Approved 4-25-91
Date

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Carol H. Sader at
Chairperson

5:00 ~~a.m.~~/p.m. on April 1, 19__ in room 254-E of the Capitol.

All members were present except:

Representative Bishop, excused

Committee staff present:

Emalene Correll, Research
Bill Wolff, Research
Norman Furse, Revisor
Sue Hill, Committee Secretary

Conferees appearing before the committee:

Pat Johnson, Executive Administrator, Kansas Board of Nursing
Terri Roberts, Executive Director of Kansas State Nurses' Association
Bob McDaneld, Administrator, State Board of Emergency Medical Services
Darlene Whitlock, Registered Nurse, Emergency Nurses Association (Written testimony only)
Tom Pollan, Director of Sedgwick County, Emergency Medical Services
Tuck Duncan, Medevac Medical Services, Inc.
Tad McFarlane, Director of Douglas County Emergency Medical Services and Emergency Preparedness.
Charles Borchers, Director of Scientific/Legal Affairs, B.F.Ascher Co.
Tom Hitchcock, Kansas State Board of Pharmacy
Dr. Patrick Hays, Senior Laboratory Scientist, Department of Health and Environment

Chairperson Sader called meeting to order at 5:10 p.m. She drew attention to three sets of minutes and requested members to read them carefully.

Rep. Cribbs moved to approve minutes for March 22, 1991, March 25, 1991 at 1:30 p.m. and March 25, 1991 at 5:00 p.m. meeting all approved as presented. Motion seconded by Rep. Amos. No discussion. Vote taken. Motion carried.

Chair drew attention to **SB 271** and requested a staff briefing.

Ms. Correll gave a comprehensive explanation of **SB 271** highlighting policy issues, i.e.,to do away with the level of attendant certification currently called "crash injury management;" to respond, throughout the bill, at every attendant level to the Attorney General's Opinion that these people are not authorized to function in a non emergency situation; to bring instructor-coordinator under the law relating to Certification from the Board. Ms. Correll answered questions.

HEARINGS BEGAN ON SB 271.

Pat Johnson, Executive Administrator, Kansas Board of Nursing, offered hand-out (Attachment No. 1), directing attention to a protocol check list for Mobile intensive care technicians (MICTs), and Attorney General's Opinion # 90-134. She detailed rationale for their request for the Attorney General's opinion. Ms. Johnson noted before **SB 271** was amended by the Senate, the Board of Nursing had concerns in regard to language allowing Emergency Medical Services (EMS) technicians to practice under protocols; education of EMS technicians. After amendments were approved by the Senate, the Board of Nursing supports those amendments. She detailed each change, then noted, as **SB 271** now reads, it provides an update to meet present needs of the EMS programs without expanding into nursing. She answered questions.

HEARINGS CONTINUED ON SB 271.

Terri Roberts, Executive Director, Kansas State Nurses' Asociation, offered hand-out (Attachment No. 2). She noted the State Board of Nursing, the Kansas State Nurses' Association and Kansas Emergency Medical Services Board worked very diligently together with the Senate Committee to bring about changes that appear currently in **SB 271.** She noted this practice act is only about 2 years old. They were all surprised that there had been no exemptions for students when the act was written. She answered questions.

Bob McDaneld, Administrator, State Board of Emergency Services, offered hand-out, (Attachment No.3). He encouraged members, as they examine **SB 271,** to remember an instructor-coordinator is a qualified instructor, but not all qualified instructors are instructor-coordinators. Simply, this means because someone is a qualified instructor does not mean he/she needs to meet the requirements for being an instructor-coordinator. It clearly was not the intent of the Board to require registered nurses or physicians to become instructor-coordinators. He answered numerous questions.

Darlene Whitlock, Emergency Nurses Association, offered written testimony (Attachment No. 4). Ms. Whitlock attended meeting held at 2:20, but was unable to return for 5:00 p.m. meeting.

Tom Pollan, Director, Sedgwick County, Emergency Medical Services, gave hand-out (Attachment No. 5. He noted support for **SB 271**, but pointed out issues that still neeed to be addressed, i.e., an amendment to allow current training programs for Emergency Medical Technicians - Intermediates (EMT-I) and Mobile Intensive Care Technicians (MICT) to continue their required field internships; the establishment of a certification for "instructor-coordinators"; to allow first responders and attendants to provide their professional services within a medical facility. He stated the urgent importance of passage of **SB 271** to allow for completion of training programs. He stated there are 4 programs waiting to be completed. Clarification on this issue is vital. He answered numerous questions.

Tuck Duncan, Medevac, written testimony only (Attachment No.6). Mr. Duncan attending meeting held at 2:20 p.m., but was unable to return for 5:00 meeting.

Ted McFarlane, Director of Douglas County Emergency Medical Service and Emergency Preparedness, offered hand-out (Attachment No.7.) as written testimony only. Mr. McFarland attended meeting held at 2:20 but was unable to return for 5:00 p.m. meeting.

HEARINGS CLOSED ON SB 271.

At this point, Chair appointed a sub-committee to deal with issues in the bill. Rep. Neufeld as Chair, along with Rep. Hackler, and Rep. Amos. Chair noted because of time constraints, it would be important for this Sub-Committee and Staff and the agencies involved to try and work out these concerns prior to meeting tomorrow at 1:30 p.m.

Chair requested a staff briefing on **HB 2608.** Mr. Furse gave a detailed explanation of the bill.

HEARINGS BEGAN ON HB 2608.

Written testimony only from Charles Borchers, Director of Scientific and Legal Affairs, B. F. Ascher & Company, (Attachment No.8). Mr. Borcher could not attend 5:00 p.m. meeting in person.

HEARINGS CONTINUED ON HB 2608.

Tom Hitchcock, Executive Secretary of Kansas Board of Pharmacy, offered hand-out (Attachment No. 9). He noted a mandate by the Federal Food, Drug and Cosmetic Act (FDA) under the Prescription Drug Marketing Act (PDMA) needs to be met. The Attorney General denoted the Board of Pharmacy does not have statutory authority to promulgate the regulations, which has brought about the request for **HB 2608.** The purpose of the PDMA is to curtail the diversion and illicit distribution of legal drugs. He urged passage of **HB 2608.** Mr. Hitchcock noted drug wholesalers need this legislation. If these wholesalers are not registered, the fine is 6 figures and the penalty is 10 years in jail. Mr. Hitchcock realizes it is very late in the Session, but noted the importance of this legislation.

HEARINGS CLOSED ON HB 2608.

Chair drew attention to **SB 68**, and gave background information on the bill.

Rep. Amos made a motion to pass **SB 68** favorably and have it placed on the consent calendar. Rep. Cribbs seconded the motion. No discussion. Vote taken. Motion carried.

Chair drew attention to **SB 235.**

After a short discussion, Rep. Neufeld made a motion to report **SB 235** unfavorably. Rep. Carmody seconded the motion. Discussion ensued. Vote taken. Motion carried.

Chair thanked all members for their cooperation and diligence at this late hour.

Chair called attention to hand-out (Attachment No. 10), a memorandum from Department of Health/Environment regarding questions asked on **SB 254.**

(Attachment No. 11), is printed testimony from Patrick L. Hays, Department of Health/Environment on **SB 254.**

Chair noted committee work is well on track, and the agenda for next meeting will be discussion on **HCR 5008, SB 271, HB 2608.**

Chair adjourned meeting at 7:00 p.m.

GUEST REGISTER

HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE

5:00 p.m.

DATE 4-1-91

NAME	ORGANIZATION	ADDRESS
Bob McDaniel	Board of EMS	Topeka
Pat Johnson	Board of Nursing	Topeka
Tom Pollan	Sedgwick & Cons Kansas Kansas Wichita	
Terri Roberts	KSNA	Topeka

Kansas State Board of Nursing

Landon State Office Building
900 S.W. Jackson, Rm. 551
Topeka, Kansas 66612-1256
913-296-4929

Patsy L. Johnson, R.N., M.N.
Executive Administrator
913-296-3068

TO: The Honorable Representative Carol Sader, Chairperson and Members of the Public Health & Welfare Committee

FROM: Patsy L. Johnson, R.N., M.N.
Executive Administrator

DATE: March 28, 1991

RE: SB 271

Thank you for allowing me to testify on SB 271 on behalf of the Board of Nursing.

Since much of the emergency medical practice consists of nursing procedures, the Board of Nursing has carefully reviewed SB 271. As confirmed by a 1990 Attorney General's opinion, mobile intensive care technicians (MICT 's) are to perform the functions as outlined in the Emergency Medical Service (EMS) statutes under emergency conditions only. (see attached opinion) The Board of Nursing requested the Attorney General's opinion because of various reports about MICT practice in emergency rooms as well as elsewhere in medical facilities. I have attached an example of a MICT emergency room skill checklist. At least 65% of the major headings would be classified as nursing practice. For the MICT, it is unlicensed nursing practice and unlawful under the Nurse Practice Act. Instructions on the checklist allow the practice to be delegated from a registered nurse to the MICT; however, such delegation by nurses is not allowed under present law. The Board of Nursing is not opposed to expanding delegation of nursing practice, and in fact, asked for introduction of HB 2530 this year.

Before SB 271 was amended, we had some concerns over the language allowing EMS technicians to practice under protocols. With the addition of the definition of "non-emergency transportation" and expansion of language on protocols (pg. 4, lines 10-19), we feel there will be no misunderstanding about practice. With this specific language, the EMS statute is not left open ended which

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5:00 pm.
attm # 1.

Janette Pucci, R.N., M.S.N.
Education Specialist
296-3782

Belva J. Chang, R.N., M.N., J.D.
Practice Specialist
296-3783

Patricia McKillip, R.N., M.N.
Education Specialist
296-3782

could allow extended practice into medical care facilities. EMS technicians may practice under medical protocols in the field for emergencies and non-emergency transportation.

Another concern involved education. The Board of Nursing supports educational activities that will allow the EMS technicians to be well prepared in their functions. Expanding on what can be taught to the mobile intensive care technician in a controlled setting by deleting (b) 65-6119, (pg. 3, line 22), serves to expand the educational opportunities. However, the Board of Nursing wants assurances that when clinical instruction is occurring in a medical facility that either a physician or a licensed professional nurse is the instructor. Based on K.A.R. 28-34-7 which delineates nursing service in hospitals, ancillary personnel performing patient care services shall be under the supervision of a registered nurse. With expanding the definition of "qualified instructor" in a medical facility, (pg. 3, line 10), we feel our concern has been addressed.

In summary, the Board of Nursing supports Emergency Medical Services in providing safe emergency and supportive care during ambulance transportation. The Board believes that EMS technicians can only work in a nursing aide or technician role in medical care facilities. Expanded delegation privileges by nurses to non-licensed personnel would allow the utilization of EMS technicians to perform at a higher level as employees in medical care facilities. SB 271 provides an update to meet present needs of EMS programs without expanding into nursing. The Board of Nursing support passage of SB 271 as has been amended.

Thank you for allowing me to testify to SB 271. I will be glad to answer any questions.

PLJ:bph

P Hall
4-1-91
5:00 pm.
attm 1-2

STATE OF KANSAS

OFFICE OF THE ATTORNEY GENERAL

2ND FLOOR, KANSAS JUDICIAL CENTER, TOPEKA 66612-1597

ROBERT T. STEPHAN
ATTORNEY GENERAL

December 13, 1990

MAIN PHONE: (913) 296-2215
CONSUMER PROTECTION: 296-3751
TELECOPIER: 296-6296

ATTORNEY GENERAL OPINION NO. 90- 134

Pat Johnson
Executive Administrator
Kansas State Board of Nursing
Landon State Office Bldg., Room 551
Topeka, Kansas 66612-1256

Re: Public Health -- Emergency Medical Services -- Mobile Intensive Care Technicians; Authorized Activities

Synopsis: Mobile intensive care technicians (MICTs) are authorized by statute to perform certain tasks during emergencies when in contact with a physician or nurse. If prior voice contact with a physician or nurse is not practicable under the circumstances, an MICT may act pursuant to protocols. It was not intended that these tasks be performed by MICTs in non-emergency settings. However, if a physician delegates performance of professional services to an MICT, the MICT may function pursuant to the physician's order. Cited herein: K.S.A. 65-2872; K.S.A. 65-4306 (Ensley 1980); K.S.A. 1989 Supp. 65-6112, 65-6119.

* * *

Dear Ms. Johnson:

You request our opinion regarding the scope of practice of mobile intensive care technicians (MICTs). Specifically you ask to what extent an MICT may, in non-emergency situations, perform the activities listed in K.S.A. 1989 Supp. 65-6119(d).

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attn # 1-3

may perform the acts listed in K.S.A. 65-4306 (Ensley 1980), which was the prior version of K.S.A. 1989 Supp. 65-6119(d)). We stated,

"1. There must be 'voice contact or a telemetered electrocardiogram' monitored by a physician or authorized registered professional nurse;

"2. Direct communication must be maintained with the physician or nurse; and

"3. The physician or nurse must order the MICT to perform the act."

Following that opinion, the statute was amended by L. 1981, ch. 254, § 2, adding subsection (e) which is quoted above. The additional language relates to emergency situations making prior voice contact impracticable. Our 1981 opinion was therefore modified by the amendment.

Reference to emergencies in subsection (e) does not mean that the tasks enumerated in subsection (d) may be performed in non-emergency situations. The title of the act regulating MICTs is valid indicia of legislative intent for construing the scope of practice. See Arredondo v. Duckwall Stores, Inc., 227 Kan. 842, 846 (1980) (title of an act supplied by legislature is not part of statute, but should not be ignored). The title of the bill is, "An act concerning the regulation of emergency medical services . . . providing for the regulation of persons engaged in emergency medical service and ambulance service activities. . . ." L. 1988, ch. 261. Emergency medical services are defined in the act as services which provide "effective and coordinated delivery of such emergency care as may be required by an emergency, including . . . the performance of authorized emergency care by . . . a mobile intensive care technician." K.S.A. 1989 Supp. 65-6112(g). The term "emergency" has been construed by our courts to mean "an unforeseen combination of circumstances which calls for immediate action." Trinity Universal Ins. Co. v. Farmers Cooperative Exchange of Morland, 171 Kan. 501, 504 (1951). The legislature is presumed to have had knowledge of this construction when enacting the act regulating MICTs. See Bell v. City of Topeka, 220 Kan. 405, 417, appeal after remand, 224 Kan. 147 (1978).

We believe that under authority of their license, MICTs may perform the functions listed in K.S.A. 1989 Supp. 65-6119(d) in emergency situations only.
The legislature did not intend MICTs to practice in settings

P. Hall
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in which those tasks are foreseeable as part of a patient's plan of care.

Our opinion does not overlook situations in which a physician may delegate to an unlicensed person the performance of professional services. K.S.A. 65-2872(g). Medical doctors may use technicians for assistance in practicing the healing arts. State ex rel. v. Doolin & Shaw, 209 Kan. 244, 262 (1972). When a physician delegates such an act to a person who is also licensed as an MICT, the person acts by virtue of the healing arts act, not by virtue of the MICT licensure act. The act under which MICTs are licensed does not limit the practice of delegation by a physician.

In conclusion, it is our opinion mobile intensive care technicians are authorized by statute to perform certain tasks during emergencies when in contact with a physician or nurse. If prior voice contact with a physician or nurse is not practicable under the circumstances, an MICT may act pursuant to protocols. It was not intended that these tasks be performed by MICTs in non-emergency situations. However, if a physician delegates performance of professional services to an MICT, the MICT may function pursuant to the physician's order.

Very truly yours,

ROBERT T. STEPHAN
ATTORNEY GENERAL OF KANSAS

Mark W. Stafford
Assistant Attorney General

RTS:JLM:MWS:bas

Passed 4-1-91
Attm # 1-5

*** CIRCLED ITEMS ARE NURSING FUNCTIONS**

MICT E.R. SKILL CHECKLIST

EMPLOYEE _____

All Emergency Room MICT'S shall be knowledgeable in all areas listed in this checklist. Your supervisor will review the checklist with you at the end of your ninety day evaluation period.

The following is a skills checklist only. All patient care functions and procedures, except in a true emergency, are to be performed under the direction of a physician or registered nurse authorized by a physician.

Employee is responsible for obtaining and completing checks.
Observer is to date and initial checks.

CODE:

O - Observed
RD - Returned Demonstration
Q - Qualified
NA - Non Applicable
PR - Procedure Read

	O	RD	Q	NA	PR
1. Admission of Patient					
a. Emergency room record					
2. Animal Bites					
a. Care					
b. Notification of proper authorities					
3. Arrhythmias, recognition					
a. PAC					
b. PVC					
c. Atrial fib					
d. Vent Tachycardia					
e. Vent Fibrillation					
f. 1°, 2°, 3°, Heart Block; Cardiac Stand Still					
4. Beds, Operation of					
5. Burn Care					
a. Reverse Isolation					
b. Supplies					
c. Cleansing					
d. Fluid Resuscitation					
6. Casts					
a. Plaster					
b. Fiberglass					
c. Charge Sheets					

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attn 1-6

	O	RD	Q	NA	PR
7. Charges					
a. Emergency room Charge Sheets					
b. Profile Cards					
c. Emergency Room Record					
8. Chest Tubes					
a. Preparation/Insertion Procedure					
9.. Child Abuse Procedure					
10. Cleaning Schedule					
11. CPR					
a. Procedure for Calling Code					
b. Certification in Basic Life Support, and ACLS					
12. Communications					
a. Doctor on call					
b. Contact Physician					
c. Ambulance - Radio					
13. Death					
a. Form					
b. Mortician					
c. DOA					
14. Eye Injury					
a. Eye Tray - Slit l-					
b. Flourescent Dye					
c. Visual Acuity					
15. Catheterization					
a. Foley, straight					
16. Fractures					
a. Splinting					
b. Casting					
c. Circulation check					
d. Neuro check					
17. Gunshot Wounds - Procedure					
18. Head Injuries - Procedure					
a. Neuro Check					
b. Vital Signs (VS)					
19. Hand Injuries					
a. Range of Motion (ROM)					
b. Circulation					
c. Dressings					

	O	RD	Q	NA	PR
20. I.V. Therapy					
a. Catheter, Butterfly					
b. Heparin lock and flush					
c. Labeling					
d. Life Care Pump					
e. Subclavian (set-up only)					
21. Ipecac Protocol					
22. Isolation					
a. Spinal Tap					
b. Communicable Diseases					
c. Infected Wounds					
23. Lacerations					
a. Range of Motion (ROM)					
b. Neuro Function					
c. Circulation					
d. Cleansing					
e. Tetanus Status					
24. Medications					
a. Stock Supply					
b. Administration					
25. Mast Trousers					
a. Uses					
b. Discontinuing					
26. Monitor					
a. Strips					
b. Application of Leads					
c. Paper Reloading					
d. External pacing					
27. Myocardial Infarction					
a. Standing Orders					
28. Multiple Injuries					
a. Evaluation					
29. N-G Tube					
a. Gastric Irrigation for Overdoses					
				Revised	
				4-1-91	
30. Paging System				Attn*	5:00 p.m. 1-8

	O	RD	Q	NA	PR
31. Pathology Specimen					
a. Requisition					
b. Specimen					
32. Pediatric Emergencies					
a. Croup - Epiglottitis					
b. Poisonings					
c. Fever - Seizures					
d. Burns					
e. Asthma					
33. Poisonings, Overdose - Procedure					
34. Pharmacology of Cardiac Drugs					
a. Anti-arrhythmic Drugs					
35. Pre-op Care					
a. Emergency Room Record					
36. Respiratory Therapy					
a. Requisition and Charges					
37. Rape					
a. Psychological and Psycho Social Needs					
b. Collection of Evidence					
38. Safety					
a. Bed Rails					
b. Restraints					
c. Fire Plan					
d. Disaster Plan					
e. Transportation of Patient					
f. Stretcher					
g. Wheelchair					
39. Supplies					
a. Exchange Carts					
b. Permanent Carts					
c. Requisitioning from CS					
d. Weekly Order					
40. Stab Wounds					
a. Care					
b. Reporting to Authorities					
41. Standing Orders					

P&PC
4-1-91

Attn 1-9

	O	RD	Q	NA
42. Trays and Carts				
a. Minor - Chest Tube				
b. Tracheostomy - Peritonial Tap				
c. Cutdown				
d. Spinal				
e. Nose Bleed				
f. Amniocentesis				
g. Emergency OB pack				
h. Crash Cart				
1. contents				
2. checklist				
3. Defibrillator				
43. Transfer of Patient - Procedure				
44. Unconscious Patient				
a. Safety				
45. Wound Care				
a. Prep				
b. Aseptic Technique				
c. Dressings				

Signature: _____
Emergency Room Patient Care Coordinator

Signature: _____ MICT

PAPCO
4-1-91
~~5:00~~ pm.
attn 1-10

KSNA

the voice of Nursing in Kansas

FOR MORE INFORMATION CONTACT:

Terri Roberts, J.D., R.N.
Executive Director
Kansas State Nurses' Association
700 S.W. Jackson Suite 601
Topeka, Kansas 66603-3731
(913) 233-8638

April 1, 1991

S.B. 271 EMERGENCY MEDICAL SERVICES

Chairman Sader and members of the House Public Health and Welfare Committee, my name is Terri Roberts, R.N. and I am a registered nurse representing the Kansas State Nurses' Association.

We appreciate the opportunity to appear before this committee and would like to support the concepts and amended version of S.B. 271. KSNA, the Kansas State Board of Nursing and Bob McDaneld from the Emergency Medical Services Board worked extensively on the revisions as they appear in S.B. 271 now.

The Kansas State Nurses' Association is supportive of the regulation of medical care attendants through a state agency, and recognize that this agency as it is structured now is only three years old. We support the exemption for students so that they may perform those skills they will be held accountable for in their roles.

P&HW
4-1-91
5:00 pm
Attm # 2

We support the role of emergency medical attendants in the delivery of care, as they have been trained and in the settings in which they have been trained to manage care.

State of Kansas
BOARD OF EMERGENCY MEDICAL SERVICES

109 S.W. 6TH STREET, TOPEKA, KS 66603-3805
(913) 296-7296 *Administration*
(913) 296-7403 *Education & Training*
(913) 296-7299 *Examination & Certification*
(913) 296-7408 *Planning & Regulation*

Bob McDaneld
Administrator

Joan Finney
Governor

DATE: April 1, 1991

TO: House Public Health and Welfare Committee

FROM: Bob McDaneld

SUBJECT: Testimony on SB 271

SB 271 was introduced by the Senate Local Government Committee at the request of the Board of Emergency Medical Services. The bill passed the Senate without opposition. SB 271 would make a number of significant changes to the current emergency medical services statutes. I will explain each of these changes later in this testimony.

The board is requesting two minor amendments to SB 271. I would request that "qualified instructor" (line 10, page 3) be amended to provide the board more flexibility in approving instructors for training programs. In addition, Sec. 8 (line 16, page 9) should be amended to clarify the types of initial courses of training. I have enclosed suggested substitute language.

Recommended statutory changes in SB 271 include:

Amend K.S.A. 65-6112 and related statutes to delete the "crash injury management technician" level of certification from authorized levels of attendant certification. A new section permits currently certified crash injury management technicians to apply for certification as a first responder or emergency medical technician as prescribed in rules and regulations adopted by the board. Almost all crash injury management technicians are members of the Kansas Highway Patrol. The KHP is now training its troopers as first responders instead of crash injury management technicians and supports this bill.

Amend K.S.A. 65-6112 to clarify the definition of "emergency medical service" and add a definition of non-emergency transportation to ensure that ambulance attendants may legally provide non-emergency medical care in the pre-hospital phase of patient care and transportation.

Amend K.S.A. 65-6120 to permit emergency medical technicians-intermediate to provide intra-venous therapy without first establishing direct voice contact with a physician when approved by the local component medical society in written protocols.

(Continued on next page.)

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Attm 3

Amend K.S.A. 65-6129 to permit the board to regulate instructor-coordinators in the same way as the board regulates other levels of personnel. This would include establishing fees for certification and certification renewal, creating a certification examination, and mandating continuing education requirements.

Amend K.S.A. 65-6129 to permit regaining an attendant's or instructor-coordinator's certificate within two years of its expiration without taking an examination.

Amend K.S.A. 65-6145 to permit a person enrolled in an initial course of training program or continuing education approved by the board to perform the activities authorized for that level of certification when the person is being supervised by a qualified instructor, as defined in the bill.

The Board of Emergency Medical Services believes these changes are necessary for Kansas emergency medical services to continue providing training programs and pre-hospital care. I request your support of SB 271, with the amendment proposed by the board.

I have enclosed a memorandum which describes each level of attendant certification to assist committee members with terminology used in emergency medical services.

RM/st
enc.

P&C
4-1-91
5:00pm
Attm # 3-2

Proposed Amendment to Senate Bill No. 271
(As Amended by Senate Committee)

On page 3, in line 10, by striking all after "person"; by striking all in line 11; in line 12, by striking all before the period and inserting "who provides instruction in an initial course of training or continuing education approved by the board";

On page 9, in line 17, by striking "or" and inserting "as an attendant or a first responder or any"; in line 18, by striking "approved by the board";

P N & W
4-1-91
5:00 pm.
atch 2-3

State of Kansas
BOARD OF EMERGENCY MEDICAL SERVICES

109 S.W. 6TH STREET, TOPEKA, KS 66603-3805
(913) 296-7296 *Administration*
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(913) 296-7408 *Planning & Regulation*

Bob McDaneld
Administrator

Joan Finney
Governor

TYPES OF EMERGENCY MEDICAL SERVICES CERTIFICATION

FIRST RESPONDER (FR) There are 532 certified first responders. They complete a 45 hour training program and pass a written and practical examination. They have statutory authorization to provide basic first aid and stabilization. These individuals work for law enforcement, rescue squads, and fire services.

CRASH INJURY MANAGEMENT TECHNICIAN (CIMT) There are 420 certified crash injury management technicians. They complete a 72 hour training program and pass a written and practical examination. They have statutory authorization to provide basic first aid and stabilization. This training program was replaced at the national level by the first responder. Almost all of those certified as CIMT are KHP troops. The KHP has changed its training program to first responder and will be supporting Board of EMS legislation to remove CIMT as a level of certification.

EMERGENCY MEDICAL TECHNICIAN (EMT) There are 5607 certified emergency medical technicians. They complete a 120 hour training program and pass a written and practical examination. They have statutory authorization to provide basic first aid, insert oropharyngeal airways, apply medical anti-shock trousers, stabilize injuries, and extricate patients. These individuals work for the 190 ambulance services which provide basic life support. Many of them are volunteers. A number of fire departments also train their firefighters as EMTs.

EMERGENCY MEDICAL TECHNICIAN-INTERMEDIATE (EMT-I) There are 224 certified emergency medical technicians-intermediate. A person certified as an EMT may take an additional 40 hour training program in intra-venous therapy and pass a written and practical examination. They have statutory authorization to provide all the activities of an EMT, and in addition, provide intra-venous therapy. Most EMTs-I work for volunteer services, although some work as the second attendant on a service which provides advanced life support.

EMERGENCY MEDICAL TECHNICIAN-DEFIBRILLATOR (EMT-D) There are 75 certified emergency medical technicians-defibrillator. A person certified as an EMT may take an addition 27 hour training program in manual defibrillation and pass a written and practical examination. They have statutory authorization to provide all the activities of an EMT, and in addition, provide defibrillation and cardiac monitoring of heart attack victims. Most EMTs-D work for volunteer services.

(Continued on next page.)

P&W
4-1-91
5:00pm
attm 3-4

EMERGENCY
EMERGENCY
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EMERGENCY
NURSES ASSOCIATION

ENA
Kansas State Council

Senate Bill 271 Emergency Medical Services

I would like to thank the committee for this opportunity to address them about Senate Bill 271 concerning the Emergency Medical Services.

I would first like to introduce myself. I am Darlene Whitlock. I am a registered nurse in the Emergency Department at Stormont Vail Regional Medical Center. My current job is as education coordinator for the department and also as coordinator for classes in our outreach network. I have been an emergency nurse for 18 years both here and in Emporia. I am also an Emergency Medical Technician. I have had an association with the Board of EMS for many years, first as an examiner for the, then Bureau of EMS and later as a member of the Board of EMS. I served as an examiner until recently, but I continue to teach all levels of prehospital caregivers. As a matter of fact, I am giving a lecture tonight to an EMT class at Washburn University. I have taught classes in many areas of the state. I have the highest regards for the various providers I have met over the years, and I would want you to know that I feel Kansas is fortunate to have this group of people.

I am here today representing the Kansas Council of Emergency Nurses Association. I am the current president. We are affiliated with the national Emergency Nurses Association and have members from across the state. My political experience is limited to my current term on the Board of Education for USD 372 at Silver Lake, but I feel that public officials usually want to hear from constituents to gather information about issues being considered.

Attach
4-1-91
5:00 pm
Attm # 4

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NURSESASSOCIATION

ENA
Kansas State Council

The Emergency Nurses Association and the Kansas Council of Emergency Nurses recognize the contribu tion that all levels of prehospital caregivers give to patients in the field. We are in support of SB 271 as it is ammended. We feel that it is in the best interests of health care that providers practice in their area of education and expertise. We feel that a harmonious relationship currently exists between the field based and the hospital based caregivers. We hope to continue this. We do feel however that the education and area of expertise is different for nurses and paramedics. While some areas may overlap, some are very different.

I appreciate the staff from the Board of Emergency Medical Services working with Ms.Roberts and Ms.Johnson to amend the bill to its current language so that it is acceptable to our group.

Again, thank you for this opportunity to address you and I would be happy to answer any questions you might have.

Respectfully,

Darlene S. Whitlock

Darlene S. Whitlock,RN,BA,CEN,EMT
President Ks.Council ENA

PHCW
4-1-91
Attm 4-2

SEDGWICK COUNTY, KANSAS
EMERGENCY MEDICAL SERVICES
OFFICE OF THE DIRECTOR

538 N. MAIN
WICHITA, KANSAS 67203-3754
(316) 383 - 7994

TO: Chairperson Sader and Honorable Members of the House on Public Health and Welfare.

FROM: Tom Pollan, Director
Chairman - Kansas Association of EMS Administrators
Legislative Liaison - Kansas EMT Association

DATE: April 1, 1991

RE: S.B. 271

First, allow me to express my appreciation for your allowing me the opportunity to present information on SB 271. It is my sincere desire to present information that will assist you in making the best decision possible on this critical issue.

I am representing three different organizations: Sedgwick County EMS (EMS), the largest provider of pre-hospital emergency and non-emergency medical services within Kansas; Kansas Association of Emergency Medical Service Administrators (KAEMSA), which represents the administrators who operate services to provide care and transportation of the sick and injured across Kansas; and the Kansas Emergency Medical Technicians Association (KEMTA), the largest association representing the grassroots personnel that provide emergency medical services within the State. All of these organizations have the same basic objective - to provide the very best care for our citizens.

Sedgwick County EMS, KAEMSA, and KEMTA appear in support of SB 271 in concept. However, there are technical issues that must be addressed before this bill becomes law.

In reviewing SB 271, there are three key changes that have been addressed for varying reasons. First, the Board of EMS, in an attempt to offset questions that were raised following an AG's opinion, submitted amendments that would allow students in an approved training program to take part in patient care activities while under the supervision of a "qualified instructor." This amendment is desperately needed to allow current training programs for Emergency Medical Technicians - Intermediates (EMT-I) and Mobile Intensive Care Technicians (MICT) to continue their required field internships. Sedgwick County EMS has discontinued its support of these training programs until this bill is law. There

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attm # 5

are four training programs that are urgently waiting to utilize Sedgwick County EMS to complete their required field internship training. All three organizations are in support of this change.

Second, is the establishment of a certification for "instructor coordinators." Section 7 (Page 7 Line 10 - 22) sets out the criteria for certifying instructor coordinators through a process similar to what attendants have been required to complete for several years. A instructor coordinator will be required to take an approved course of instruction, make application to the Board of EMS, pass an examination, and pay a "user fee" for the right to teach programs approved by the Board of EMS. All of this, except the "fee," has been in place through rules and regulations. Although I am not deeply concerned about the above process being applied to instructor coordinators, I do have a question on who is recommending the "credentialing" by certification of instructor coordinators. K.S.A. 65-5001 states that the credentialing process is the responsibility of the Secretary of Health and Environment. Additionally, the definition of "certification" under K.S.A. 65-5001 would not allow for the credentialing of instructor coordinators by certification. K.S.A. 65-5001 states:

> **"(b) "Certification" means the process by which a nongovernmental agency or association or the federal government grants recognition to an individual who has met certain predetermined qualifications specified by the nongovernmental agency or association or the federal government."** (Emphasis added)

By implementing this bill, are you superseding K.S.A. 65-5001? If yes, and you have the authority to do so, I would ask that you select the appropriate level of credentialing and establish that all attendants and instructor coordinators under new Section 7 and all existing EMS statutes be "licensed."

Finally, all three of the organizations are supportive of any additions that deem First Responders and Attendants as "Health Care Providers." We are also very supportive of defining "emergency and non-emergency" care and how that might relate to the type of services First Responders and Attendants may provide. However, we are not supportive of any inclusion in this Bill that would limit the environment in which First Responders and Attendants can provide their critically needed professional services.

This appears to be the real issue that is before you today - - where is it that a First Responder or an Attendant can provide their professional services? Yes, even the Courts have annotated "ambulance services as professional services" (Curtis Ambulance vs. Shawnee County Board of County Commissioners, 811 F.2d. 1371, 1381 (1987)). Why is it then that First Responders and Attendants have not gained official status of a "Health Care Provider"? Could it be that other groups within the recognized and established list of

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Attm # 5-2

Health Care Providers are fearful of our admittance? Is it the belief of those already within the inner circle that our acceptance will open the medical facilities' doors and allow First Responders and Attendants to provide their professional services within the inner circle's hollowed structures? Yes, these are the real issues before you today.

However, S.B. 271 as amended, with or without the words "during an emergency" or the new definition of "Non-emergency transportation" will not resolve the issue of First Responders and Attendants working within a medical facility. That issue was resolved in 1972 and was reaffirmed in the Attorney General's Opinion No. 90-134. I offer the following taken from the AG's Opinion regarding the case annotation on physician's rights to delegate professional services:

> **"Our opinion does not overlook situations in which a physician may delegate to an unlicensed person the performance of professional services. K.S.A. 65-2872(g). Medical doctors may use technicians for assistance in practicing healing arts. State ex rel. v. Doolin & Shaw, 209 Kan. 244, 262 (1972). When a physician delegates such an act to a person who is also licensed as an MICT, the person acts by virtue of the healing arts act, not by virtue of the MICT licensure act. The act under which MICTs are licensed does not limit the practice of delegation by a physician."** (Note even the AG thinks MICT's are licensed)

The AG's Opinion summarizes in its conclusion stated that, "However, if a physician delegates performance of professional services to an MICT, the MICT may function pursuant to the physician's order." Clearly there is no limitation placed on where an MICT may provide those professional services.

Even the AG's Opinion fails to openly address the issue of whether or not MICT's can perform their professional services within a medical facility. Yet the opinion was requested by Ms. Pat Johnson, Executive Administrator of the Kansas State Board of Nursing (KSBN), who openly stated, "We don't care what MICT's and EMT's do outside of the hospital," to support her concerns that MICT's were providing nursing practices within medical facilities. This appears to be the concern of the professional nursing groups as well; that there are MICT's who are performing nursing practices within a medical facility and that this violates the nursing practice act. Their overall concern is to protect their "turf." One group has even stated that they don't want our service inside the hospital because it will lower the level of care provided within a medical facility. Yet on the other hand they state that we are doing an outstanding job of providing patient care outside the hospital. One has to ask the question, what is so magical about a set of glass doors? Could it be that it makes a difference

P Hall
4-1-91
5:00 pm
Attn 5-3

of who is holding the door, instead of what is in the best interest of patient care?

It seems apparent that the course of the stream of MICT's providing professional services within a medical facility has already been set. The only difficulty is that the waters are muddy due to the term "during an emergency" that leaves it to a very narrow definition of what is an emergency. The insertion of the new definition of "nonemergency transportation" also misses the point as well. We would submit the following terms and definition on page 3 (line 3 - 5), that will clear the waters.

> **(p) "Nonemergency service" means the care and/or transport of a sick or injured person under a foreseen combination of circumstances calling for continuing medical care of such person."**

We believe that by changing the terms and definition and allowing First Responders and Attendants to the inner circle of Health Care Providers will clear the waters and improve the health care system for our citizenry. We urge you to not set limits on where we may provide our professional services and to keep our supervision under the Board of EMS and the Board of Healing Arts.

Thank you for your time and consideration of these issues. Should you have any questions, please feel free to contact me.

Sincerely,

Tom Pollan

PHRCC
4-1-91
5:00pm
attmt # 5-4

MEDEVAC

April 1, 1991

To: House Committee on Public Health and Welfare

From: R.E. "Tuck" Duncan and Thomas L. Little
Medevac Medical Services, Inc.

RE: Senate Bill 271

We appear in support of Senate Bill 271.

This bill is necessary in order to clarify permissible activities of E.M.I.C.T.s in light of the Attorney General's Opinion 90-134 affecting E.M.I.C.T. activities in non-emergency situations.

While the law provides that ambulance services are organizations which transport sick or injured persons "whether or not such persons may be in need of emergency or medical care in transit," [K.S.A. 65-6112(c)] the Attorney General's opinion limits the utilization of an E.M.I.C.T.'s capabilities to only times when "an unforeseen combination of circumstances which calls for immediate action." [A.G.Opin. 90-134 p.3].

There are times when an E.M.I.C.T. may need to perform during intensive care "non-emergency" transport, or neonatal "non-emergency" transport, tasks for which they are qualified as set out in K.S.A. 65-6119(d), which the Attorney General states may not be perform in non-emergency situations [at p.3].

The Senate Committee amended the bill in a manner we proposed to provide a definition of non-emergency transports that allows the personnel licensed under the Emergency Medical Services Act to perform tasks for which they are licensed. A "non-emergency" transport is one in which an individual is in need of continuing medical care where a foreseen combination of circumstances calls for continuing action. This action may be prescribed by protocol, written orders of a doctor or nurse, or vis a vi voice contact with a medical care faciltiy.

The bill as amended, we believe, meets the concerns of all interested parties. Therefore, we request that the Committee act favorably on this bill.

Thank you for your consideration of this matter.

(18wp)SB271(h).doc

PH+CW
4-1-91
5:00 pm
Attm # 6

Douglas County

Department of Emergency Medical Services and Emergency Preparedness

Ted McFarlane, Director

REFERENCE SB 271 AS AMENDED BY THE SENATE COMMITTEE 4/1/91

My name is Ted McFarlane, I am the Director of Douglas County EMS and EP. We provide paramedic level care to the citizens of Douglas County. I would like to speak in support of Senate Bill 271 as amended by the Senate Local Government Committee. But I have a few concerns.

SB 271 tries to clarify when and where a Kansas Certified Mobile Intensive Care Technician (MICT or Paramedic) can provide patient care services. The Attorney General identified a legal problem concerning paramedic level care both in and out of hospitals in a recent opinion. The AG interprets the current law as stating that paramedic level services can only be provided in an emergency situation. There are many instances when advanced care is provided in out of hospital nonemergency settings. In our service last year there were 378 such instances. Transports to hospitals and from hospital to hospital were involved. It is vital that paramedics be authorized to perform to their level of training and certification irrespective of whether the situation is classified as an emergency or not.

I personally believe that paramedics should be allowed to function to their level of training in all situations with the only restrictions being those developed by the local physician medical community. As a compromise, I think requiring either licensed professional nurse or physician supervision in hospital situations is reasonable. This would best serve the patient.

Specifically,

in section 1(p) I would like to see the definition of "non-emergency transportation" changed to include the "transport and care surrounding the transportation".

in section 8(d) I would like to see the phrase "approved by the Board" deleted. We do a lot more training than required by the law, and requiring Board approval on all this training is unnecessary and a burden to us and the Board.

I urge your favorable consideration of SB 271.

PH & W
4-1-91
5:00 pm
attn

Ambulance Service Division
225 Maine Street
Lawrence, Kansas 66044
(913) 843-7777

Emergency Preparedness Division
Judical and Law Enforcement Center
111 East Eleventh
Lawrence, Kansas 66044
(913) 841-7700 Extension 259

B.F. ASCHER & COMPANY, INC. • *Pharmaceuticals* • 15501 West 109th, Lenexa, Kansas 66219 • (913)888-1880

April 1, 1991

Members of the House
Public Health & Welfare Committee
STATE CAPITOL BUILDING
Topeka, Kansas 66612

Dear Members of the Committee:

The Federal Prescription Drug Marketing Act of 1987 (PDMA) (enacted in April 1988) required the Food and Drug Administration to issue regulations setting forth guidelines for State licensing of wholesale drug distributors. The FDA published the final rule describing the guidelines in the Federal Register, Vol. 55, No. 179 dated September 14, 1990. The guidelines prescribe minimum standards, terms and conditions for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution. The PDMA prohibits wholesale distribution of prescription drugs in interstate commerce unless the wholesale distributor is licensed by a State in accordance with these guidelines.

The PDMA prohibition against interstate distribution of prescription drugs by persons who are not licensed by the State in accordance with these Federal guidelines takes effect 2 years after the date of publication of the final rule. In other words, the effective date is September 14, 1992. Any person who distributes prescription drugs in violation of this prohibition is subject to imprisonment for not more than 10 years or a fine of not more than $250,000, or both.

B. F. Ascher & Company, Inc., was founded in 1949 and has operated as a Kansas corporation since moving into the State in 1981. B. F. Ascher & Company, Inc., develops, packages, labels, markets and distributes both prescription and non-prescription drugs on a national basis. We are proud to be a resident of Kansas and a contributor to the economic welfare of the State.

I am here today to urge favorable action on House Bill No. 2608. As I understand this legislation, it will enable the Board of Pharmacy to adopt the Federal guidelines and allow B. F. Ascher & Company to operate in conformity to the new Federal law.

While September 14, 1992 seems far away, I have been assured by Mr. Dana Killinger, Attorney for the Board of Pharmacy that passage of the bill in

PH+W
4-1-91
Attm #8
5:00pm.

Mailing Address: P.O. Box 717, Shawnee Mission, Kansas 66201-0717
Cable Code: BFACO Lenexa, Kansas
Telefax No. 913-888-2250

the current session is very important since much work needs to be done to have the Federal guidelines adopted by the deadline date. I understand that a number of State agency approvals are still required after enactment.

I have attached a copy of the Federal Register pages of September 14, 1990 describing the final rule for Guidelines for State Licensing of Wholesale Prescription Drug Distributors.

I thank Committee Chairperson Representative Carol Sader and members of the Committee for the opportunity to present this information for your consideration.

Sincerely,

Charles H Borchers

Charles H. Borchers
Director of Scientific & Legal Affairs

CHB/klr

attachments

PNRCC
4-1-91
Attn
8-2
5:00pm

Friday
September 14, 1990

Federal Register

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 205

Guidelines for State Licensing of Wholesale Prescription Drug Distributors; Final Rule

21 CFR Part 205

Applicability to Blood and Blood Components Intended for Transfusion; Guidelines for State Licensing of Wholesale Prescription Drug Distributors

PHACC
4-1-91

Attn
8-3
5:00pm.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 205

[Docket No. 88N-0258]

RIN 0905-AC81

Guidelines for State Licensing of Wholesale Prescripton Drug Distributors

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to implement those sections of the Prescription Drug Marketing Act of 1987 (PDMA) that require FDA to issue regulations setting forth guidelines for State licensing of wholesale drug distributors. The guidelines prescribe minimum standards, terms, and conditions for the storage and handling of prescription drugs for human use (hereinafter prescription drugs) and for the establishment and maintenance of records of their distribution. PDMA prohibits wholesale distribution of prescription drugs in interstate commerce unless the wholesale distributor is licensed by a State in accordance with these guidelines. In this rule, FDA has tentatively determined that PDMA does not apply to the distribution of blood and blood components intended for transfusion. In a separate notice elsewhere in this issue of the Federal Register, FDA invites further comment on this matter.

EFFECTIVE DATE: September 14, 1990.

FOR FURTHER INFORMATION CONTACT: Diane P. Goyette, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 13, 1988 (53 FR 35325), FDA published a proposed rule to issue guidelines for State licensing of wholesale drug distributors as required by the Prescription Drug Marketing Act of 1987 (Pub. L. 100-293, 102 Stat. 95). PDMA amends the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) to provide, among other things, that no person may engage in the wholesale distribution in interstate commerce of drugs subject to section 503(b) of the act (21 U.S.C. 353(b)) (prescription drugs for human use), unless such person is licensed by the State in accordance with federally prescribed minimum standards. PDMA requires that these minimum standards be established in "guidelines" issued by FDA regulation. The guidelines must prescribe minimum standards, terms, and conditions for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution (21 U.S.C. 353(e)(2)).

The State licensing guidelines established by this regulation should not be confused with FDA guidelines issued under the agency's rules governing administrative practices and procedures (21 CFR 10.90). Guidelines issued under § 10.90 suggest procedures or present standards of general applicability that are not legal requirements, but that one can rely on as acceptable to FDA. Such guidelines allow persons to choose alternate courses of conduct that comply with the general standards or suggested procedures. In contrast, PDMA directs that the guidelines issued by this regulation "* * * shall *prescribe requirements* for the storage and handling of (prescription) drugs and for the establishment and maintenance of records of (their) distribution * * *" (emphasis added). Moreover, PDMA requires that wholesale drug distributors who distribute human prescription drugs in interstate commerce be licensed in accordance with the minimum requirements set forth in these guidelines (21 U.S.C. 353(e)(2)). Thus, the guidelines prescribed by this regulation are binding substantive rules that have the force and effect of law.

Unless express reference is made to guidelines issued under § 10.90 (as in paragraph 25, below), all references to guidelines in this document are made to these "Guidelines for State Licensing of Wholesale Prescription Drug Distributors" established under the requirements of PDMA.

The PDMA prohibition against interstate distribution of prescription drugs by persons who are not licensed by the State in accordance with these Federal guidelines takes effect 2 years after the date of publication of this final rule. Any person who distributes prescription drugs in violation of this prohibition is subject to imprisonment for not more than 10 years or a fine of not more than $250,000, or both (21 U.S.C. 333(b)(1)).

In developing the guidelines, FDA followed the recommendation of the House of Representatives' Committee on Energy and Commerce that it consider the "Model Regulations for Wholesale Drug Distribution" issued by the National Association of Boards of Pharmacy (NABP). FDA also considered the "Proposed Uniform Standards of Practice for Wholesale Drug Distribution," which have been adopted by the National Wholesale Druggists' Association (NWDA).

Additionally, FDA has carefully considered the approximately 50 comments received on the proposed rule. The comments came from members of Congress, trade associations, professional groups, individual pharmaceutical manufacturing firms, wholesale drug distributors, chain drug store companies, State boards of pharmacy, individual hospital and retail pharmacies, and pharmacists. Highlights of this final rule and the agency's economic analysis are followed by a summary and discussion of the comments in section VII below.

II. Highlights of the Final Rule

This final rule establishes guidelines for State licensing of wholesale prescription drug distributors as required under PDMA. The guidelines provide minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution. The guidelines ensure that all prescription drug wholesalers who distribute drugs in interstate commerce will operate according to these minimum standards while leaving States discretion to impose stricter licensing requirements. In response to comments and further internal deliberations, the final rule modifies certain provisions of the proposal to meet these objectives better. The major provisions of the final rule are summarized as follows:

1. *Scope.* The final rule applies to all wholesale distributors of human prescription drugs in interstate commerce.

2. *Definitions.* Section 205.3 sets forth definitions as they apply to this final rule. The distribution of drug samples by manufacturers' representatives, distributors' representatives, and the distribution of blood and blood components intended for transfusion by registered blood establishments are excluded from the definition of wholesale distribution in the final rule. These activities are, therefore, not subject to the licensing requirements under the guidelines.

3. *Wholesale drug distributor licensing requirement.* Section 205.4 of the final rule sets forth the requirement that a wholesale distributor conducting interstate transactions in a State be licensed by the State. This requirement is mandated by section 503(e)(2)(A) of the act.

PH-cw 4-1-91
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5:00 pm.

4. *Minimum required information for licensure.* Section 205.5 of the final rule sets forth minimum information to be required from each licensing applicant.

5. *Minimum qualifications.* The final rule sets forth certain minimum qualifications for licensing under § 205.6. The agency believes that careful screening of applicants is necessary and prudent in reducing the opportunities for diversion of prescription drugs. State authorities must consider an applicant's history, which may reflect upon the applicant's ability to prevent drug diversion. Where granting a license would not be in the public interest, State authorities may deny a license to an applicant.

6. *Personnel.* The final rule establishes minimum personnel standards for licensees under § 205.7. Employees must be qualified by education and/or experience to perform their duties.

7. *Violations and penalties.* Section 205.8 of the final rule provides for suspension or revocation of licenses, and permits fines, imprisonment, or civil penalties upon conviction of violations of Federal, State, or local drug laws.

8. *Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.* The final rule sets forth the minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distributions. The final rule includes sections describing physical requirements of facilities where prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed. Such facilities must have certain characteristics, outlined in § 205.50(a) of the final rule, that make them suitable places for the storage of prescription drugs. Facilities must also have adequate security systems and be capable of ensuring a proper environment for the storage of prescription drugs.

a. *Wholesaler examination of incoming shipments of prescription drugs.* The final rule requires examinations of incoming and outgoing shipments to prevent acceptance of prescription drugs that are contaminated or otherwise unfit for distribution. The proposed section has been clarified in the final rule to limit the required inspection of incoming shipments of prescription drugs by wholesale distributors to a visual examination, adequate to reveal shipping container damage that would suggest damage to the contents. The final rule also deletes the requirement that the inspection of incoming shipments extend to an examination of the delivery vehicle.

b. *Handling of prescription drug products returned to the wholesale distributor.* Section 205.50(e) includes detailed instructions for the handling of returned, damaged, and outdated prescription drugs. The final rule permits the wholesaler to send back to the original supplier prescription drug products that have been returned to the wholesaler under circumstances that cast doubt on the product's integrity. This change is consistent with stated agency policy with regard to returned prescription drug products under PDMA.

c. *Recordkeeping requirements.* Section 205.50(f) sets forth recordkeeping requirements to ensure a high degree of accountability for all prescription drug transactions. Proposed § 205.50(f)(1) has been revised so that wholesale distributors are not required to include the expiration dates of prescription drugs in the records of their transactions under the final rule. Records must be retained for a period of 2 years following disposition of the prescription drug product under § 205.50(f)(2) of the final rule. Section 205.50(f)(3) of the final rule provides that records kept at the inspection site or immediately retrievable by computer or other means must be readily available for authorized inspection during the retention period. Those that are kept at another location must be made available within 48 hours of an authorized request.

d. *Written policies and procedures.* Section 205.50(g) sets forth minimum standards for the establishment and maintenance of written policies and procedures related to the receipt, security, storage, inventory, and distribution of prescription drugs. By following such pre-established procedures, a firm can better assure proper storage and distribution of prescription drugs on a consistent basis.

e. *Responsible persons.* Section 205.50(h) of the final rule requires the maintenance of lists of persons in responsible company positions. Such lists provide a deterrent to drug diversion.

f. *Compliance with Federal, State, and local law.* Section 205.50(i) of the final rule emphasizes that wholesale drug distributors must operate in compliance with all applicable laws and regulations.

g. *Salvaging and reprocessing.* Section 205.50(j) of the final rule states that wholesale drug distributors are subject to any applicable Federal, State, or local laws relating to salvaging or reprocessing. Salvaging and reprocessing operations can be very complex and are outside the scope of traditional wholesaler activities. Additional controls are therefore necessary to ensure that these operations are carried out in the appropriate fashion. Accordingly, § 205.50(j) of the final rule makes clear that FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals in 21 CFR parts 210 and 211 apply to wholesalers' salvaging and reprocessing operations.

III. Economic Analysis

FDA has examined the economic consequences of the changes implemented by the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354).

As recommended by Congress, FDA consulted the NABP Model Regulations for Wholesale Drug Distribution in the development of the standards set by these guidelines. (See H. Rept. 100-76, p. 17.) The agency believes that the standards in these guidelines represent the norm of current practices and procedures among drug wholesalers and expects minimal incremental costs to occur when these standards become effective 2 years after the publication of this final rule. Any substantial costs that may arise will be attributable to the statute itself. Thus, this rule is not expected to produce economic consequences beyond those contemplated by the act. Accordingly, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291. For similar reasons, the agency certifies, in accordance with the Regulatory Flexibility Act, that this final rule will not have a significant impact on a substantial number of small entities.

IV. Executive Order 12612; Federalism

Executive Order 12612 requires Federal agencies to carefully examine regulatory actions to determine if they would have significant impact on federalism. Using the criteria and principles set forth in the Order, the agency has considered the impact of this final rule on the States, on their relationship with the national government, and on the distribution of power and responsibilities among the various levels of government.

FDA is required by statute to issue this regulation to establish guidelines setting forth minimum standards for State licensing of wholesale prescription drug distributors. The regulation is to include minimum requirements for recordkeeping, storage, and handling of prescription drugs. States are affected to the extent that their wholesale distributors are not permitted to

PH&W 4-1-91 5:00pm. Attm# 8-5

distribute prescription drugs in interstate commerce unless they are licensed by the State in accordance with these guidelines. Under these guidelines, however, States are free to adopt standards that exceed the minimum requirements. They also maintain maximum administrative discretion, and can develop their own policies to achieve program objectives. States have had the opportunity to participate in the development of these guidelines through the notice and comment rulemaking process.

FDA certifies that it has examined this final rule, and while it may have some effect on federalism issues, for the reasons stated above, these effects are not significant and do not require an assessment under Executive Order 12612. Moreover, the agency's action is mandated by law; the agency has no discretion in carrying out its legal mandate by regulation.

V. Paperwork Reduction Act of 1980

This final rule contains information collections which have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 and assigned OMB control number 0910–0251. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Prescription Drug Marketing Act of 1987; Guidelines for State Licensing of Wholesale Prescription Drug Distributors.

Description: The reporting requirement includes the submission of certain descriptive information concerning each wholesale drug distributor (e.g., corporate address, contact person address) (§ 205.5). The recordkeeping requirements include establishing and maintaining inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs (§ 205.50(f) and (h)).

Description of respondents: State or local governments; businesses or other for-profit organizations; small businesses or organizations.

Estimated annual reporting and recordkeeping burden:

Section	Annual number of respondents	Annual frequency	Average burden per response (minutes)	Annual burden hours
202.5(a)	7,300	1	15	1,825
205.50(f) and (h)	7,300	1	20	2,434
Total				4,259

FDA, as a result of the comments received on the proposal, has deleted the provision in § 205.50(f)(1)(iii) requiring distributors to maintain records of expiration dates of prescription drugs. As reflected in the table above, this change will reduce the estimated burden from 30 minutes per response to 20 minutes, and from 3,650 annual burden hours to 2,434. There were no comments received on the Paperwork Reduction Act clearance submission or on the burden estimates.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a) (7), (8), and (10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Comments on the Proposed Rule

A. General Comments

1. Several comments addressed general issues raised by the proposed rule. Some comments questioned whether FDA should be regulating wholesale drug distributors, saying that regulations for State licensure of drug wholesalers should be left to the individual States. Other comments argued that the proposed rule is unnecessary and duplicative because State regulatory and private quality control systems already in place adequately address the goals of PDMA, and that the pharmacists' role in drug distribution precludes the need for wholesaler licensing by State or Federal authorities.

Section 503 of the act, as amended by PDMA, requires FDA to publish these State guidelines. It is not left to the agency's discretion (21 U.S.C. 353(e)(2)(B)). Moreover, the legislative history of PDMA reveals that Congress examined existing drug distribution systems, State licensing schemes, private quality control systems, and the role of pharmacists in meeting the goals of PDMA, and concluded that, although such programs might be individually effective, a national strategy was necessary to protect the public health.

These Federal guidelines set minimum standards for States to follow in designing their licensing systems. The guidelines assure that all wholesale drug distributors conducting business in interstate commerce will comply with the same minimum requirements. The agency believes that the guidelines leave States sufficient discretion to determine appropriate structures for the regulation of wholesale distributors conducting business in their States.

2. Some comments argued that the proposed guidelines should be modified or abandoned because they duplicate, and at times contradict, provisions of FDA's CGMP regulations (21 CFR parts 210 and 211).

The agency's CGMP regulations include provisions that are similar to some requirements in these guidelines. However, the CGMP regulations do not apply to the traditional activities of wholesale drug distributors (see 43 FR 45027), whereas these guidelines are expressly applicable to the traditional activities of wholesale drug distributors. FDA is unaware of any inconsistencies within its regulatory scheme that would dictate changes in these guidelines.

The provisions of this rule and other FDA regulations may have common elements, but the agency finds that this is appropriate. FDA finds that the guidelines are not only consistent with other Federal regulations, but complement the Federal scheme to enable FDA to have better control over the distribution of prescription drugs. The agency's views on the relationship between these guidelines and the current good manufacturing practice provisions of the act are discussed in paragraph 25 below.

3. Some comments discussed the economic impact of the proposed rule on wholesale distributors. Generally, these.

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comments contended that the proposed rule would impose substantial additional costs on wholesalers, without a corresponding benefit. Some comments estimated that new paperwork and personnel expenses would impose a burden. Other comments expressed concern that additional costs will force smaller, marginally profitable wholesale distributors out of business. The comments asserted that the proposed rule would impose many new procedural burdens on wholesale distributors that go beyond current practice and would be expensive to implement.

As noted earlier, the agency considered both the NABP "Model Regulations for Wholesale Drug Distribution" and the NWDA "Proposed Uniform Standards of Practice for Wholesale Drug Distribution" in developing these guidelines. Therefore, the agency believes that the guidelines represent the norm of current practice and procedure among drug wholesalers. The comments offered no examples of significant deviation from current procedures to bolster the general claim that implementation of these minimum requirements would have substantial economic consequences. Moreover, the comments suggested no specific changes in the proposed requirements to lessen the asserted economic impact.

When Congress passed PDMA, it determined that some changes should be made in the wholesale distribution system to protect the public from prescription drugs of questionable integrity. While some additional expenses are anticipated as these changes are implemented, the agency does not expect these minimum requirements to impose costs that are overly burdensome. The agency has reviewed this rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act and finds it satisfactory.

4. One comment asserted that compliance with the minimum standards set forth in the rule will greatly increase paperwork burdens. The comment also stated that the proposed guidelines governing the handling of prescription drugs, particularly those provisions dealing with destruction of returned or damaged prescription drugs, could have a significant effect on the human environment.

The agency has concluded that the standards described in these guidelines represent current procedure among responsible wholesale distributors. It is not expected that unreasonable, new paperwork burdens or significant effects on the human environment will be created.

5. One comment asked that FDA clarify its authority to enforce these guidelines.

These guidelines are minimum standards for State licensing of wholesale drug distributors. State licensing authorities are the primary agencies responsible for establishing and enforcing wholesaler licensing schemes in the States in accordance with the guidelines. FDA, however, will enforce section 503(e)(2)(A) of the act (21 U.S.C. 353(e)(2)(A)), which prohibits wholesale distribution of prescription drugs in interstate commerce in a State, except by persons licensed by the State in accordance with these minimum guidelines.

This specific authority under PDMA does not replace or dimish the agency's authority over wholesalers under other statutory provisions, including the adulteration, misbranding, and new drug provisions of the act.

B. Scope

6. Two comments requested that manufacturers' distribution centers be specifically excluded from the scope of the licensing requirements because they are adequately governed by FDA's CGMP regulations.

FDA does not find it necessary to make the change requested. Congress intended that all wholesale distributors of human prescription drugs, with certain specific exceptions, be licensed according to these gudielines. Manufacturers' warehouses that are conducting wholesale distributions are wholesale distributors and are subject to the licensing requirements unless their activities fall under one of the specific exclusions defined under § 205.3(f) of the final rule.

7. Three comments addressed issues raised by application of these guidelines to the distribution and sale of blood and blood components by blood establishments and hospitals. Two of these comments requested clarification of PDMA's scope and urged FDA to "exempt" blood establishments from all of PDMA's provisions. The comments contended that application of PDMA to blood distributors would seriously disrupt the nation's blood services. The third comment suggested that the agency could, by notice and comment rulemaking, exempt blood and blood components from PDMA by declaring that they are not prescription drugs for PDMA purposes.

After considering these comments and reviewing PDMA's purpose and legislative history, FDA has tentatively determined that PDMA does not apply to blood and blood components intended for transfusion. However, in a notice published elsewhere in this issue of the **Federal Register**, FDA is inviting further comments on this matter.

PDMA, by its literal terms, applies to all drugs that are subject to section 503(b) of the act; that is, to all human prescription drugs. There is no doubt that blood and blood components intended for transfusion are prescription drugs. See, e.g., 21 CFR 606.121(c)(8)(i); 21 CFR 610.61(f). See also May 25, 1982, 47 FR 22513; August 1, 1981, 46 FR 40121. However, if PDMA, and particularly PDMA's restrictions on the resale of prescription drugs, were considered applicable to the distribution of such blood and blood components, the result would be to seriously impede the present blood distribution system, thereby substantially interfering with, and reducing, our nation's blood supply. Because application of PDMA to blood and blood components intended for transfusion would produce this untenable result, FDA believes that Congress did not intend to subject such blood and blood components to PDMA's provisions.

Moreover, the legislative history lacks any discussion of PDMA's application to blood and blood components intended for transfusion and also clearly shows that Congress intended that PDMA remedy problems associated with the distribution of those drugs that are popularly referred to as "medicines" or "pharmaceuticals." See, *e.g.*, Public Law 100–293, section 2 (1988) (Congressional Findings). As is discussed in further detail in the companion notice to this final rule that is published elsewhere in this issue of the **Federal Register**, blood and blood components intended for transfusion are unique drug products that are distributed in an entirely different way than other prescription drugs. For example, such blood and blood components are not promoted through samples and coupons. FDA believes that the fact that such blood and blood components are not part of the system of distribution and marketing that Congress intended to regulate under the terms of PDMA further signals that Congress did not intend to include blood and blood components intended for transfusion within the scope of PDMA.

Accordingly, FDA's tentative determination is to limit the scope of these guidelines so that they do not apply to blood and blood components intended for transfusion. This limitation is accomplished by amending the definitions in § 205.3 to add new paragraph (f)(8), which specifically excludes from the definition of "wholesale distribution" the sale, purchase, or trade of blood and blood

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components intended for transfusion. FDA is also adding definitions of "blood" and "blood component" in § 205.3 of the final rule.

If further comments on this issue in response to the companion notice persuade FDA to include distribution of blood and blood components intended for transfusion in these guidelines, FDA will amend the guidelines to cover such blood and blood components.

C. Definitions

8. On its own initiative, the agency has changed the definition of "prescription drug" in proposed § 205.3(c) (now § 205.3(e)) by removing the reference to State law. The applicability of these guidelines is limited to wholesale distributions in interstate commerce of drugs that are "prescription drugs" under section 503(b) of the act.

9. Several comments addressed proposed § 205.3, which sets forth definitions of terms to be used in the wholesaler licensing regulations. One comment requested clarification of the meaning of "under common control" as used in proposed § 205.3(d)(4) (now § 205.3(f)(4)).

Neither PDMA nor its legislative history defines the term "under common control" which is used in section 503(c)(3)(B)(iii) of the act (21 U.S.C. 353(c)(3)(B)(iii)). The term, however, has been used in other Federal regulatory schemes which were in use at the time PDMA was enacted into law. Both the Security Exchange Commission and the Environmental Protection Agency define "common control" to mean the power to direct or cause the direction of the management and policies of a person or an organization, whether by the ownership of stock, voting rights, by contract, or otherwise. See 17 CFR 230.405, 40 CFR 66.3(f). FDA has included this definition in this final rule.

10. A number of comments perceived a conflict between the definitions of "wholesale distribution" (proposed § 205.3(d)) and "wholesale distributor" (proposed § 205.3(e)). The comments noted that chain drug warehouses are specifically included in the definition's list of "wholesale distributors" while intracompany sales are specifically excluded from the scope of the definition of "wholesale distribution." The comments contended that the business of chain drug warehouses is generally limited to intracompany distribution of products, namely, to retail stores that are under common ownership or within a corporate structure. The comments stated that these activities should be considered "intracompany sales," and thus should be excluded from "wholesale distribution" and the licensing requirements of the regulations.

The agency does not find the definitions of "wholesale distribution" and "wholesale distributor" to be inconsistent. A "wholesale distributor" is any person who "engages in wholesale distribution of prescription drugs." The legislative history includes a discussion of the scope of the definition of "wholesale distribution" for the purposes of these guidelines. It was clearly the intent of Congress to require licensing of the wholesale distributions of human prescription drugs by chain drug warehouses (see H. Rept. 100–76, p. 17).

Some chain drug warehouses may limit distribution of prescription drug products to subdivisions within a corporate structure, and those distributions would fall under the "intracompany sales" exception and not be considered wholesale distributions under § 205.3(f). A chain drug warehouse that sells prescription drugs to a franchised store or to establishments outside the corporate umbrella, however, would be engaging in wholesale distribution, as defined in § 205.3(f) of this final rule, and its distributions in interstate commerce would be subject to the licensing requirements.

11. Several comments suggested that the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives be specifically excluded from the definition of "wholesale distribution" and thus from the licensing requirement. The comments argued that licensing persons who distribute prescription drug samples is inconsistent with the intent of PDMA and would make the current practice of sample distribution by representatives virtually impossible.

Other comments argued that manufacturers' and distributors' representatives should be licensed and be required to store and handle samples in accordance with the guidelines or the guidelines will fail to assure that prescription drugs are stored properly in all cases.

After considering the comments and reviewing PDMA's purpose and legislative history, FDA has determined that the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives, done in accordance with other applicable provisions of the act, is not "wholesale distribution" within the meaning of § 205.3(f) of these guidelines and will not be subject to licensing under this final rule. FDA believes that this result is consistent with a congressional intent to establish a separate, comprehensive regulatory scheme designed specifically for prescription drug samples.

The licensing of manufacturers' representatives and distributors' representatives as wholesalers would go beyond the intent of PDMA. PDMA was enacted to address certain problems in the human drug distribution system that Congress believed threatened the integrity of the nation's prescription drug supply. Wholesale distribution of drugs and sample distribution by manufacturers' representatives and distributors' representatives were two of the areas where Congress believed more controls were necessary. However, PDMA addressed these two areas in somewhat different ways.

In the case of wholesale distribution, Congress sought to improve storage and handling practices and accountability by requiring that wholesale distributors of human prescription drugs be licensed under State licensing requirements that meet prescribed minimum Federal standards. The legislative history suggests that Congress expected these licensing standards to be based on the NABP "Model Regulations for Wholesale Drug Distribution," a model inapplicable to the control of sample distribution. (H. Rept. 100–76, p. 17.) Moreover, the House Report also indicates that Congress intended the licensing requirement to be confined to "* * * distribution by chain drug warehouses, wholesale drug warehouses, and all sellers of prescription drugs in wholesale quantities to persons or firms other than the consumer or patient." (H. Rept. 100–76, p. 17.) The reference in the House Report supports a conclusion that PDMA's licensing provisions are not intended to cover the distribution of prescription drug samples, which, by statutory definition, are never sold (section 503(c)(1) of the act; 21 U.S.C. 353(c)(1)).

Congress chose a different method of regulation with regard to the distribution of prescription drug samples. These requirements are set forth in section 503(d) of the act, and establish express and comprehensive provisions governing the storage, handling, distribution, and disposition of prescription drug samples by manufacturers, their distributors, and representatives. The scope and specificity of these provisions indicate that Congress determined that sample distributions be conducted under this separate regulatory scheme. Section 503(d) and the legislative history of

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PDMA contain no suggestion that any additional regulatory scheme, such as licensing prescription drug sample distribution as wholesale activity, was either necessary or contemplated by Congress.

Accordingly, the agency is adding § 205.3(f)(7) to the final rule, excluding the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives from the "wholesale distribution" definition and the licensing requirements.

Because sample distribution by manufacturers' representatives and distributors' representatives will not be subject to State licensing in accordance with these guidelines, the agency does not intend that such sample distribution be subject to the storage and handling requirements of these guidelines. The agency disagrees with the contention of some comments that excluding such sample distribution from these storage and handling requirements will prevent prescription drugs from being properly stored in all cases. Under section 503(d)(3)(B) of the act, manufacturers and distributors must store prescription drug samples under conditions that will maintain their stability, integrity, and effectiveness, and take measures to assure that their prescription drug samples are kept free of contamination, deterioration, and adulteration. Manufacturers and distributors are thus responsible for the proper handling of prescription drug samples throughout their distribution.

12. One comment asked if those entities excluded from the "wholesale distribution" definition in proposed § 205.3(d) (1) through (8) would also be excluded from the storage, handling, and recordkeeping requirements of § 205.50.

The guidelines require only those persons engaged in the wholesale distribution in interstate commerce of prescription drugs to be subject to the guidelines' minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of the distribution of such drugs. By definition, therefore, the entities involved in the transactions listed in § 205.3(f) (1) through (8) of the final rule are not wholesale distributors under PDMA and are not subject to other provisions of the guidelines. Of course any person engaged in manufacturing, processing, packing, or holding of a drug is subject to all pertinent provisions of the act, including the current good manufacturing practice provisions of section 501(a)(2)(B) of the act (21 U.S.C. 352(a)(2)(B)).

13. A number of comments suggested that the definition of "wholesale distributor" be expanded to include manufacturers' representatives, sales agents, doctors, various kinds of clinics, and others. The comments asserted that addition of these categories to the definition would make the regulations more specific and all-inclusive and would assure compliance with storage and labeling requirements wherever prescription drugs are handled.

Section 205.3(g) of the final rule defines "wholesale distributor" to include anyone engaged in wholesale distribution of prescription drugs. The list of wholesale distributors enumerated in the guidelines is not exhaustive, but, as it clearly states, only illustrates the type of persons or firms who could, depending on the nature of their activity, be considered wholesale distributors under these provisions. The determinative consideration is the nature of the activity, not whether the entity is listed among the examples. If an activity is wholesale distribution and is not excluded under § 205.3(f) of the final rule, then the person engaged in the distribution is a wholesale distributor and his or her activity in interstate commerce must be licensed. FDA concludes that no purpose would be served by adding to the examples given in § 205.3(g).

14. One comment suggested that the phrase in proposed § 205.3(e) (now 205.3(g)), which included "retail pharmacies that conduct wholesale distributions" in the definition of wholesale distributors, be clarified. The comment asked that more guidance be given to determine when a retail pharmacy would be conducting wholesale distributions requiring licensure.

The nature of the operations of a retail pharmacy determines when it is a wholesale distributor. If its activities fit the definition of wholesale distribution and do not fall under any of the exclusions, the guidelines provide that the retail pharmacy is a wholesale distributor and must be licensed as such.

15. Another comment pointed out that the definition of "wholesale distributor" lists both "manufacturers" and "manufacturers' warehouses" as examples. The comment asked if both could be required to obtain licensure under the guidelines. The comment added that requiring a manufacturer to obtain licensure in a State if its warehouse is already licensed would be redundant, costly, and wasteful.

Both a manufacturer and its warehouse could be required to obtain a license as wholesale distributors under these guidelines if both are engaged in wholesale distributions as defined in § 205.3(f) of the final rule, and if the licensing State has no single license provision as permitted by § 205.5(b). Under § 205.5(b), States can set up a system permitting a single license for a business entity operating more than one facility in a State. Under such a system, one license would suffice for the regulation of a manufacturer and its warehouse, but both facilities would be subject to all of the licensing requirements.

D. Wholesale Drug Distributor Licensing Requirement

16. Several comments addressed the wholesale drug distributor licensing requirement described in proposed § 205.4. One comment asserted that the concept of interstate shipment is essential to the licensing requirement, but was not included in the section of the proposed guideline.

FDA does not agree that interstate shipment is a key element of the wholesaler licensing requirement under PDMA. The statute says that "(n)o person may engage in the wholesale distribution in interstate commerce (of prescription drugs) * * * in a State unless such person is licensed by the State in accordance with * * *" these guidelines (21 U.S.C. 353(e)(2)(A)). A product may be in interstate commerce before it has been shipped from one State to another. For example, a product manufactured in one State from components made in other States is in interstate commerce even if the finished product is shipped only within the State of manufacture. While FDA does not find interstate shipment to be an essential part of the licensing requirement, the agency does not find it necessary to otherwise clarify the licensing requirement by revising § 205.4 of the final rule to more closely reflect the statutory language. As revised, the final rule requires all wholesale distributors of prescription drugs who engage in interstate commerce in a State to be licensed by the State.

17. Numerous comments addressed the second sentence of proposed § 205.4. As proposed, that section said that the "mere shipment of prescription drugs into the State does not necessarily require licensing." Several comments argued that the word "necessarily" should be deleted from the sentence because it changes the meaning of the licensing requirement from that intended by Congress, as revealed in the legislative history of PDMA. Many other comments argued that the entire second

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sentence of proposed § 205.4 should be removed from the final rule. These comments contend that the sentence could undermine the efforts of several States that currently license all wholesale drug distributors who ship prescription drugs into the State.

Proposed § 205.4 was derived from the discussion of the wholesale drug distributor licensing requirement in the legislative history accompanying PDMA. That discussion states, in pertinent part, that—

> Subparagraph 503(e)(2)(A) is intended to ensure that any person or firm engaging in the wholesale distribution of pharmaceuticals to any person or firm for resale shall be licensed in the state in which it does business and that the state licensing requirements meet certain minimum standards. The mere shipment of pharmaceuticals into a state would not trigger the requirement that the distributor be licensed in that state. However, the operation of a facility from which a wholesaler makes shipments outside the state would trigger the licensing requirement with respect to the state in which the facility is located.
>
> (H. Rept. 100–76, p. 17)

The legislative history indicates that when the Congress used the words "in the State" in section 503(e)(2)(A) of the act, it was referring to the physical location of the facility from which a wholesaler makes shipments. Thus, PDMA only requires that wholesalers who have a facility in a State be licensed by that State, and that wholesalers who have their facility outside the State, but who ship into the State, need not be licensed by that State pursuant to PDMA. However, States are free to require the licensing of any wholesaler who ships into the State, even if the wholesaler does not have a facility in the State, subject to all pertinent constitutional constraints. But the failure of such out-of-State wholesalers to have such a State license would not be a violation of section 503(e)(2)(A) of the act. The agency has concluded that the changes made to § 205.4 indicate the proper scope of PDMA, and that the second sentence of the proposed § 205.4 was unclear and is unnecessary.

E. Minimum Required Information for Licensure

18. Several comments discussed the provisions pertaining to minimum information required for licensure in proposed § 205.5. Some comments asserted that certain information required by § 205.5(a) is burdensome and unnecessary, because it is already a matter of public record. The comments contended that the State licensing authority is not entitled to have this information and that it is of no value to the State for the purpose of licensing. A few comments recommended that § 205.5(a) be revised to indicate that only information relating directly to activities conducted in the licensing State be required.

The agency has reviewed the information requirements and finds that the information does not go beyond the minimum necessary for a State licensing authority to enforce its licensing system. Furthermore, because the information is readily available in corporate records, it will not be overly burdensome for a wholesale distributor seeking licensure to supply it to the State.

The information required for licensure, described in § 205.5(a) of the final rule, goes no further than information that is pertinent to activities within the licensing State. In designing its licensing scheme, however, each state is free to require such additional information as it finds appropriate.

19. Several comments recommended against the single licensing provision in proposed § 205.5(b) that would allow a State to issue a single license to a business entity operating more than one wholesale distribution facility within the State. This section also allows a State to issue a single license to a parent entity that has divisions or affiliate companies conducting wholesale distributions at more than one location within the State. The comments argued that separate licenses would provide better accountability and more effective application of sanctions.

The agency disagrees. In cases where a State chooses to include a single licensing provision in its wholesaler licensing scheme, other sections of these guidelines will assure that all of the wholesale distribution facilities subject to the license are adequately regulated. Section 205.5(a) (1) through (4) requires that comprehensive information about the identity, nature, and location of a business be submitted to obtain a license. This information must include names and addresses of contact persons for all facilities used by the licensee. The agency believes that this information will provide a sufficient guarantee of accountability and effective application of sanctions under a single licensing provision. States are, of course, free to design single licensing schemes with other guarantees or to choose not to provide for single licensing at all.

20. Two comments recommended that proposed § 205.5(b) be amended to allow for license reciprocity. Under this plan, a State could grant wholesale distributor licenses based on reciprocal agreements with other States having comparable licensing requirements. The comments are concerned that States may refuse to license by reciprocity if the issue is not addressed in these guidelines.

Reciprocal licensing arrangements between State licensing authorities have traditionally been a matter within the exclusive discretion of the States. This final rule does not prohibit States from allowing license reciprocity with other States, and FDA would not discourage such cooperative arrangements, but the agency declines to include a reciprocal licensing provision in these minimum guidelines.

21. Two comments objected to proposed § 205.5(c), which states that the State licensing authority shall be notified of any changes in the information required under § 205.5(a) within 5 days of the change. Both comments found the 5-day time period to be unreasonably short. One comment suggested a 30-day reporting period, while the other argued that an annual report of such changes would be sufficient.

The agency is removing the 5-day notice requirement in § 205.5(c) and leaving the determination of the time period up to the State licensing authority. The State licensing authority receives and maintains the information required under § 205.5(a) and is thus in the best position to determine appropriate time frames for notification of changes in this information.

F. Qualifications of Personnel

22. One comment asserted that proposed § 205.6(b), which describes the right of a State licensing authority to deny a license that would not be "in the public interest," is too vague and should be removed.

FDA has provided a general—"in the public interest"—standard for the State licensing authority to deny a license. A State may choose to further define what it believes to be "in the public interest." The agency, however, declines to do so in these minimum guidelines.

23. Some comments objected to proposed § 205.7, which sets forth minimum personnel standards for licenses. The comments found the proposed minimum personnel standards to be an "unwarranted intrusion" into the right of wholesalers to choose their own employees. They recommended that § 205.7 be removed, saying that the requirement that personnel employed in wholesale distribution meet certain minimum education and experience standards goes beyond the intent of PDMA.

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The agency disagrees with the contention that requiring a minimum education and training level for personnel employed in wholesale distribution is overly intrusive, inappropriate for these guidelines, or beyond the intent of Congress. The guidelines do not specify the kinds of education and experience required for personnel. Rather, the impact of the guidelines is to assure that personnel have an acceptable level of proficiency to carry out the licensing requirements. The agency believes that it is reasonable and appropriate to require that personnel involved in the handling, recordkeeping, and distribution of prescription drugs be competent to perform these important tasks.

G. Violations and Penalties

24. One comment suggested that removing the words "or any felony" from proposed § 205.8(a) would make the section on violations and penalties "more fair." The comment believed that the language in this section of the proposed rule could allow suspension or revocation of a wholesaler license for the criminal act of a single employee or for a felony involving a business that is completely separate and distinct from the corporation's wholesale distribution operation.

The agency believes that the determination of grounds for suspension or revocation of wholesaler licenses is a matter more appropriately left to the discretion of the State licensing authority. The agency is removing the words "or any felony" from § 205.8(a) of the final rule.

On its own initiative, FDA is revising proposed § 205.8(b), which sets forth the requirement that State licensing laws provide for suspension and revocation of licenses for violations of the licensing provisions. As proposed, § 205.8(b) implied that even insignificant or minor technical violations of wholesaler licensing laws could be the basis for suspension and revocation of licenses. As a minimum licensing requirement, FDA intended that significant or consistent infractions of State licensing provisions would be necessary to justify suspension and revocation of licenses. States are free to impose stricter requirements, but FDA should not do so. FDA is removing the word "any" from this section in the final rule to convey more accurately the agency's intended meaning, and is stating that State licensing laws shall provide for suspension or revocation of licenses "where appropriate," considering the facts of the violation in question.

H. Minimum Requirements for the Storage and Handling of Prescription Drugs

1. General Comments

25. Several comments objected to the reference to "current good manufacturing practices" in the introductory paragraph to proposed § 205.50. The comments asserted that the agency lacks the authority to impose such requirements on wholesale drug distributors. One comment contended that current good manufacturing practices are "not applicable to the proposed guidelines," and added that making them applicable would be beyond FDA's statutory authority. Another comment stated that the reference to current good manufacturing practices reflected the agency's "confusion." The comment argued that the agency is only entitled to regulate wholesaler operations in "housekeeping and stockkeeping" matters. The comment added that wholesalers deal only with drugs in containers sealed by the manufacturer, so wholesale distributors could not be subject to manufacturing standards.

FDA agrees that it may be confusing to refer, in § 205.50, to "current good manufacturing practices." The provision has been revised accordingly. FDA disagrees, however, that it lacks authority to apply current good manufacturing practice requirements to wholesalers, or that its authority over wholesalers extends only to "housekeeping and stockkeeping matters." Section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)) provides that a drug shall be deemed to be adulterated if "* * * the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to * * * current good manufacturing practice * * *." This section, through the operation of section 301(k) of the act (21 U.S.C. 331(k)), applies to drug wholesalers, retailers, pharmacies, and hospitals, as well as to manufacturers.

While the statutory current good manufacturing practice provisions of the act apply to wholesalers, FDA has not yet issued specific CGMP regulations covering traditional wholesaler activities. (FDA has previously stated that the CGMP regulations set forth in 21 CFR part 211 do not apply to wholesalers engaging in activities that are traditional to those establishments (see 43 FR 45027)). In the absence of specific CGMP regulations governing wholesaler activities, FDA advises that the minimum requirements in § 205.50 of these guidelines may be relied upon by wholesalers to meet applicable obligations under section 501(a)(2)(B) of the act. FDA intends, in the near future, to issue a guideline under § 10.90 of its procedural regulations (21 CFR 10.90), describing acceptable current good manufacturing practices for wholesalers that reflect the approach taken in this final rule.

26. Two comments made the general claim that the storage and handling provisions in proposed § 205.50 are too specific and restrictive. The comments argued that wholesale distributors should be free to choose systems and facility designs that will achieve the goals of PDMA.

The agency disagrees. Congress directed FDA to establish guidelines to "assure uniform standards covering the proper storage and handling of pharmaceuticals by wholesale distributors without regulatory duplication at the State and Federal level," and recommended consideration of the NABP model guidelines for licensing wholesalers in developing this guideline. (H. Rept. 100–76, p. 17). The storage and handling provisions of § 205.50 are responsive to this Congressional direction.

2. Facilities

27. Some comments asserted that proposed § 205.50(a)(3), which says that wholesale distribution facilities must have a designated area for the quarantine of outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs, is burdensome and would result in inefficient use of space by wholesale distributors. One comment stated that this problem could be minimized by specifying that one quarantine area for all substandard goods would be sufficient to comply with the minimum standards. Another comment suggested that deficient products could be identified and isolated by means of computerized inventory control, which would prevent inadvertent shipment without requiring separate quarantine space.

The agency has removed the word "separate" from § 205.50(a)(3), to clarify that a single quarantine area for outdated, damaged, deteriorated, misbranded, and adulterated prescription drugs is permissible. States can, of course, impose quarantine requirements that are stricter than this minimum guideline.

The agency does not believe that a computer-controlled quarantine system, which does not provide for physical separation of the drugs, is appropriate. A contaminated or adulterated prescription drug product is quarantined not only to ensure that it will not be

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distributed to the consumer, but also to prevent it from coming into contact with other drugs it might contaminate. The agency has no knowledge of computer or other systems that would be as effective as physical separation in achieving these goals. In addition, the comments have not shown that providing a physical space for the separation of damaged goods would be burdensome.

28. One comment asked for clarification of the phrase "opened or used outside the care, custody, or control" as used in the description of quarantine procedures required under proposed § 205.50(a)(3). The comment is concerned that the phrase could be interpreted to require quarantine of prescription drugs in circumstances where there has been no compromise of the physical integrity of the drug.

The agency is removing this phrase from the final rule. Section 205.50(a)(3) of the final rule requires that prescription drugs whose immediate containers have been opened or apparently damaged must be quarantined. It is not necessary that there be actual injury to a drug product for quarantine to be required. A suggestion of product damage—such as a dirty or broken immediate product container—would trigger the quarantine requirement.

29. Another comment stated that repackaging facilities should be listed under § 205.50(a) to ensure that storage and labeling standards envisioned by PDMA will be complied with at all facilities where prescription drugs are handled.

The agency does not agree that it is necessary to add repackaging or other facilities under § 205.50(a). These provisions apply to all "wholesale distributors," specifically to any facility that stores, handles, warehouses, or holds prescription drugs for wholesale sale. The provisions thus have a broad application that clearly includes repackaging facilities.

3. Security

30. Two comments argued that the security provisions described at proposed § 205.50(b) are too restrictive and suggested more general alternatives. One of the comments particularly objected to the requirement of an "internal alarm system," noting that other types of systems could be as effective for a given wholesale distribution business. The comment said that wholesale distributors should be free to choose the best alarm system for their facility.

The agency agrees that the requirement that the alarm system be "internal" is too specific and goes beyond the minimum standards to be set by these guidelines. The agency is thus removing this word from § 205.50(b) (2) and (3). Wholesale distributors can choose any alarm system design, consistent with State law and regulations, that is adequate to detect unauthorized entry into the facility and to protect the prescription drug inventory from theft and diversion. The type of alarm system that will satisfy this requirement will depend upon the characteristics of the facility, the wholesale operation, and the State's licensing law.

4. Storage

31. One comment asserted that the storage provisions at § 205.50(c) were too specific and suggested that they be removed. The comment argued that it should be "satisfactory" for FDA to require only that prescription drugs be stored at appropriate temperatures and under proper conditions.

The agency's obligation to impose reasonable storage requirements for prescription drugs goes beyond the general standard suggested by this comment. Congress has mandated that FDA set standards for the storage and handling of prescription drugs by wholesale distributors. These are meant to be minimum standards, but they must be adequate to serve as direction to States in setting up their licensing systems. General statements about "appropriateness" and "adequacy" do not offer sufficient direction to the States. The requirements of § 205.50(c) conform to the storage provisions of the NABP model guideline and, as discussed in paragraph 26, are in line with congressional intent.

32. One comment stated that the storage requirements in proposed § 205.50(c) should specifically exclude wholesale distributors from responsibility for the condition of prescription drugs during transport.

While FDA recognizes practical difficulties involved in maintaining proper storage and handling conditions for prescription drugs in transit, it believes that prescription drugs must be properly handled at all points in the distribution process. Drugs that are improperly handled at any point in the distribution process are subject to enforcement action under the adulteration and misbranding provisions of the act.

It should be noted, however, that the proposed rule does not place the responsibility for assuring proper storage conditions for prescription drugs in transit on the wholesale distributor. The guidelines require that incoming shipping containers be visually inspected by the wholesale distributor for obvious defects or problems caused by improper storage conditions in transit or at any other point in their distribution. Based on this inspection, the wholesale distributor can elect to accept or to refuse acceptance of prescription drugs that appear to be adulterated or misbranded. Responsibility for the condition of shipped drugs does not fall upon the wholesale distributor until acceptance is made.

33. A number of comments asked for clarification of the meaning of "room temperature" as used in the storage requirements in § 205.50(c)(1). The comment asked if FDA meant "controlled room temperature," as the term is used in the United States Pharmacopeia (USP), or "ambient" room temperature. The comments noted that maintaining a "controlled" room temperature would require more sophisticated equipment and higher utility outlays than "ambient" room temperature.

Properly stored prescription drugs must be protected from temperature extremes at all times. To ensure that this minimum standard is met, the agency is requiring that storage facilities be maintained at "controlled room temperature," which is defined in the USP as a temperature that is maintained between 15 and 30 °C (USP XXII (1990), p. 7). This requirement can be met using standard building thermostats and conventional heating ventilating, and air conditioning systems. The agency does not expect this minimum requirement to be burdensome or necessitate the purchase of sophisticated, expensive equipment.

34. A number of comments objected to the proposed requirement in § 205.50(c)(2) that temperature and humidity be recorded on manual, mechanical, electromechanical, or electronic equipment or logs. The comments asserted that this requirement was too costly and argued that current distribution systems include safeguards to ensure proper storage of the few prescription drug products requiring special treatment.

The agency disagrees with the claim that requiring records of storage conditions will impose unnecessary burdens on wholesale distributors. Section 205.50(c)(2), which describes the requirement, does so in very broad terms. The provision allows for operators of facilities to choose from a wide range of possible recording and documentation methods, as long as the choice is appropriate for their facility.

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One of the listed choices is a "manual" procedure by which temperature and humidity information could be written in a log by an employee who reads a thermometer and hydrometer. This option is neither expensive nor burdensome. Other options are similarly reasonable in cost and operation.

5. Examination of Goods and Vehicles

35. Several comments concerned the proposed requirement in § 205.50(d)(1) that wholesalers inspect incoming prescription drugs and delivery vehicles. All of the comments recommended that the scope of any inspection be limited to obvious, apparent defects that can be discovered through a visual inspection. The comments cited the difficulty of determining transit conditions, and questioned the ability and expertise of personnel employed by the wholesale distributor to discover latent defects in vehicles or prescription drugs. The comments argued that requiring more in-depth inspections would be burdensome, costly, and could interfere with commercial relationships.

Some comments noted that a drug may be shipped in more than one vehicle and that only the last one would be available for inspection by the wholesaler. Inspection of this last vehicle would not assure that all transit vehicles were sound and protective of product integrity.

The agency generally agrees with these assertions and has modified the proposed inspection provisions in the final rule so that inspection of the delivery vehicle is no longer required, and inspection of incoming prescription drugs is limited to a visual examination of shipping containers. This inspection should be aimed at detecting damage that would suggest possible contamination of the container's contents. Some level of inspection must be conducted by wholesale distributors to identify the prescription drug and to remove obviously damaged drugs from the distribution system. Wholesale distributors must employ personnel who can perform such inspections.

Moreover, it is in the wholesale distributor's interest to employ personnel who have the ability and expertise to conduct inspections of incoming prescription drug shipments adequate to detect drugs that are not suitable for acceptance. One of the stated purposes of requiring inspection of incoming shipments is to provide an opportunity for wholesale distributors to refuse acceptance of prescription drugs that are unfit for distribution. Once the wholesale distributor has inspected the shipped drugs and elected to accept them, the distributor is responsible for the condition of the drugs. Until that time, the shipper or manufacturer remains responsible for delivering a prescription drug product in acceptable condition.

6. Returned, Damaged, and Outdated Prescription Drugs

36. Several comments addressed proposed § 205.50(e), which describes the obligations of wholesalers with respect to returned, damaged, and outdated prescription drugs. The comments found the entire section to be redundant because its subject matter is covered in other FDA regulations. The comments cited 21 CFR 211.204 and 211.208 as examples of regulations that make proposed § 205.50(e) unnecessary. These are the sections of FDA's CGMP regulations that pertain, respectively, to returned drugs and salvaged drug products.

As discussed previously in this document, the CGMP regulations set forth in 21 CFR part 211 apply to wholesale distributors only when they are engaged in activities that fall outside the scope of a traditional wholesale distribution practice (see 43 FR at 45027). A wholesaler who chooses to handle returned, damaged, or outdated drugs within the scope of traditional wholesale distribution practice is not subject to the CGMP requirements in 21 CFR part 211. Thus, the provisions of § 205.50(e) are not redundant with respect to these procedures. Of course, as stated in § 205.50(j) of this final rule, a wholesaler who engages in repackaging, salvaging, reprocessing, or other manufacturing activities is subject to the GCMP requirements in 21 CFR part 211.

37. Another comment suggested that § 205.50(e) be removed, saying the role that pharmacists play in the distribution of prescription drugs to consumers makes the provision unnecessary.

The requirements of this section are intended to prevent distribution of potentially adulterated or misbranded prescription drugs to consumers. FDA agrees that pharmacists play an important role in achieving this goal, but this does not replace the need for wholesale distributors to take measures, such as those described in proposed § 205.50(e), to remove prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated from wholesale distribution.

38. One comment recommended that proposed § 205.50(e)(2), which requires that prescription drugs in damaged containers be quarantined and physically separated from other drugs, be removed. The comment stated that the requirements of this section are adequately covered by proposed § 205.50(e)(1), which deals with quarantine of adulterated drugs.

The agency disagrees that proposed § 205.50(e)(2) is unnecessary and should be removed. Section 205.50(e)(1) states the requirement that adulterated drug products be quarantined, but does not specifically address the situation, described in § 205.50(e)(2), where damage to prescription drug product containers suggests that the quality of their contents has been compromised. The agency expects that this is the most common circumstance where quarantine is necessary and believes that it must be specifically addressed in the guidelines.

39. Another comment requested that "palletized bulk shipments" be specifically excluded from the container inspection requirement in proposed § 205.50(e)(2), because the language could be interpreted to mean that a prescription drug product would have been quarantined, destroyed, or returned the moment the outer seal of the bulk shipment is opened.

The agency has clarified § 205.50(e)(2) in the final rule to require quarantine when the prescription drug product is damaged or the condition of the sealed immediate or sealed secondary drug container suggests that the contents have been damaged. The guideline does not require quarantine when only the outer seal of a bulk shipment of prescription drug products is opened and this seal is not the immediate or secondary container of the product.

40. Several comments objected to the proposed requirements in § 205.50(e) for handling returned prescription drugs, finding them confusing and inconsistent within the proposal. The comments contend that unlike proposed § 205.50(e)(1) and (e)(2), proposed § 205.50(e)(3) does not allow for return of substandard prescription drugs to the manufacturer as an option for wholesale distributors. Other comments asserted that the requirements of proposed § 205.50(e)(3) were inconsistent with guidance given in FDA's August 1, 1988, letter on PDMA to regulate industry and other interested persons with regard to the handling of returned prescription drugs. That letter provided that hospitals, health care entities, or charitable institutions could destroy unwanted prescription drugs or return them to the manufacturer. The August 1, 1988, letter was supplemented by November 3, 1988, and January 26, 1990, letters that permitted these entities to return prescription drugs under certain specified circumstances.

The agency agrees and has added language to permit the return of

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prescription drugs to the manufacturer or supplier under § 205.50(e)(3) of the final rule.

41. Several comments objected to the requirement in proposed § 205.50(e)(3) that wholesale distributors perform "examination, testing, or other investigation" to determine that a prescription drug meets standards of safety, identity, quality, strength, and purity before returning the product to their shelves. Other comments contended that reshelving of returned drugs products after examination and testing is inconsistent with PDMA because it allows such products to be redistributed. Some of the comments questioned the analytic capability of distributors to comply with the requirement, saying that most wholesale distributors do not now conduct such testing. One comment argued that the requirement could fairly be imposed on manufacturers, but not on wholesalers, and another recommended that only a visual examination be required, with further investigations performed by the manufacturer if the distributor's visual inspection suggested a problem.

PDMA was enacted to decrease the risk that counterfeit, adulterated, misbranded, subpotent, or expired prescription drugs will reach the American consumer. It would violate the purpose of PDMA to allow returned prescription drugs to be distributed to the public without certain assurances. It is not inconsistent with PDMA, however, to permit reshelving of returned drugs that have been shown, through adequate testing measures, to meet acceptable standards.

Section 205.50(e)(3) of the final rule offers several options for the disposition of returned prescription drugs. Under the provision, the wholesaler is allowed to send the returned drug back to the manufacturer, destroy the returned drug, or reshelve it if it meets the testing standards outlined. The wholesaler is not required to choose the testing alternative. If the testing alternative is chosen, the wholesale distributor may elect to have a qualified outside laboratory conduct the analysis if it does not have the appropriate in-house capability. If the wholesale distributor chooses to conduct the testing procedures, pertinent CGMP requirements must be followed, and analyses should be adequate to detect problems with the drug's safety, identity, strength, quality, and purity. The agency does not want to limit testing to a visual examination that could fail to detect potential problems.

7. Recordkeeping

42. Several comments objected to the requirement in proposed § 205.50(f)(1)(iii) that expiration dates be included in disposition records, saying that the requirement would be costly, burdensome, and unnecessary. The comment added that current procedures, such as pharmacists checking dates before dispensing prescription drugs, are adequate to keep expired drugs out of the distribution system as intended by PDMA.

The comments provide adequate evidence that maintaining records of expiration dates is not current standard business practice in the industry, and that incorporating the requirement into current practice may impose some unnecessary burdens on wholesale distributors. The agency is removing proposed § 205.50(f)(1)(iii) and will not require that wholesale drug distributors maintain records of expiration dates of prescription drugs at this time. FDA may impose the requirement in the future if experience with these guidelines suggests it is necessary.

Although not required at this time, the agency encourages keeping records of drug expiration dates. In the agency's view, drug disposition records that include expiration dates are more complete, better facilitate recalls, and help to ensure that outdated drug products are not distributed to American consumers.

43. Several comments questioned the requirement in proposed § 205.50(f)(2), which states that records of the disposition of prescription drugs by wholesale distributors must be available for inspection by authorized officials for a period of 2 years following the expiration dates of such drugs. The comments suggested several alternatives to associating the retention period to the expiration date of the drug.

As previously mentioned, FDA has removed proposed § 205.50(f)(1)(iii), which set forth the requirement that wholesale distributors maintain records of expiration dates of prescription drugs. FDA will therefore not require a record retention time period linked to the expiration date of the drug. Instead, the agency is changing the pertinent provision to establish a record retention period of 2 years following the date of disposition of the prescription drug product. FDA has concluded that this retention period is sufficient to enable the agency to respond to public health emergencies related to the distribution of prescription drugs. The agency anticipates that a vast majority of prescription drugs would be consumed, expired, or destroyed within this time.

44. Several comments objected to proposed § 205.50(f)(3), which established the 24-hour time period allowed for making records available to an authorized official. Calling the time period "unreasonable," the comments suggested it be changed to 72 hours. The comments claimed this would make the requirement consistent with other, unspecified FDA record production requirements.

The provision has been changed in the final rule to allow 2 working days for the production of records that are not kept at the inspection site and are not immediately retrievable by computer or other means. The agency finds this to be a reasonable and appropriate time frame, and is consistent with analogous record production requirements of other government agencies (see, for example, 21 CFR 1304.04).

8. Written Policies and Procedures

45. Some comments addressed the written policies and procedures requirements for licensed wholesale drug distributors in proposed § 205.50(g). The comments agreed that it is appropriate to require a procedure for distributing oldest stock first, but objected to the requirement that deviation from this procedure be justified and documented, arguing that this provision would add to recordkeeping burdens and operating costs.

The agency believes that consistent stock rotation practices, as contemplated in proposed § 205.50(g)(1), are an effective means of ensuring that outdated stock will not be distributed to the consumer. The agency agrees that documentation of deviations from proper stock rotation practices goes beyond minimum standards and has removed the documentation requirement from the final rule. The guidelines now permit deviations from proper stock rotation practices if the deviation is temporary and appropriate.

46. Several comments addressed the proposed provisions in § 205.50(g) (2) and (3) on recall procedures. One comment suggested removal of § 205.50(g)(3)(iii), which requires that there be a procedure for recall of a prescription drug that is to be replaced by a superior product or package design. The comment noted that such a product withdrawal has little to do with health and safety and should be handled at the discretion of the manufacturer and distributor.

The agency agrees that product withdrawals undertaken to enable a manufacturer to replace one packaging design with another for reasons other

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than the promotion of public health and safety goes beyond the scope of this rulemaking. The final rule reflects this change.

47. Several other comments asserted that procedures currently followed by drug manufacturers, wholesale and retail drug distributors, and pharmacists have been quite effective in dealing with recalls. The comments contended that the recall procedures proposed in § 205.50(g) (2) and (3) would impose substantial economic burdens on wholesale distributors without offering any significant improvement in recall accuracy and should therefore be removed from the final rule.

The agency disagrees. The agency believes it necessary that all entities involved in the distribution of prescription drugs have procedures in place for the efficient handling of drug recalls. In this way, each party will be aware of its role in removing potentially dangerous products from the drug distribution system. While prescription drug manufacturers have a primary role in implementing a drug recall, other entities in the drug distribution system must share responsibility for ensuring that all drugs subject to recall are prevented from reaching the American consumer.

48. One comment asserted that the requirement in § 205.50(g)(3) that a wholesale distributor have procedures sufficient to handle "any crisis" is too vague. The comment suggested that the section describe specific procedures to follow in case of strike, fire, flood, and natural disaster or emergency.

Specific procedures for crisis situations, such as a strike, fire, flood, or other natural disaster, are best left to the individual States. It would not be appropriate for the agency to attempt to describe plans for handling specific kinds of crises.

49. Two comments questioned the expertise of the wholesale distibutor for making the determination, required in proposed § 205.50(g)(5)(i), that prescription drug stock in wholesale distribution has an expiration date that is sufficient for a drug to get to the consumer. Both suggested that it would be more appropriate for a pharmacist or physician to make such a judgment.

The agency agrees that making the determination required under proposed § 205.50(g)(5)(i) may require a degree of judgment that is beyond the expertise of wholesale distribution personnel. The agency has therefore removed this requirement from the final rule.

51. One comment objected to the 2-year retention requirement, under proposed § 205.50(g)(5)(ii), for documents relating to the disposition of outdated stock. The comment recommended that requiring retention for 1 year from the expiration of the prescription drug would be consistent with FDA's CGMP regulations in 21 CFR part 211.

A 2-year record retention requirement is consistent with the other record retention provisions in these guidelines, and the agency is not persuaded that the change recommended by this comment is appropriate.

9. Responsibility

52. One comment suggested that § 205.50(h) be amended to clarify whether manufactures could be "held liable" for using unlicensed wholesale distributors. This comment was not specific as to what kind of liability was of concern.

The liability of manufacturers for actions in tort is governed by State law and is beyond the scope of this rulemaking.

53. Another comment asserted that the requirement in proposed § 205.50(h) that a list of qualifications of management, directors, and others in charge be maintained is an "unnecessary police state intrusion and subject to a difference of opinion." The comment said that such a list is irrelevant to achieving the goals of PDMA and would be difficult and costly for State boards to administer.

The agency disagrees with the contention that the list of responsible persons required by this section is unnecessary or excessively burdensome. The agency expects that a majority of wholesale distribution businesses would have this information readily available. The information required in this list is minimum information necessary for administration of these guidelines by the State licensing authorities.

10. Compliance With Other Laws

54. Proposed § 205.50(i) required wholesale drug distributors to operate in compliance with all applicable laws and regulations, including local laws. Proposed section 205.50(j) required wholesale drug distributors to comply with only applicable Federal and State laws relating to salvaging and reprocessing, but did not require wholesale drug distributors to comply with local laws relating to salvaging and reprocessing. On its own initiative, FDA is amending § 205.50 to make paragraphs (i) and (j) consistent, and to make it clear that wholesale drug distributors must comply with local laws relating to salvaging and reprocessing.

This substantive rule is being made effective immediately upon publication. The agency has found that there is good cause for this immediate effective date (see 5 U.S.C. 553(d)(3)). PDMA provides that the licensing requirements for wholesale distributors mandated by section 503(e)(2)(A) of the act (21 U.S.C. 353(e)(2)(A)) will not go into effect until the expiration of 2 years after the date this regulation is promulgated and takes effect (see section 8(b)(2) of PDMA). States and wholesalers will have 2 years in which to conform their activities to this rule before any enforcement action could be taken by FDA. Thus, the normal 30-day delay in effectiveness is subsumed in the 2-year delay mandated by PDMA. There is no need to have the rule take effect 2 years and 30 days after publication, because the 2-year period provides ample time for the States and wholesalers to conform their activities to the requirements of this rule. In addition, Congress has indicated its interest in having this rule promulgated expeditiously (see section 8(a)(2) of PDMA). The waiver of the 30-day delay is consistent with the congressional desire that FDA promulgate this rule in a short time.

List of Subjects in 21 CFR Part 205

Drugs, Labeling, Manufacturing, Warehouses, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, chapter I, subchapter C of title 21 of the Code of Federal Regulations is amended by adding new part 205 to read as follows:

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Sec.

Authority: Secs. 501, 502, 503, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 371, 374).

§ 205.1 Scope.

This part applies to any person, partnership, corporation, or business firm in a State engaging in the wholesale

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distribution of human prescription drugs in interstate commerce.

§ 205.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.

§ 205.3 Definitions.

(a) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(b) *Blood component* means that part of blood separated by physical or mechanical means.

(c) *Drug sample* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(d) *Manufacturer* means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(e) *Prescription drug* means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(f) *Wholesale distribution* and *wholesale distribution* means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

(g) "Wholesale distributor" means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

§ 205.4 Wholesale drug distributor licensing requirement.

Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.

§ 205.5 Minimum required information for licensure.

(a) The State licensing authority shall require the following minimum information from each wholesale drug distributor as part of the license described in § 205.4 and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) The State licensing authority may provide for a single license for a business entity operating more than one facility within that State, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within that State when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) Changes in any information in paragraph (a) of this section shall be submitted to the State licensing authority as required by such authority.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0251)

§ 205.6 Minimum qualifications.

(a) The State licensing authority shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:

(1) Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under Federal, State, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State licensing authority or to Federal, State, or local law enforcement officials those records required under this section; and

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(8) Any other factors or qualifications the State licensing authority considers relevant to and consistent with the public health and safety.

(b) The State licensing authority shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

§ 205.7 Personnel.

The State licensing authority shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

§ 205.8 Violations and penalties.

(a) State licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties.

(b) State licensing laws shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

§ 205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

The State licensing law shall include the following minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(a) *Facilities.* All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) *Security.* (1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) *Storage.* All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all stored drugs.

(d) *Examination of materials.* (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) *Returned, damaged, and outdated prescription drugs.* (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) *Recordkeeping.* (1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 2 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not

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electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

(g) *Written policies and procedures.* Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) *Responsible persons.* Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) *Compliance with Federal, State, and local law.* Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0251)

Dated: June 9, 1990.

James S. Benson

Acting Commissioner of Food and Drugs.

[FR Doc. 90–21616 Filed 9–13–90; 8:45 am]

BILLING CODE 4160–01–M

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4-1-91
5:02 pm.

Attn: 8-18

Kansas State Board of Pharmacy

LANDON STATE OFFICE BUILDING
900 JACKSON AVENUE, ROOM 513
TOPEKA, KANSAS 66612-1220
PHONE (913) 296-4056

STATE OF KANSAS

JOAN FINNEY
GOVERNOR

HB 2608 TESTIMONY

HOUSE PUBLIC HEALTH

AND WELFARE COMMITTEE

APRIL 1, 1991

MADAM CHAIRMAN, MEMBERS OF THE COMMITTEE, MY NAME IS TOM HITCHCOCK AND I SERVE AS THE EXECUTIVE SECRETARY OF THE BOARD OF PHARMACY. I APPEAR BEFORE YOU TODAY ON BEHALF OF THE BOARD IN SUPPORT OF HB 2608.

THE BOARD OF PHARMACY, UNDER KSA 65-1643, ALREADY HAS STATUTORY AUTHORITY TO REGISTER A WHOLESALER WHICH DISTRIBUTES DRUGS TO PHARMACIES IN KANSAS. THERE IS, HOWEVER, NOW THE MANDATE BY THE FEDERAL FOOD, DRUG AND COSMETIC ACT (FDA) UNDER THE PRESCRIPTION DRUG MARKETING ACT (PDMA) THAT EACH STATE SHALL NOT ONLY REGISTER, PERMIT OR LICENSE THE WHOLESALERS BUT ALSO PROMULGATE REGULATIONS THAT WILL MORE SPECIFICALLY REGULATE SUCH OPERATIONS. UPON A REQUEST, THE ATTORNEY GENERAL DENOTED THE BOARD DID NOT HAVE STATUTORY AUTHORITY TO PROMULGATE THE REGULATIONS, THUS THE REQUESTED STATUTORY CHANGE. THE PURPOSE FOR THE PDMA IS AN EFFORT TO CURTAIL THE DIVERSION AND ILLICIT DISTRIBUTION OF LEGAL DRUGS.

THE BOARD OF PHARMACY RESPECTFULLY REQUESTS THE FAVORABLE PASSAGE OUT OF COMMITTE OF HB 2608.

THANK YOU.

PHHCW
4-1-91
5:00 pm
Attm 9

KANSAS HEALTH AND ENVIRONMENTAL LABORATORY
Department of Health and Environment

MEMORANDUM

TO: Staff, House of Representatives, Public Health & Welfare Committee

FROM: Dr. Patrick Hays, Senior Laboratory Scientist, KDHE State Laboratory

DATE: March 28, 1991

SUBJECT: Questions asked by committee members during discussion of Senate Bill 254 on March 27

1. Statutory requirements for prenatal syphilis testing has been present in Kansas since the mid-1940s. At the present time, this testing is required in all but five states and territories.

2. My best guess of less than 1% positive rate for syphilis among prenatal clients was verified in our database of annual reports. In addition, conversations with the Bureau of Disease Control, STD director, Jerry Johnson, established that the rate of congenital syphilis cases has reached 174/100,000 nationally, while two such cases occurred in Kansas last year. One of these cases was due to lack of secondary prenatal testing after this woman was exposed to syphilis during her pregnancy. Penicillin is the therapy of choice for treatment of infected prenatal cases even if desensitization is required.

3. For the last four fiscal years, we have had approximately 280 new syphilis infections per year with a total of about 30,000 specimens tested annually; however, last year the total number of specimens rose to 43,000 with no increase in positive specimens, and this year we estimate over 45,000 specimens will be analyzed with no significant rise in positive determinations.

4. The reagent costs for screening a VDRL assay is 30 cents while the $2.00 cost mentioned relates to the total cost if confirmation by an FTA-ABS assay is required. A one to one ratio of cost per specimen is not possible since a minimum quantity of reagents and controls must be prepared each day whether a small or large number of specimens are being analyzed. The technical time of specimen preparation, data entry, and records manipulation are the personnel time savings that we hope to more efficiently utilize in areas less available for testing such as hepatitis B infections among health department prenatal clients which is now a standard of practice in the private medical sector.

PH&W
4-1-91
5:00 pm
attm # 10

State of Kansas
Joan Finney, Governor
Department of Health and Environment
Kansas Health and Environmental Laboratory
Forbes Field, Bldg. 740, Topeka, KS 66620-0002
(913) 296-1620
FAX (913) 296-6247

Stanley C. Grant, Ph.D.,
Acting Secretary

Testimony presented to

House Public Health and Welfare Committee

by

The Kansas Department of Health and Environment

Senate Bill 254

Successful control of syphilis and other sexually transmitted diseases in Kansas is dependent upon closely coordinated efforts in health education, patient care, and clinical laboratory support. K.S.A. 65-153f does help to assure the uniform quality of prenatal laboratory tests for the prevention of congenital syphilis. Although prevention of the devastating effects of congenital syphilis warrants continuation of the prenatal screening requirement, from a statewide perspective, prenatal clients are generally at lower risk for syphilis than many other client groups. Thus, 16,000 routine prenatal syphilis serology tests now performed by the state laboratory each year would be more appropriately performed in approved private laboratories.

The primary role for the state public health laboratory is to focus first on diagnostic and prevention programs in high risk behavior clients, to support local health department prevention and treatment programs, and to provide reference laboratory services which confirm initial screening results detected in private clinical laboratories. However, the present wording of K.S.A. 65-153f places the state public health laboratory in a competitive position with approved private laboratories performing routine screening tests on low-risk clients. It is for this reason that a modification in the wording of this statute is recommended.

The state public health laboratory is publicly funded and thus has major obligation to ensure that laboratory services provided with public funds are consistent with public health priorities. This statutory change will help to align public health priorities with appropriate state laboratory services.

Testimony presented by: Patrick L. Hays, Ph.D.
Senior Public Health Laboratory Scientist
Kansas Health and Environmental Laboratory
March 27, 1991

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4-1-91
5:00 pm.
attm # 11

Charles Konigsberg, Jr., M.D., M.P.H., Director of Health (913) 296-1343
Ronald Hammerschmidt, Ph.D., Acting Director of Environment (913) 296-1535
Lorne Phillips, Ph.D., Director of Information Systems (913) 296-1415
Roger Carlson, Ph.D., Director of the Kansas Health and Environmental Laboratory (913) 296-1619