



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**

INSPECTION INFORMATION

Institution Name: _____ Registration Number: _____

Date: _____

GENERAL INFORMATION

Facility Type:

Business/employer Correctional/Jail Inpatient Hospice

Institution of higher learning (university/college) Juvenile detention

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

DEA Number: _____

Pharmacist in Charge/Practitioner: _____

Yes No N/A Policy & procedures—K.A.R. 68-7-21(b)(2)

Yes No N/A Documentation of quarterly review—K.A.R. 68-7-21(b)(3)

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

Yes No N/A Patient dispensing log—K.A.R. 68-7-21(c)(1)

FACILITIES

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

Yes No N/A Drugs stored per manufacturer—K.A.R. 68-7-21(b)(2)

Yes No N/A No outdated, mislabeled, or adulterated drugs—K.S.A. 65-1634 & K.S.A. 65-657(a)(b)

SECURITY

Yes No N/A Medication security—K.A.R. 68-7-21

Yes No N/A Controlled substances locked or dispersed—K.A.R. 68-20-15a & 21 C.F.R. 1301.71 & 1301.75

REVIEW OF INVENTORY & 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



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C-V Pseudoephedrine sales—K.S.A. 65-1643(j)

If on a college/university campus, verify if they perform OTC sales of pseudoephedrine or C-V cough syrups.

If they do:

- Yes No N/A Report pseudoephedrine sales to NPLeX
- Yes No N/A Log book for C-V cough syrups
- Yes No N/A Correct ID for either

REVIEW OF PRESCRIPTION FILES - Of those observed

- Yes No N/A Files (C-II separate)—21 C.F.R. 1304.04(h) & K.A.R. 68-20-16(a)
- Yes No N/A Scheduled: no preprinted blanks—K.A.R. 68-20-18(c)
- Yes No N/A C-II properly canceled—K.A.R. 68-20-19(e)
- Yes No N/A Controlled substances not filled past expiration—K.A.R. 68-20-19 & K.A.R. 68-20-20
- Yes No N/A Strict conformity—K.S.A. 65-1637(a)
- Yes No N/A Proper substitution—K.S.A. 65-1637(a)(4) & K.S.A. 65-657(o)
- Yes No N/A APRN/PA supervising doctor—K.S.A. 65-28a08(d) & K.S.A. 65-1130(d)

PRESCRIPTION LABELS—K.A.R. 68-7-14

- Yes No N/A Name, address, & phone number of facility
- Yes No N/A Name of prescriber or PA/APRN
- Yes No N/A Full name of patient
- Yes No N/A Prescription number
- Yes No N/A Date filled or refilled
- Yes No N/A Adequate directions for use
- Yes No N/A Beyond Use Date
- Yes No N/A Brand name or generic name of the drug
- Yes No N/A Name of manufacturer or distributor
- Yes No N/A Strength of drug
- Yes No N/A Quantity dispensed
- Yes No N/A Auxiliary labels if needed
- Yes No N/A Child proof packaging—FDA Poison Prevention Packaging Act



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

Yes No N/A Proper control system for recall purposes

Labels—K.A.R. 68-7-16

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

COMMENTS