Kansas	**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

Clear Answers

INSPECTION INFORMATION

Pharmacy 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 Pharmacy 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 Combat Meth Self-Certification—21 C.F.R. 1314.35 & 21 C.F.R. 1314.40

○C ○N/I ○N/C ○U ○N/A K-TRACS poster—K.A.R. 68-21-4(a)

○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

Specialty pharmacy: ☐Yes ☐No

Type: _____

Is the facility accredited by a national accreditation organization: ☐Yes ☐No

If so, by whom: _____

Participates in 340B: ☐Yes ☐No

Qualifying 340B entity: _____

Dispensing oxygen: ☐Yes ☐No

Transfilled by: _____

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

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

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○C ○N/I ○N/C ○U ○N/A Outdated, mislabeled, or adulterated drugs have been removed from stock —K.S.A. 65-1634 & K.S.A. 65-657(a)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. 68-2-12a

○C ○N/I ○N/C ○U ○N/A Access to current KS Pharmacy Laws/Regulations—K.S.A. 65-1642 & K.A.R. 68-2-12a

○C ○N/I ○N/C ○U ○N/A Policy and procedures—K.A.R. 68-7-12(c) *

○C ○N/I ○N/C ○U ○N/A Necessary equipment and supplies—K.S.A. 65-1642 & K.A.R. 68-2-12a

SECURITY

○C ○N/I ○N/C ○U ○N/A Secure when pharmacist is not on duty—K.A.R. 68-2-11

○C ○N/I ○N/C ○U ○N/A Prepackaging/Repackaging area secure when pharmacist is not in attendance in area—K.A.R. 68-7-15(e)

○C ○N/I ○N/C ○U ○N/A Keys only with pharmacist(s)—K.A.R. 68-2-11

○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 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 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)

ELECTRONIC DATA STORAGE SYSTEMS—K.A.R. 68-9-1 & 21 C.F.R. 1306.22(f)(3) *

Type of automation: _____

○C ○N/I ○N/C ○U ○N/A Daily back-up of system

○C ○N/I ○N/C ○U ○N/A Maintain the original prescription

○C ○N/I ○N/C ○U ○N/A Prevent modification or manipulation

○C ○N/I ○N/C ○U ○N/A Daily print-outs or log book (requires signature)

C-V OTC SALES

○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)

○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

○C ○N/I ○N/C ○U ○N/A Lawful prescription for C-V pseudoephedrine—K.S.A. 65-1643(j)(2)

VACCINATIONS/IMMUNIZATIONS

○C ○N/I ○N/C ○U ○N/A Vaccination protocol—K.S.A. 65-1626(vvv)

○C ○N/I ○N/C ○U ○N/A Documentation of study & training—K.S.A. 65-1635a(a)

○C ○N/I ○N/C ○U ○N/A Current CPR certificate—K.S.A. 65-1635a(a)

○C ○N/I ○N/C ○U ○N/A Written immunization record—K.S.A. 65-1635a(b)

Review of_____vaccination records

○C ○N/I ○N/C ○U ○N/A Record reported—K.S.A. 65-1635a(b)

To whom: _____

INCIDENT REPORTS—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

CQI REPORTS—K.A.R. 68-19-1

○C ○N/I ○N/C ○U ○N/A Meet each quarter of each calendar year, every 90 days

○C ○N/I ○N/C ○U ○N/A PIC in attendance at the meeting *

○C ○N/I ○N/C ○U ○N/A List of persons in attendance

○C ○N/I ○N/C ○U ○N/A List all reportable incident reports

○C ○N/I ○N/C ○U ○N/A Review all reportable incident reports

○C ○N/I ○N/C ○U ○N/A List newsletters reviewed

○C ○N/I ○N/C ○U ○N/A Description of preventative steps for each incident reviewed

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. 68-7-12(e)&(f) *

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. 1305.12 & 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 Files (C-II separate)—21 C.F.R. 1304.04(h) & K.A.R. 68-20-16(a)

○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 Dating on C-II scripts is compliant (no changes)

○C ○N/I ○N/C ○U ○N/A Issuance of multiple C-II prescriptions—21 C.F.R. 1306.12

○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 Controlled substance prescriptions have full address of patient (no PO boxes)

—K.A.R. 68-9-1(a)(9)(D) & 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. 68-9-1(a)(9)(D) & K.A.R. 68-20-18(c)

○C ○N/I ○N/C ○U ○N/A Fax number or agent ID—K.S.A. 65-1637(b) & K.A.R. 68-20-18(d)(1)

○C ○N/I ○N/C ○U ○N/A First and last name of the agent—K.S.A. 65-1637(b)

○C ○N/I ○N/C ○U ○N/A Supervising doctor for APRN/PA

—K.S.A. 65-28a08(b), K.S.A. 65-1130(d), K.A.R.100-28a-13(f), & K.A.R. 60-11-104a(c)

C N/I N/C U N/A LTCF/Hospice identified—21 C.F.R .1306.11(f)&(g)

C N/I N/C U N/A Storage of electronic prescriptions—K.A.R. 68-9-1

Review of _____ electronic prescription records

Format: ☐ electronic ☐ electronic and printed

PRESCRIPTION LABELS—K.A.R. 68-7-14

C N/I N/C U N/A Name, address, & telephone number of dispensing pharmacy

C N/I N/C U N/A Name of prescriber or PA/APRN

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 Date filled or refilled

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

C N/I N/C U N/A Beyond-use date

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

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

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

C N/I N/C U N/A Quantity dispensed

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

PHARMACY PROCESSES

C N/I N/C U N/A Provides FDA required medication guides with all new & refill prescriptions—21 C.F.R. 208.24

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

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

C N/I N/C U N/A Observation of counseling—K.A.R. 68-2-20(b)(5)

C N/I N/C U N/A Medication profile review—K.S.A. 65-1642(c) & K.A.R. 68-2-20(b)(9)

C N/I N/C U N/A Provides direct supervision—K.S.A. 65-1626(n)

C N/I N/C U N/A Documentation of pharmacist performing prescription verification—K.A.R. 68-2-20(b)

C N/I N/C U N/A Resale of medication prohibited except for limited exceptions—K.A.R. 68-12-2

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)

LTC FACILITY

○C ○N/I ○N/C ○U ○N/A Drug distribution to LTC facilities—K.A.R. 68-7-10

○C ○N/I ○N/C ○U ○N/A E-Kit supply and maintenance—K.A.R. 68-7-10(d)

○C ○N/I ○N/C ○U ○N/A Automation housed at LTC facilities—K.A.R. 68-9-3 *

Stocked by: _____

○C ○N/I ○N/C ○U ○N/A Controlled substance in automation at LTC facilities—21 C.F.R. 1301.27 *

DEA number of automation: _____

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

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

AUTOMATED DRUG DELIVERY SYSTEMS—K.A.R. 68-9-2 *

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

SHARED SERVICES—K.A.R. 68-7-20

Shared order processing pharmacy: _____

Shared order filling pharmacy: _____

○C ○N/I ○N/C ○U ○N/A Common electronic file or appropriate technology

○C ○N/I ○N/C ○U ○N/A Same owner or written contract

○C ○N/I ○N/C ○U ○N/A Joint policies and procedures manual

○C ○N/I ○N/C ○U ○N/A Maintain records identifying each R. Ph, Pharm. Intern, Pharm. Tech in all pharmacy processes

○C ○N/I ○N/C ○U ○N/A Mechanism for tracking order

○C ○N/I ○N/C ○U ○N/A All pharmacies identified on prescription label

COMMENTS