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

INSPECTION INFORMATION

Facility Name:_____ Registration Number:_____

Date:_____ Clear Answers

GENERAL INFORMATION

Yes No N/A Registrations displayed: State & DEA—K.S.A. 65-1645(e)

DEA Number:_____

Pharmacist in Charge Name:_____

Pharmacists:

Yes No N/A Pharmacist License posted—K.S.A. 65-1641

Yes No N/A Technician Registration(s) posted—K.S.A. 65-1663(h)

Yes No N/A Name tags—K.A.R. 68-2-15

RECORDS

Yes No N/A Duration of Record Keeping—K.S.A. 65-1642(b)(c)(3) & K.A.R. 68-20-16(a)

Yes No N/A Policy & procedures P&T approved—K.A.R. 68-7-11(b)

Yes No N/A Quarterly Checks—K.A.R. 68-7-11(e)

Yes No N/A Electronic Supervision—K.A.R. 68-22-1 thru 5

Yes No N/A Is the facility accredited by a national accreditation organization?

If so, by whom?_____

Yes No N/A 340B participant?

Qualifying 340b entity: _____

REVIEW OF INVENTORY AND INVOICE RECORDS

Yes No N/A Annual Inventory of controlled substances—K.A.R. 68-20-16

Date:_____

Yes No N/A C-II inventory filed separately—K.A.R. 68-20-16

Yes No N/A C-II invoices filed separately—K.A.R. 68-20-16

Yes No N/A DEA 222 forms completed—21 C.F.R. 1305.12(e)

Yes No N/A DEA 222 forms for C-II transfers—K.A.R. 68-20-17

Yes No N/A Controlled Substance Ordering System in lieu of above

Yes No N/A Power of Attorney—21 C.F.R. 1305.07

Yes No N/A Review of invoices—non-controlled & controlled

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FACILITIES

◯Yes ◯No ◯N/A Pharmacy clean, well lit, etc.—K.S.A. 65-625 & 65-656(o)

◯Yes ◯No ◯N/A Drugs stored per manufacturer—K.S.A. 65-1634

Room Temperature:_____

Refrigerator Temperature: _____

◯Yes ◯No ◯N/A No outdated, mislabeled, or adulterated drugs—K.S.A. 65-1634 & K.S.A. 65-657(a)(b)

NECESSARY EQUIPMENT/LIBRARY

◯Yes ◯No ◯N/A Reference material available—K.A.R. 68-7-11(i)

◯Yes ◯No ◯N/A Access to KS Pharmacy Laws/Regulations

◯Yes ◯No ◯N/A Necessary Equipment—K.S.A. 65-1642

◯Yes ◯No ◯N/A Compounded Sterile Product is USP 797 compliant—K.A.R. 68-13-1

◯Yes ◯No ◯N/A Hood(s) inspected per schedule

Hood Inspection Schedule Date:_____

◯Yes ◯No ◯N/A Compounding limited quantities-FDA

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

Type of packaging used:_____

◯Yes ◯No ◯N/A Proper storage as manufacturer recommends

◯Yes ◯No ◯N/A Proper control system for recall purposes

Labels—K.A.R. 68-7-11(h)

◯Yes ◯No ◯N/A Brand name or generic name with manufacturer and distributor's name

◯Yes ◯No ◯N/A Strength and quantity

◯Yes ◯No ◯N/A Lot number, date repackaged, and person responsible for repackaging or suitable record if not on label

◯Yes ◯No ◯N/A Expiration date

◯Yes ◯No ◯N/A Auxiliary labels if necessary

EMERGENCY DEPARTMENT

◯Yes ◯No ◯N/A Emergency Department on site?

◯Yes ◯No ◯N/A Dispensing Med Packs to ER patients

◯Yes ◯No ◯N/A Report to K-TRACS if over a 48-hour supply

TRAINING OF TECHNICIANS

Ratio during inspection:_____

◯Yes ◯No ◯N/A Technician Training Course—K.A.R. 68-7-11(j)

◯Yes ◯No ◯N/A Documentation of Annual Review

SECURITY

Yes No N/A Secure when pharmacist is not on duty—K.A.R. 68-2-11

Yes No N/A Controlled drugs locked or dispersed—21 C.F.R. 1301.75

PHARMACIST RESPONSIBILITIES

Yes No N/A Pharmacist to interpret order—K.A.R. 68-7-11(l)

Yes No N/A Strict conformity—K.A.R. 68-7-11(l)

Yes No N/A Supervise technicians—K.S.A. 65-1626(g)

Yes No N/A Perform the final check—K.S.A. 65-1626(g)

Yes No N/A "After the fact" review within 7 days—K.A.R. 68-7-11(l)

AUTOMATED DRUG DELIVERY

Yes No N/A Secure/account/track drugs in & out—K.A.R. 68-9-2(b)

Yes No N/A Loading/unloading under pharmacist supervision—K.A.R. 68-9-2(b)(7)

Yes No N/A Inspected monthly—K.A.R. 68-9-3(f)(9)

PHARMACIST NOT ON DUTY

Yes No N/A Access to pharmacy by designated RN/PA(s)—K.A.R. 68-7-11(d) & (n)(2) & K.S.A. 65-1648

Yes No N/A Single dose transfer from stock bottle—K.A.R. 68-7-11(d)(2)(B)(3)

Yes No N/A Log of inpatient drug removal—K.A.R. 68-7-11(d)(1)

Yes No N/A Limited outpatient supply—K.S.A. 65-1648(a)

Yes No N/A Prescription order maintained on file—K.A.R. 68-7-11(b)(2)(B)

Yes No N/A Log of outpatient distribution—K.A.R. 68-7-11(d)(2)(B)

PRESCRIPTION LABELS—K.A.R. 68-7-18(c)(2) & 68-7-14

Yes No N/A If ER or outpatient dispensing, label appropriately

Yes No N/A If parenteral preparation, labeled appropriately

Yes No N/A Child proof packaging—FDA Poison Prevention Packaging Act

COLLABORATIVE PRACTICE

Yes No N/A Agreements

Yes No N/A In Date (signed within last 2 years)

Yes No N/A All required elements

COMMENTS