Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056	**INSPECTION:** **Institutional Drug Room** Form I-12

Clear Answers

INSPECTION INFORMATION

Institution Name:_____ Registration Number:_____

Inspector Name: _____ Date: _____

FACILITY TYPE:

☐Business/Employer ☐Correctional/Jail ☐Inpatient Hospice

☐Institution of Higher Learning (University/College) ☐Juvenile Detention

C-Compliant N/I-Needs Improvement N/C-Not Compliant
U-Unassessed N/A-Not Applicable

GENERAL INFORMATION

Person(s) on duty: _____

○C ○N/I ○N/C ○U ○N/A Registration(s) 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 Combat Meth Self-Certification—21 C.F.R. 1314.35 & 21 C.F.R. 1314.40

○C ○N/I ○N/C ○U ○N/A Supervised by appropriate, licensed staff—K.S.A. 65-1637a

FACILITIES

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

○C ○N/I ○N/C ○U ○N/A Drugs stored per manufacturer—K.A.R. 68-7-21(b)(2)

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○C ○N/I ○N/C ○U ○N/A Outdated, mislabeled, or adulterated drugs have been removed from stock —K.S.A. 65-1634 & K.S.A. 65-657(a)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 Policy & procedures—K.A.R. 68-7-21(b)(2)

SECURITY

○C ○N/I ○N/C ○U ○N/A Medication security—K.A.R. 68-7-21

○C ○N/I ○N/C ○U ○N/A Controlled substances locked or dispersed—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-20-15a

RECORDS

○C ○N/I ○N/C ○U ○N/A Documentation of staff training for Combat Meth Self-Certification—21 C.F.R. 1314.35

○C ○N/I ○N/C ○U ○N/A K-TRACS reporting—K.S.A. 65-1683

○C ○N/I ○N/C ○U ○N/A Documentation of quarterly review—K.A.R. 68-7-21(b)(3)

○C ○N/I ○N/C ○U ○N/A Patient dispensing log—K.A.R. 68-7-21(c)

○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)

C-V OTC SALES

○C ○N/I ○N/C ○U ○N/A Documentation of C-V OTC pseudoephedrine/ephedrine sales—K.S.A. 65-1643(j)(1)(B) & K.A.R. 65-16,102

Log type: _____

○C ○N/I ○N/C ○U ○N/A Report pseudoephedrine sales to NPLEx—K.S.A. 65-16, 102

○C ○N/I ○N/C ○U ○N/A Log book for C-V OTC products (ex. cough syrups)—K.A.R. 68-20-22

○C ○N/I ○N/C ○U ○N/A Appropriate ID used/obtained/accepted for sale of C-V OTC products —K.S.A. 65-1643(j)(1)(b) & K.A.R. 68-20-22(d)

INCIDENT REPORTS—K.A.R. 68-7-21(b)(4) & K.A.R. 68-7-12b(c)

○C ○N/I ○N/C ○U ○N/A Timely preparation

○C ○N/I ○N/C ○U ○N/A Name, address, age, & phone number of complainant

○C ○N/I ○N/C ○U ○N/A Name of all employees involved

○C ○N/I ○N/C ○U ○N/A License/Registration number of all employees involved

○C ○N/I ○N/C ○U ○N/A Signature of all employees involved

○C ○N/I ○N/C ○U ○N/A Date of incident

○C ○N/I ○N/C ○U ○N/A Date of report

○C ○N/I ○N/C ○U ○N/A Description of the incident

○C ○N/I ○N/C ○U ○N/A Prescriber's name

○C ○N/I ○N/C ○U ○N/A Prescriber contacted

○C ○N/I ○N/C ○U ○N/A Documented steps taken to avoid a repeat of each reportable incident—K.A.R. 68-7-21(b)(3)

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 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 DEA 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

REVIEW OF PRESCRIPTION FILES

○C ○N/I ○N/C ○U ○N/A C-II prescriptions maintained separately or readily retrievable —21 C.F.R. 1304.04(h) & K.A.R. 68-20-16(a)

○C ○N/I ○N/C ○U ○N/A C-III-V prescriptions maintained separately or readily retrievable—21 C.F.R. 1304.01(b) and 1304.04(h)

○C ○N/I ○N/C ○U ○N/A Controlled substance prescriptions have full address of patient (no PO Boxes)—K.A.R. 68-20-18(c)

○C ○N/I ○N/C ○U ○N/A Controlled substance prescriptions have address and DEA number of prescriber—K.A.R. 68-20-18(c)

○C ○N/I ○N/C ○U ○N/A Controlled substance files are void of preprinted prescriptions—K.A.R. 68-20-18(c)

○C ○N/I ○N/C ○U ○N/A C-II prescriptions properly canceled—K.A.R. 68-20-19(e)

○C ○N/I ○N/C ○U ○N/A Controlled substances filled prior to expiration of prescriptions—K.A.R. 68-20-19 & K.A.R. 68-20-20

○C ○N/I ○N/C ○U ○N/A Dispensing in strict conformity—K.S.A. 65-1637(g)&(h) & K.S.A. 65-657(n)

Review of _____ prescription records

○C ○N/I ○N/C ○U ○N/A Supervising doctor for APRN/PA on prescription—K.S.A. 65-28a08(d) & K.S.A. 65-1130(d)

PRESCRIPTION LABELS—K.A.R. 68-7-21(d)

○C ○N/I ○N/C ○U ○N/A Full name of patient

○C ○N/I ○N/C ○U ○N/A Prescription number

○C ○N/I ○N/C ○U ○N/A Brand name or generic name of the drug

○C ○N/I ○N/C ○U ○N/A Strength of the drug

○C ○N/I ○N/C ○U ○N/A Name of manufacturer or distributor

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

○C ○N/I ○N/C ○U ○N/A Storage instructions if needed

○C ○N/I ○N/C ○U ○N/A Beyond-use date

○C ○N/I ○N/C ○U ○N/A Adequate directions for use

○C ○N/I ○N/C ○U ○N/A Name of the institutional drug room

○C ○N/I ○N/C ○U ○N/A Provides side effect statement with all new and refill prescriptions—21 C.F.R. 209.11

PREPACKAGING/REPACKAGING—K.A.R. 68-7-15

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

○C ○N/I ○N/C ○U ○N/A Documentation of the pharmacist that supervised each repackaging

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

PREPACKAGING/REPACKAGING LABELS—K.A.R. 68-7-16

○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

COMMENTS