BEFORE THE STATE BOARD OF PHARMACY
OF THE STATE OF KANSAS

IN RE: THE MATTER OF

LARRY DEANE COURTNEY
License No. 1-08821
648 Allcutt
Bonner Springs, KS 66102

STIPULATION OF FINDING OF FACT AND ORDER

This matter comes before the State Board of Pharmacy for the State of Kansas, this 5th day of April, 1997.

The State Board of Pharmacy appears by Karla Kneebone, President and Presiding Officer; Barry Sarvis, Vice-President; Dan Katzer, Pharmacist; Vicki Schmidt, Pharmacist; Lori Moore, Pharmacist; and Dr. Margaret Young, Consumer Representative. Also appearing are Larry Froelich, Executive Secretary, and the attorney for the Board, Dana W. Killinger. Larry D. Courtney appears personally.

Larry D. Courtney states that he has been advised of his procedural rights under the Pharmacy Practice Act and Administrative Procedure Act, wherein counsel for the Board advised Larry D. Courtney of his rights to a formal hearing wherein he had a right to be represented by counsel, call witnesses on his behalf, cross-examine the Board's witnesses and other procedural rights. Counsel further advised Larry D. Courtney of the statutory sections of the law which were allegedly violated and the statute

giving the Board jurisdiction in this matter. Whereupon Larry D. Courtney waived his right to a Formal Hearing.

Larry D. Courtney further states that no issue of fact exists and wishes to stipulate to the following findings of fact and accepts the order of the State Board of Pharmacy, to-wit:

1. Larry D. Courtney is a licensed pharmacist in the State of Kansas, having License No. 1-08821.

2. That Larry D. Courtney is the Pharmacist in Charge at Miller Pharmacy, Registration #2-07761, located at 840 S. 55th Street, Kansas City, Kansas 66106.

3. That on or about November 13, 1996, pharmacist, Robert Dall, an employee of Miller Pharmacy filled Prescription No. 384999 which was prescribed by the practitioner for clonidine 0.1 mg. was filled in error with lorazepam 1 mg. by the pharmacist, in violation of K.S.A. 65-1637(a). Sometime after the error was made, Robert Dall advised Larry D. Courtney of said error and Druggist Mutual was notified but no incident report was prepared by Larry D. Courtney, Pharmacist in Charge, a violation of K.A.R. 68-7-12(d).

The State Board of Pharmacy for the State of Kansas pursuant to K.S.A. 65-1627(a)(8) has jurisdiction and power to revoke, suspend or place on probation and pursuant

to K.S.A. 65-1658 fine said Larry D. Courtney.

IT IS THEREFORE ORDERED that Larry D. Courtney, License No. 1-08821, be required to take and pass the Kansas Pharmacy Law Examination within 30 days of this order at the office of the Board of Pharmacy for the State of Kansas and furnish a copy of the Policy and Procedure Manual to said office within 30 days.

Dated this 5th day of April, 1997.

Karla Kneebone
Karla Kneebone
President and Presiding Officer
State Board of Pharmacy
for the State of Kansas

I, Larry D. Courtney, have hereby read the foregoing Stipulation and Order and fully understand the violations of which I am stipulating to and understand the terms of the Stipulation.

Larry D. Courtney
Larry D. Courtney

PREPARED BY:

Dana W. Killinger
Dana W. Killinger
1505 SW Harrison St.
Topeka, KS 66612-1811
(913) 232-9616
Attorney for the State
Board of Pharmacy

BEFORE THE STATE BOARD OF PHARMACY
OF THE STATE OF KANSAS

In the Matter of

LARRY D. COURTNEY,
License No. 8821,

STIPULATION OF FINDING OF FACT AND ORDER

This matter comes before the State Board of Pharmacy for the State of Kansas, this _____ day of April, 1992.

The State Board of Pharmacy appears by Hoyt Kerr, President and Presiding Officer, Dana Creitz, Vice-President; Kathleen Mahanna, Pharmacist; Barbara Renick, Pharmacist; Charlotte Brock, Pharmacist; and Margaret Young, Consumer Representative. Also appearing are Tom C. Hitchcock, Executive Secretary, and the attorney for the Board, Dana W. Killinger. Larry D. Courtney appears personally.

Larry D. Courtney states that he has been advised of his procedural rights under the Pharmacy Practice Act and Administrative Procedure Act, wherein Counsel for the Board advised Larry D. Courtney of his rights to a formal hearing wherein he had a right to be represented by counsel, call witnesses on his behalf, cross examine

the Board's witnesses and other procedural rights. Counsel further advised Larry D. Courtney of the statutory sections of the law which were allegedly violated and the statute giving the Board jurisdiction in the matter. Whereupon Larry D. Courtney waived his right to formal hearing.

Larry D. Courtney further states that no issue of fact exists and wishes to stipulate to the following findings of fact and accepts the order of the State Board of Pharmacy, to-wit:

1. That Larry D. Courtney, is a licensed pharmacist in the State of Kansas, having License No. 8821.

2. That Larry D. Courtney is the Pharmacist In Charge at McDaneld Drug located at 840 South 55th Street, Kansas City, Kansas 66106, having Registration No. 7761.

3. That as a result of an inspection of said pharmacy on or about November 21, 1991, by a Board Inspector, the following violations were discovered:

(a) Prescription #339080 written for Ortho Novum 1/50 was authorized by the physician to be refilled (one month supply) ten (10) times. Said Prescription had been refilled fifteen (15) times with one month's

supply, a violation of 21 U.S.C. 353 (b)(1)(B)(iii) and K.S.A. 65-1637(a).

(b) Prescription #345857, Prescription #345874, Prescription #345976 and Prescription #345874 all for controlled substances, had no red "C" in the lower right corner of the prescription, a violation of 21 C.F.R. 1304.04(h)(2).

(c) Prescription #335554, Prescription #335553, Prescription #338415, Prescription #333296, Prescription #334341, Prescription #332363, Prescription #334591, Prescription #338258, Prescription #338036, Prescription #337904, Prescription #340105, Prescription #340104, Prescription $340103, Prescription #340318, Prescription #335837 and Prescription #337422, all were more than one year old and had been refilled beyond the one year limitation without obtaining a physicians authorization, a violation of K.S.A. 65-1637(e).

(d) Prescription #343874, a controlled substance had no physicians DEA number or physicians address, a violation of 21 C.F.R. 1306.05(a) and K.A.R. 68-20-18(c)(1).

4. That as a result of an inspection of said pharmacy on or about February 13, 1992, by a Board Inspector, the

following violations were discovered:

(a) Prescription #347496, Prescription #347461, Prescription #347403, Prescription #347377, Prescription #347278 and Prescription #347200 all for controlled substances had incomplete or no patient address, a violation of 21 C.F.R. 1306.05(a), and K.A.R. 68-20-18(c)(1).

(b) Prescription #347461, Prescription #347414, Prescription #347403, Prescription #347278 and Prescription #346890 all for controlled substances and had incomplete or no physicians address, a violation of 21 C.F.R. 1306.05(a) and K.A.R. 68-20-18(c)(1).

(c) Prescription #347461, Prescription #347403 and Prescription #347278 all for controlled substances had no physicians DEA number, a violation of 21 C.F.R. 1306.05(a) and K.A.R. 68-20-18(c)(1).

(d) Prescription #347403, Prescription #347377, Prescription #347308, Prescription #347278, Prescription #347069 and Prescription #346976, all for controlled substances had no date, a violation of 21 C.F.R. 1306.05(a) and K.A.R. 68-20-18(c)(1).

(e) Prescription #347496, Prescription #347432,

Prescription #347411, Prescription #347403, Prescription #347381, Prescription #347377, Prescription #347294, Prescription #347243, Prescription #347213, Prescription #347200, Prescription #347089, Prescription #347069, Prescription #347064, Prescription #346947, Prescription #346830 and Prescription #346829, all for controlled substances had no red "C" in the lower right corner of the prescription, a violation of 21 C.F.R. 1304.04(h)(2).

5. That Larry D. Courtney has failed to comply with the statutory and regulatory requirements imposed by the State upon pharmacists licensed by the State.

6. That the State Board of Pharmacy of the State of Kansas pursuant to K.S.A. 65-1627 (5), (6) & (8) has jurisdiction and power to revoke, suspend or place on probation said Larry D. Courtney.

IT IS THEREFORE ORDERED that Larry D. Courtney, License No. 8821 be

(sanctions, if any, to be imposed by Board)

DATED: This _____ day of _____, 1992.

_____
Hoyt Kerr, President
Kansas State Board of Pharmacy

I, Larry D. Courtney, have hereby read the foregoing Stipulations and Order and fully understand the violations to which I am stipulating to and understand the terms of the Stipulation.

_____
Larry D. Courtney

PREPARED BY:

_____
Dana W. Killinger, Attorney
Kansas State Board of Pharmacy

APPROVED:

_____
Tom C. Hitchcock, Executive
Secretary, Kansas State Board
of Pharmacy

KANSAS INSPECTION AND RATING OF PHARMACIES

Pharmacy Name McDonald Drug Reg No. 7761 Renewal 750
Street 840 S. 55 City Kansas City County Wyandotte
Pharmacist-in-Charge Larry Courtney Lic. No. 8821 - 2618
Other Pharmacists DEA No. AM 2475956
(for additional pharmacists—see attached List)

PHARMACY PRACTICE & RECORDS	
OTC Sales (Schedule V)	77
Exempt Sales 11-14-91	
Prescription Files	✓
Prescriptions properly written	✓
Name of person telephoning prescription	✓
Labeling of prescription complete	
Controlled Substances	✓
Separate file for Schedule II prescriptions	✓
✱ Rx stamped with red letter "C"	✓
Refills properly recorded	✓
✓ Patient address on prescription	✓
Doctor name, address & DEA number on Rx	✓
Purchase Records	
Order blanks properly marked	✓
Invoices for C-III, IV, V available	✓
Inventory date 5-1-91	✓
Security & Storage	
Computer Systems	NA
Label & Rx containers	
Daily print-out	
Monthly print-out	
Pharmacy Practice	
Number of supportive personnel on duty	1
Tablet & capsule counter properly used	✓
Safety Closure Containers	✓
Auxilary Labels	✓
Consumer counseling	—
(A) (B) (C)	
LIBRARY	1985
USP-NF	1991
USP-DI	✓
Medical Dictionary	✓
Policy & Procedure Manual	
(Last update original)	
One text in each of the following:	
Toxicology	✓
Pharmacology	✓
Drug Interactions	✓
KANSAS LAWS (Current)	1991
Kansas Pharmacy Act	
Controlled Substances Act	
OPTIONS:	
New Product Information	✓
Facts & Comparisons	✓

OTHER MISCELLANEOUS	
Rx Department Condition	
Adequate stock—neat & clean	✓
Pharmaceuticals & biologicals IN DATE	✓
Adequate working area	✓
Uncluttered Rx counter	✓
Doors clean & uncluttered	✓
Rest room facilities available	✓
Pharmacist neatly attired	✓
Smoking restricted in Rx Dept.	✓
Display of Certificates	
Pharmacy registration & renewal	✓
Pharmacist registration & renewal	✓
Name of pharmacist on duty	✓
Equipment	
Typewriter or computer equipment	✓
Numbering machine	✓
Red Letter "C" stamp	✓
Prescription files	✓
Prescription counter with storage	✓
Sink with running hot & cold water with proper sewage disposal	✓
Bottles & ointment jars	✓
Refrigeration	✓

RECEIVED
NOV 07 1991
KANSAS STATE BOARD OF PHARMACY

✱ Rx 345857 - not stamped with Red C
Rx 345874 (A) (B) (C)
✱ Rx 345976 - Rx not stamped with Red C (Xanax)

Any pharmacy receiving the rating of (C) for two or more inspections in succession may be called before the Board of Pharmacy to show cause why the registration should not be revoked or refused.

Date of Inspection 11-21-91

Date of Last Inspection 9-10-90

RATING X

REMARKS: Rx's refilled on 11-20-91 that were more than 1 year old. Numbers 335554 - 335553 338415 - 333296 - 334341 332363 - ~~338291~~ - ~~338289~~
Refilled on 11-21-91 - 334591 - 338258
Refilled on 11-19-91 338036 - 337904
340105 - 340104 - 340103
340318 - 335837 - 337422
#339080. Above 17 Rx's refilled on 11-19-91, 11-20-91 and 11-21-91 were more than one year old and not authorized.

✱ Rx 345962 - No patient address

✱ Rx 339080 (A) (B) (C) Ortho Novum 1/50 written 6-11-90 for 10 months Has been refilled 15 times

Pharmacist Signature Larry D. Courtney, RPh

Inspector Signature James R. Kinderknecht

✱ Rx 345874 Lortab 7.5mg filled 10-30-91 No DEA #) No red C & no address

Inspector's [redacted] Report

[redacted] 2-14-92

RECEIVED

FEB 14 1992

KANSAS STATE BOARD OF PHARMACY

To: Tom Hitchcock
Executive Secretary
Kansas State Board of Pharmacy

I inspected McDonald Pharmacy on 2-13-92 for compliance of your letter sent to Larry Courtney, R.Ph. (PIC) - McDonald Pharmacy on Dec. 6, 1991. I reviewed prescriptions on file from Jan. 1, 1992 to Feb. 10, 1992. McDonald Pharmacy is non-computerized. Problem areas noted in your letter:

1) I didn't find any prescriptions being refilled past one year from the origination date.

2) I didn't find any prescriptions being refilled that weren't in conformity with refill instructions marked on prescription However, I didn't verify with various doctors as to authenticity of refill authorizations on rewritten prescriptions of both controlled and non-controlled prescriptions

3) McDonald Pharmacy has two files.
   (a) C II file
   (b) C III, C IV, C V and non-controlled

I found (15) Rx's with No Red C in file (b)

Inspector's [redacted] Report

[redacted] 2-14-92

4) 21 CFR 1306.05 (a)
Requirements on controlled Rx's

I noted the following:

6 - Prescriptions with incomplete patient address.
5 - " " " physician "
3 - " " missing physician DEA #
6 - " with No date on Rx.
16 - " " No red C

James E. Kinderknecht
Inspector

twice
C 2-1-92
T +
2-10-92

NAME: McDaneld Pharmacy PERMIT NO.:

ADDRESS: 840 S. 55th Kansas City DATE: 2-13-92

PRESCRIPTION NUMBER	INCOMPLETE PATIENT ADDRESS	INCOMPLETE PHYSICIAN ADDRESS	INCOMPLETE PRODUCT DESCRIPTION	MISSING PHYSICIAN DEA #	MISSING PHYSICIAN SIGNATURE	C-II Rx MISSING	AMPHETAMINE DIAGNOSIS MISSING	MISSING DATE	EXCESSIVE
Darvocet-N 347496	✓	also No Red C						Filled 2-10-92	
romethazCodeine 347461	✓	✓		✓				Filled 2-7-92	
Vicodin 347432		No Red C						Filled 2-5-92	
Xanax 347414		✓						Filled 2-5-92	
Tylenol #3 347411		No Red C						Filled 2-4-92	
Xanax 347403	✓	✓	No Red C	✓	No date on Rx			?	
Fiorinal #3 347381		No Red C						Filled 2-3-92	
Vicodines 347377	✓	No Red C			No date on Rx			?	
Dalmane 30mg 347308					No date on Rx			?	
Meprobamate 347278	✓	✓		✓	No date on Rx			Filled 2-[illegible]-92	
Restoril 347294		No Red C						Filled 1-27-92	
Vicodin 347243		No Red C						Filled 1-27-92	
Klonopin 347213		No Red C						Filled 1-24-92	
Darvocet-N 347200	✓	No Red C						Filled 1-24-92	
Equagesic 347089		No Red C						Filled 12-31-91	
hydrocodone 347067		No Red C			No date on Rx			?	
Darvocet N 347064		No Red C						Filled 1-16-92	
Xanax 346976					No date on Rx			?	
Halcion 346947		No Red C						WRITTEN 12/23/91 filled ?	
Tylenol #3 346890		✓						Filled 1-8-92	
Halcion 346830		No Red C						Filled 1-6-92	
Tylenol #3 346829		No Red C						Filled 1-6-92	
	6	Dr. address 5	No red C 16	3					

RECEIVED
FEB 14 1992
KANSAS STATE BOARD OF PHARMACY

2-13-92
James R. Underwood
Inspector

Larry D. Carter RPh

of Appeals, which had reversed without considering merits, to review District Court's decision that regulation was beyond power of Commissioner. Id.

Regulations of Commissioner of Food and Drugs requiring labels, advertisements, and other printed matter relating to prescription drugs to designate the established name of the particular drug involved every time its trade name is used anywhere in such material was "final agency action" within Administrative Procedure Act, sections 551 et seq. and 701 et seq. of Title 5. Id.

Determination by Secretary that "device" within this chapter has been misbranded and may therefore not be imported is not subject to judicial alteration unless arbitrary and capricious. Church of Scientology of Cal. v. Richardson, C.A.Cal.1971, 437 F.2d 211.

Orders of federal district court granting claimants' motions for summary judgment but granting United States leave to amend libels for condemnation of allegedly misbranded drugs were not final orders and were not appealable. U. S. v. Various Articles of Drugs Consisting of Unknown Quantities of Prescription Drugs, C.A.N.J.1963, 314 F.2d 850.

Order granting claimant's motion for summary judgment on issue of alleged misbranding of drugs retained in original sample packages but denying summary judgment as to drugs which had been repackaged, which had been mislabeled as to drug contents, or as to which expiration date had passed, and denying United States injunctive relief was final order and appealable. Id.

On appeal from conviction for shipping willfully misbranded articles in interstate commerce, court of appeals would not ignore defendant's failure to request instruction for verdict and to claim that there was not sufficient evidence to warrant verdict and review 178 pages of jury transcript to determine sufficiency, where Government was merely fined $50 for each defendant was merely fined $50 for each violation of former section 30 of this title creating misdemeanors. Alberty v. U. S., C.C.A.Cal.1967, 91 F.2d 161.

On appeal from conviction for shipping willfully misbranded capsules and other articles in interstate commerce, defendant could not object to question put to her by prosecutor concerning treatment of many babies as result of taking food made by defendant and not involved in case, even though question was improper, where defendant apparently was satisfied with negative answer and did not allege misconduct. Id.

§ 353. Exemptions in case of drugs and devices—Regulations for goods to be processed, labeled, or repacked elsewhere

(a) The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(b) (1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a), (i) (2) and (3), (k), and (l) of said section, and the packaging requirements of subsections (g), (h), and (p) of such section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of the filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to any drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription". A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement required in the preceding sentence.

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be in-

...eals fixed by the board and upon the ...ment to the board of all applicable fees, a ...son holding an inactive status license from ...e board shall be entitled to cancellation of ...e inactive status license and to renewal of ...nsure as a pharmacist.

(b) If the renewal fee for any pharmacist's ...ense has not been paid by August 1 of any ..., the license is hereby declared void, and ...e license shall be reinstated except upon pay...ent of any unpaid renewal fee plus a penalty ...e fixed by the board as provided in K.S.A. ...16-45 and amendments thereto and proof ...isfactory to the board of compliance with the ...ntinuing education requirements fixed by the ...rd. The penalty fee established by this sec...n immediately prior to the effective date of ...e act shall continue in effect until a different ...nalty fee is fixed by the board by rules and ...gulations as provided in K.S.A. 65-1645 and ...endments thereto. Payment of any unpaid ...newal fee plus a penalty fee and the sub...ssion of proof satisfactory to the board of ...mpliance with the continuing education re...irements fixed by the board shall entitle the ...ense to be reinstated. The nonpayment of ...newal fees by a previously licensed phar...ist for a period exceeding three years shall ...t deprive the previously licensed pharmacist ...e right to reinstate the license upon the ...yment of any unpaid fees and penalties and ...on compliance with the continuing education ...irements fixed by the board, except that ...e board may require such previously licensed ...rmacist to take and pass an examination ...roved by the board for reinstatement as a ...rmacist and to pay any applicable exami...tion fee.

History: L. 1953, ch. 290, § 18; L. 1962, ch. 37, § 2; L. 1967, ch. 342, § 2; L. 1974, ch. 252, § 2; L. 1975, ch. 319, § 18; L. 1982, ch. 263, § 2; L. 1984, ch. 313, § 107; L. 1986, ch. 231, § 21; L. 1987, ch. 236, § 3; L. 1988, ch. 356, § 198; L. 1990, ch. 224, § 1; L. 1991, ch. 187, § 3; July 1.

65-1633. Change of address of pharmacist. Every pharmacist who changes residential address shall within 30 days thereof by letter notify the executive secretary of the board of such change, and upon receipt of the notice the executive secretary shall make the proper alterations in the record kept for that purpose.

History: L. 1953, ch. 290, § 19; L. 1962, ch. 37, § 3; L. 1975, ch. 319, § 19; L. 1982, ch. 263, § 3; L. 1986, ch. 231, § 22; June 1.

65-1634. Responsibility for quality of drugs sold; adulteration or mislabeling unlawful. Every person holding a license, registration or permit under the pharmacy act of the state of Kansas who engages in the sale of drugs, medicines, chemicals and poisons shall be responsible for the quality of all such drugs, medicines, chemicals and poisons which such person may sell, compound or put up except when sold in the original and unbroken pack, package, box or other container of the manufacturer. If any person intentionally adulterates or mislabels any drugs, medicines, chemicals or poisons, or causes the same to be adulterated or mislabeled or exposed for sale knowing the same to be adulterated or mislabeled, such person shall be guilty of a class A misdemeanor.

History: L. 1953, ch. 290, § 20; L. 1975, ch. 319, § 20; L. 1986, ch. 231, § 23; June 1.

65-1636. Sale of drugs limited to pharmacies. Except as otherwise provided in this act, the sale and distribution of drugs shall be limited to pharmacies operating under registrations as required by this act, and the actual sale or distribution of drugs shall be made by a pharmacist or other persons acting under the immediate personal direction and supervision of the pharmacist.

History: L. 1953, ch. 290, § 22; L. 1975, ch. 319, § 22; L. 1986, ch. 231, § 24; June 1.

65-1637. Pharmacist required to be in charge of pharmacy; compounding and filling of prescriptions; brand exchange; refilling prescriptions. In every store, shop or other place defined in this act as a "pharmacy" there shall be a pharmacist in charge and the compounding and putting up of prescriptions shall be limited to pharmacists only. Except as otherwise provided by the pharmacy act of this state, when a pharmacist is not in attendance at a pharmacy, the premises shall be enclosed and secured. Prescription orders may be written, oral or telephonic. Blank forms for written prescription orders may have two signature lines. The first signature line shall state: "Dispense as written _____." The second signature line shall state: "Brand exchange permissible _____." Prescriptions shall only be filled or refilled in accordance with the following requirements:

tion granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(f) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Administration of the name, address, and registration number of the establishment maintaining such records.

(g) Notice required by paragraphs (e) and (f) of this section shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 18731, Sept. 21, 1971; 37 FR 15920, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 50 FR 40523, Oct. 4, 1985; 51 FR 5320, Feb. 13, 1986; 51 FR 26154, July 21, 1986]

§ 1304.04 Maintenance of records and inventories.

(a) Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not excuted order forms subject to § 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge.

All notifications must include:

(1) The nature of the records to be kept centrally.

(2) The exact location where the records will be kept.

(3) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(4) Whether central records will be maintained in a manual, or computer readable form.

(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other

procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.

(e) All central recordkeeping permits previously issued by the Administration will expire on September 30, 1980. Registrants who desire to continue maintaining central records will make notification to the local Special Agent in Charge as provided in paragraph (a) of this section.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained se rately from all other records of pharmacy, and prescriptions for s substances shall be maintained i separate prescription file; and

(2) Inventories and records of c trolled substances listed in Schedu III, IV, and V shall be maintai either separately from all ot records of the pharmacy or in s form that the information require readily retrievable from ordinary b ness records of the pharmacy, and scriptions for such substances shall maintained either in separate presc tion file for controlled substar listed in Schedules III, IV, and V o or in such form that they are rea retrievable from the other presc tion records of the pharmacy. scriptions will be deemed readily trievable if, at the time they are tially filed, the face of the prescrip is stamped in red ink in the lo right corner with the letter "C" less than 1-inch high and filed eit in the prescription file for contro substances listed in Schedules I an or in the usual consecutively n bered prescription file for non- trolled substances.

(21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended FR 13386, July 21, 1971. Redesignated FR 26609, Sept. 24, 1973, and amended FR 37985, Oct. 25, 1974; 45 FR 44266, Ju 1980; 47 FR 41735, Sept. 22, 1982; 51 5320, Feb. 13, 1986]

INVENTORY REQUIREMENTS

§ 1304.11 General requirements for in tories.

(a) Each inventory shall contai complete and accurate record of controlled substances on hand on date the inventory is taken. Contro substances shall be deemed to be hand" if they are in the possessio or under the control of the registr including substances returned b customer, substances ordered by a tomer but not yet invoiced, substa stored in a warehouse on behalf of registrant, and substances in the session of employees of the regist and intended for distribution as plimentary samples.

[36 FR 7796, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1305.16 Special procedure for filling certain order forms.

(a) The purchaser of carfentanil etorphine hydrochloride or diprenorphine shall submit copy 1 and 2 of the order form to the supplier and retain copy 3 in his own files.

(b) The supplier, if he determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the Administrator to handle these substances shall fill the order in accordance with the procedures set forth in § 1305.09 except that:

(1) Order forms for carfentanil etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities and (2) the substances shall only be shipped to the purchaser at the location printed by the Administration upon the order form under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.

[39 FR 17839, May 21, 1974, as amended at 54 FR 33674, Aug. 16, 1989]

PART 1306—PRESCRIPTIONS

GENERAL INFORMATION

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III AND IV

CONTROLLED SUBSTANCES LISTED IN SCHEDULE V

AUTHORITY: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973

GENERAL INFORMATION

§ 1306.01 Scope of Part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 1306.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801).

(b) The term *individual practitioner* means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(c) The term *institutional practitioner* means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(d) The term *pharmacist* means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., a pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

(e) A *Long Term Care Facility* (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

(f) The term *prescription* means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate used. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

(g) The terms *register* and *registered* refer to registration required and permitted by section 303 of the Act (21 U.S.C. 823).

(h) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or § 1301.02 of this chapter.

(21 U.S.C. 801, *et seq.*)

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further amended at 45 FR 54330, July 15, 1980]

§ 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) either registered or exempted from registration pursuant to §§ 1301.24(c) and 1301.25 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment" as defined in Section 102 of the Act (21 U.S.C. 802).

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974]

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for

controlled substances act (21 USC 828), and in part 1305 of title 21 of the code of federal regulations in effect on April 1, 1985. All transfers of schedule I and II controlled substances shall require the use of a drug enforcement agency 222 form issued by the United States attorney general. (Authorized by and implementing K.S.A. 65-4115, 65-4122, effective, E-72-24, August 25, 1972; effective January 1, 1973; amended May 1, 1987.)

68-20-18. Information concerning prescriptions. (a) *Persons entitled to issue prescriptions.* A prescription for a controlled substance may be issued only by a practitioner who is:

(1) Legally authorized to prescribe controlled substances in Kansas or any other competent jurisdiction; and

(2) either registered or exempted from registration under K.S.A. 65-4116 (d).

(b) *Purpose of issue of prescription.*

(1) To be effective, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. The person filling an unlawful prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(2) A prescription may not be issued in order for a practitioner to obtain controlled substances for supplying himself or any other practitioner for the purpose of general dispensing to patients.

(3) A prescription shall not be issued for the dispensing of narcotic drugs listed, in any schedule, to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, except in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

(c) *Manner of issuance of prescriptions.*

(1) All written prescriptions for controlled substances shall be dated and manually signed on the day issued, shall bear the full name, address, registration number of the practitioner, name and address of the patient and shall be written with ink, indelible pencil or typewriter. A practitioner shall manually sign a prescription in the same manner as he would sign a check or legal document. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible if the prescription does not conform in all essential respects to the state and federal law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription which is not prepared in the form prescribed by these regulations.

(2) An intern, resident, foreign physician, or foreign medical graduate exempted from registration under K.S.A. 65-4116(d) shall include on all prescriptions issued the registration number of the hospital or other institution and the special internal code number assigned to the intern, resident, foreign physician, or foreign medical graduate by the hospital or other institution as provided in paragraphs 68-20-10(D) (2)(c) and (f) of these regulations. This requirement is in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, foreign physician or foreign medical graduate stamped or printed on it, as well as the signature of the physician.

(3) An official exempted from registration under paragraph 68-20-10(E) of these regulations shall include on all prescriptions issued, his branch of service or agency and his service identification number. This requirement is in lieu of the registration number of the practitioner otherwise required by this section. The service identification number for a public health service employee is his social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

(d) *Persons entitled to fill prescriptions.*

(1) A prescription for controlled substances may only be filled by:

(A) a pharmacist acting in the usual course of his professional practice in a registered pharmacy, hospital drug room, or other registered place of

91 Supp

...aceutical care to a degree which constitutes ...oss negligence, as determined by the board;

(2) repeated instances involving failure to ...ithere to the applicable standard of pharma...eutical care to a degree which constitutes or...linary negligence, as determined by the board; or

(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.

(llb) "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a drug the label of which is required to bear substantially the statement "Caution: Federal law prohibits dispensing without prescription"; or (3) a drug intended for human use by hypodermic injection.

(cc) "Secretary" means the executive secretary of the board.

(dd) "Unprofessional conduct" means:

(1) Fraud in securing a registration or permit;

(2) intentional adulteration or mislabeling of any drug, medicine, chemical or poison;

(3) causing any drug, medicine, chemical or poison to be adulterated or mislabeled, knowing the same to be adulterated or mislabeled;

(4) intentionally falsifying or altering records or prescriptions;

(5) unlawful possession of drugs and unlawful diversion of drugs to others;

(6) willful betrayal of confidential information under K.S.A. 1989 Supp. 65-1654 and amendments thereto;

(7) conduct likely to deceive, defraud or harm the public;

(8) making a false or misleading statement regarding the licensee's professional practice or the efficacy or value of a drug;

(9) commission of any act of sexual abuse, misconduct or exploitation related to the licensee's professional practice; or

(10) performing unnecessary tests, examinations or services which have no legitimate pharmaceutical purpose.

History: L. 1953, ch. 290, § 3; L. 1975, ch. 319, § 2; L. 1977, ch. 217, § 1; L. 1978, ch. 242, § 1; L. 1978, ch. 243, § 1; L. 1979, ch. 193, § 1; L. 1982, ch. 182, § 138; L. 1986, ch. 235, § 1; L. 1986, ch. 231, § 9; L. 1986, ch. 236, § 1; L. 1987, ch. 235, § 5; L. 1987, ch. 236, § 1; L. 1988, ch. 297, § 2; L. 1989, ch. 193, § 1; L. 1989, ch. 192, § 2; L. 1989, ch. 192, § 3; L. 1991, ch. 272, § 10; May 2.

Attorney General's Opinions:

Registration of out-of-state pharmacists doing business in Kansas. 84-71.

Physicians' assistants; advanced registered nurse practitioners; persons authorized to issue prescription orders. 86-125.

Kansas retailers' sales tax; exempt sales; nonprescription drugs. 88-76.

Pharmacists; advance nurse practitioners; physicians' assistants; prescription orders. 89-116.

Pharmacists required to be in charge of pharmacy; brand exchange. 90-50.

Administration of over the counter medications by nurses to school students. 90-119.

65-1627. Grounds for revocation, suspension, placement in probationary status or denial of license for pharmacist, permit for retail dealer or registration for pharmacy or manufacturer or distributor; procedure. (a) The board may revoke, suspend, place in a probationary status or deny a renewal of any license of any pharmacist upon a finding that:

(1) The license was obtained by fraudulent means;

(2) the licensee has been convicted of felony and the board determines, after investigation, that such person has not been sufficiently rehabilitated to warrant the public trust;

(3) the licensee is found by the board to be guilty of unprofessional conduct or professional incompetency;

(4) the licensee is addicted to the liquor or drug habit to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(5) the licensee has violated a provision of the federal or state food, drug and cosmetic act, the uniform controlled substances act of the state of Kansas, or any rule and regulation adopted under any such act;

(6) the licensee is found by the board to have filled a prescription not in strict accordance with the directions of the practitioner;

(7) the licensee is found to be mentally or physically incapacitated to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(8) the licensee has violated any of the provisions of the pharmacy act of the state of Kansas or any rule and regulation adopted by the board pursuant to the provisions of such pharmacy act;