

Self-Inspection

**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

Self-Inspection

○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**

Self-Inspection