



STATE BOARD OF PHARMACY

800 SW Jackson, Suite 1414
Topeka, Kansas 66612-1244
www.pharmacy.ks.gov (785)296-4056

**INSPECTION:
Pharmacy
Form I-02P**

INSPECTION INFORMATION

Pharmacy Name: _____ Registration Number: _____

Date: _____

GENERAL INFORMATION

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

DEA Number: _____

PSE Certificate Expires: _____

Pharmacists:

Yes No N/A Medicare Poster

Yes No N/A K-TRACS Poster

Pharmacist in Charge Name: _____

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

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

Yes No N/A Maintain a list of the names of pharmacy technicians—K.S.A. 65-1663(g)

Yes No N/A Name tags—K.A.R. 68-2-15

Technicians:

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: _____

FACILITIES

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

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Yes No N/A No outdated, mislabeled, or adulterated drugs—K.S.A. 65-1634 & K.S.A. 65-657(a)(b)

RECORDS

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

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)



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- 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 No date changes on C-II scripts
- Yes No N/A Issuance of multiple C-II prescriptions—21 C.F.R. 1306.12
- Yes No N/A Strict conformity—K.S.A. 65-1637(a)
- Yes No N/A Proper substitution—K.S.A. 65-1637(a)(2) & K.S.A. 65-657(o)
- Yes No N/A No Post Office boxes—K.A.R. 68-9-1 & K.A.R. 68-20-18(c)
- Yes No N/A Fax number or agent ID—K.S.A. 65-1637(b) & K.A.R. 68-20-18(d)
- Yes No N/A First and last name of the agent—K.S.A. 65-1637(b)
- Yes No N/A APRN/PA supervising doctor—K.S.A. 65-28a08(d) & K.A.R.100-28a-13(e) & K.S.A. 65-1130(d) & K.A.R. 60-11-104a
- Yes No N/A LTCF/Hospice identified—21 C.F.R .1306.11(e, f, & g)
- Yes No N/A Electronic certification for E-scripts

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. 1305.13
- 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

OTHER RECORDS

- Yes No N/A Daily print-outs or log Book (requires signature)—K.A.R. 68-9-1(a)(9) & 21 C.F.R. 1306.22(f)(3)
- Yes No N/A Log book for C-V (i.e. cough syrups)—K.A.R. 68-20-22
- Yes No N/A K-TRACS reporting

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

- Yes No N/A Electronic
- Yes No N/A Point of sale
- Yes No N/A Log book signature
- Yes No N/A Valid driver's license, time, gram quantity, no PO box



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PHARMACIST IN CHARGE RESPONSIBILITIES

- Yes No N/A All personnel registered or licensed
- Yes No N/A Incident reports completed timely
- Yes No N/A Policy and procedures
- Yes No N/A Child proof packaging—FDA Poison Prevention Packaging Act
- Yes No N/A Observation of counseling—K.A.R. 68-2-20(a)(5) & (b)
- Yes No N/A Oxygen dispensed

Transfilled by: _____

PRESCRIPTION LABELS—K.A.R. 68-7-14

- Yes No N/A Name, address, & phone number of pharmacy
- 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 Does pharmacy give medication guides?
- Yes No N/A Does pharmacy dispense to LTCF?
- Yes No N/A E-Kit supply and maintenance—K.A.R. 68-7-10(d)
- Yes No N/A Automation housed at LTCF
- Stocked by: _____
- Yes No N/A Controlled substance in Automation at LTCF
- DEA Number of automation: _____



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

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. 68-7-16

- 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

INCIDENT REPORTS—K.A.R. 68-7-12b(c)

- Yes No N/A Timely preparation
- Yes No N/A Name, address, age, & phone number of complainant
- Yes No N/A Name and license number of all employees involved
- Yes No N/A Signature of all employees involved
- Yes No N/A Date of incident
- Yes No N/A Date of report
- Yes No N/A Description of the incident
- Yes No N/A Prescriber's name
- Yes No N/A Prescriber was contacted?

CQI REPORTS

- Yes No N/A CQI meets quarterly—K.A.R. 68-19-1
- Yes No N/A Preventative steps for each reportable incident

TECHNICIANS

Ratio during inspection: _____—K.A.R. 68-5-16

- Yes No N/A Technician Training Course—K.A.R. 68-5-15(b)
- Yes No N/A Documentation of Annual Review—K.A.R. 68-5-15(d)

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



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- Yes No N/A Compounded Sterile Product is USP 797 compliant—K.A.R. 68-13-1
- Yes No N/A Compounding limited quantities/prescription—FDA

SECURITY

- Yes No N/A Secure when pharmacist is not on duty—K.A.R. 68-2-11
- Yes No N/A Keys only with pharmacist(s)
- Yes No N/A Controlled drugs locked or dispersed—21 C.F.R. 1301.75

PHARMACIST RESPONSIBILITIES

- Yes No N/A Medication Profile Review—K.S.A. 65-1642(c) & K.A.R. 68-2-20(a)(9)
- 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 Document verification—K.A.R. 68-2-20(a)(4)

AUTOMATED PHARMACY SYSTEM—K.A.R. 68-9-1

- Yes No N/A Daily back-up of system
- Yes No N/A Maintain the original prescription
- Yes No N/A Prevent modification or manipulation

Type of Automation: _____

VACCINATIONS/IMMUNIZATIONS

- Yes No N/A Vaccination protocol—K.S.A. 65-1626(jj)
- Yes No N/A Documentation of training & CPR certification—K.S.A. 65-1635a
- Yes No N/A Written record & reporting—K.S.A. 65-1635(b)
Review of _____ Vaccination Records
- Yes No N/A Problems with vaccination records

COLLABORATIVE PRACTICE

- Yes No N/A In Date (signed within last 2 years)
- Yes No N/A All required elements

COMMENTS