Approved 4-12-91
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by SENATOR ROY M. EHRLICH at
Chairperson

8:00 a.m.~~p.m.~~ on April 10, 1991 in room 526-S of the Capitol.

All members were present except:

Committee staff present:

Emalene Correll, Legislative Research
Bill Wolff, Legislative Research
Norman Furse, Revisor's Office
Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:

Tom Hitchcock, Board of Pharmacy
John P. Collinsworth, MWC, Inc., Amfac Health Care
Bob McDaneld, Board of Emergency Medical Services
Steve McDowell, Department of Health and Environment
Orville Voth, Kansas Silver Haired Legislature

Chairman Ehrlich called the meeting to order at 8:00 a.m.

HB 2608 - Registrations to deliver drugs at wholesale.

Tom Hitchcock, Board of Pharmacy, submitted written testimony and appeared before the committee in support of HB 2608. Mr. Hitchcock stated the Attorney General denoted the Board did not have statutory authority to promulgate regulations mandated by the Federal Food, Drug and Cosmetic Act (FDA) and that passage of HB 2608 was needed to give them this authority. If authority was not granted to promulgate the regulations, the wholesalers and manufacturer distributors have the possibility of being fined and/or up to ten years in jail. (Attachment 1) The time line designated by the federal government, September 14, 1992, and minimum training to be determined by the Board were discussed.

John P. Collinsworth, Distribution Center manager of Amfac Health Care, Shawnee Mission, Kansas, submitted written testimony and stated his concern that strict penalties would be applied if HB 2608 was not passed. (Attachment 2)

The Chairman asked for wishes of the committee on HB 2608. Staff Furse pointed out a technical change was needed regarding wording in the bill on page 1 that should read "distribute" at wholesale, instead of "deliver" at wholesale. It was the consensus of the committee to adopt that correction. Senator Burke made the motion to recommend HB 2608 as amended favorably for passage. Seconded by Senator Langworthy. No discussion followed. The motion carried. The bill will be carried by Senator Langworthy.

SCR 1623 - Encouraging Kansas to pursue status as an EACH project state.

Bob McDaneld, Board of Emergency Medical Services, submitted written testimony and appeared in support of SCR 1623. He stated access to adequate health care is an important issue facing rural Kansans, and that small hospitals were faced with the option of reducing services or closing. Communities were losing physicians through retirement or attrition who cannot be replaced, emergency medical services were having difficulty in recruiting volunteers, and a critical shortage of nurses and allied health personnel existed. He urged the committee to support passage of this resolution. (Attachment 3)

Steve McDowell, Department of Health and Environment, submitted written testimony and appeared in support of SCR 1623. He stated the Essential Access Community Hospital (EACH) project allowed for local planning, local networking and local decision making, and that more than 20 communities in Kansas have examined the project and made application to the Office of Rural Health for participation. (Attachment 4)

The Chairman asked for wishes of the committee on SCR 1623. Senator Walker made the motion to recommend SCR 1623 favorably for passage. Seconded by Senator Hayden. No discussion followed. The motion carried. Senator Hayden will carry the resolution.

Written testimony on SCR 1623 in support of the resolution was distributed to the committee from the Kansas Hospital Association. (Attachment 5)

HCR 5008 - United States congress urged to provide comprehensive national health plan.

Orville L. Voth, Kansas Silver Haired Legislature, submitted written testimony and appeared in support of HCR 5008. Mr. Voth stated the federal government should be the major enabler of any comprehensive health care system so there would be broad universal policy parameters to guide the system. He urged the passage of the resolution as a signal to the federal congress that universal health care is a priority concern for all Kansans and a responsibility of both national and state government. (Attachment 6)

Senator Walker made the motion to recommend HCR 5008 favorably for passage, seconded by Senator Burke. No discussion followed. The motion carried. Senator Walker will carry the resolution.

Written testimony on HCR 5008 was submitted by Gigi Felix, National Association of Social Workers, Inc. in support of the resolution. (Attachment 7)

Final Action:
HB 2104 - Licensure of speech pathologists and audiologists.

Staff Furse explained balloon of HB 2104 which was distributed to the committee showing proposed amendments. (Attachment 8) Question regarding hearing evaluation at public events such as the State Fair was discussed. Representative Allen White, Audiologist from Salina, stated the bill would not affect those groups testing hearing at the Fair. Language relating to members on the board on page 3, line 3, "physician licensed to practice medicine and surgery" was discussed. It was suggested in order to avoid potential conflict, the word "physician" should be deleted and "person" inserted. It was the consensus of the committee to delete the word "physician" and insert "person", on page 3, line 3 of the bill. Senator Langworthy made the motion to adopt the amendments on page 3. The motion was seconded by Senator Hayden. No discussion followed. The motion carried. Senator Hayden made the motion to change the effective date by striking "1992" and insert "1993" on page 4, line 9 on the bill. Senator Walker expressed concern 2 and 1/2 years was too long, and that the date stated was sufficient. Senator Hayden withdrew his motion. It was the consensus of the committee to leave language on page 4, line 9. Consensus of the committee was asked on page 6. Senator Walker expressed his concern regarding the grandfathering clause requested by KDHE and felt the action taken by the House Committee covered the subject. After committee discussion Senator Walker made the motion to remove the proposed amendment requested by KDHE on page 6, line 15. The motion was seconded by Senator Vidricksen. No discussion followed. The motion carried. It was the consensus of the committee to adopt the amendment on page 8, line 9. The Chairman asked for wishes of the committee on HB 2104. Senator Walker moved to recommend HB 2404 as amended favorably for passage. The motion was seconded by Senator Vidricksen. No discussion followed. The motion carried. The bill will be carried by Senator Vidricksen.

The meeting was adjourned at 8:45 a.m.

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE
DATE 4-10-91

(PLEASE PRINT) NAME AND ADDRESS	ORGANIZATION
Cecille C. Voth, Lawrence	Silver Haired Legislature
Melissa Hungerford	KHA
Bob McDaniel	EMS
Steve McDowell	KDHE
Lyndsey D [illegible]	KDOT
Ken Bahr	Speech, Hearing Assn
Amanda Brandt	KS. Speech-Lang-Hg Assoc.
JOHN COLLINSWORTH	AMFAC HEALTH CARE
Tom Hitchcock	Bd. Pharmacy

Kansas State Board of Pharmacy

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TOPEKA, KANSAS 66612-1220
PHONE (913) 296-4056

STATE OF KANSAS

JOAN FINNEY
GOVERNOR

HB 2608 TESTIMONY

SENATE PUBLIC HEALTH

AND WELFARE COMMITTEE

APRIL 10, 1991

MR. 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 REQUIRED A 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 BY THE BOARD, 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.

Senate P H&W
Attachment #1
4-10-91

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

Senate P H&W 4-11-91
Attch #8
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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
Director of Scientific & Legal Affairs

CHB/klr

attachments

Federal Register

Friday
September 14, 1990

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

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.

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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

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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.

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(t). See also May 25, 1982, 47 FR 22518; 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.

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

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]

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MWC Inc.
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Testimony in regard to H.B. 2608.

Presented by:
John P. Collinsworth
Distribution Center Manager
MWC, Inc. dba
Amfac Health Care

At the Senate Health and Welfare Committee:
April 10, 1991
Topeka, KS

As manager of Amfac Health Care's Merriam, Kansas distribution Center, I represent the only full service pharmaceutical wholesaler still located in the state of Kansas.

On September 14, 1990, the FDA published its final **Guidelines for State Licensing of Wholesale Prescription Drug Distributors**, pursuant to the Prescription Drug Marketing Act, in the *Federal Register*. PDMA prohibits wholesale distribution of prescription drugs in interstate commerce unless the wholesale distributor or manufacturer is licensed by a state in accordance with these final guidelines. Under the provisions of PDMA, each state has two years from the date the guidelines were published in which to comply.

With this deadline only sixteen months away, Amfac Health Care, and its employees in the state of Kansas, have a vested interest in H.B. 2608 and any future legislation concerning PDMA.

Having just recently become aware of this proposed legislation, I am here to gain a greater understanding of the legislation, not to speak for or against it.

Senate P H&W
Attachment #2
4-10-91

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 10, 1991

TO: Senate Committee on Public Health and Welfare

FROM: Bob McDaneld, Administrator

SUBJECT: Testimony on Senate Concurrent Resolution 1623

Access to adequate health care is an important issue facing rural Kansans. This issue has many aspects. Small hospitals are facing the option of reducing services or closing, communities are losing physicians through retirement or attrition who cannot be replaced, emergency medical services are having difficulty in recruiting volunteers, and there is a critical shortage of nurses and allied health personnel.

The Board of Emergency Medical Services is one of three members of the public/private partnership which is exploring this issue. In cooperation with the Department of Health and Environment and the Kansas Hospital Association, the board has provided staff support to the technical advisory group which has been studying the possibility of Kansas participation in the federal EACH program.

At its February 2, 1991, meeting, the board voted to support passage of a concurrent resolution which would recognize the financial commitment of the Wesley Foundation, the uniqueness of the public/private partnership, and the volunteer work of the technical advisory group in helping to develop a comprehensive plan for insuring access to adequate health care in rural areas. The board believes the EACH program would be an important component of this plan. On behalf of the board, I urge your support of Senate Concurrent Resolution 1623.

RM/st

Senate P H&W
Attachment #3
4-10-91

State of Kansas
Joan Finney, Governor

Department of Health and Environment
Division of Health

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

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Testimony Presented

to

Senate Public Health and Welfare Committee

by

The Kansas Department of Health and Environment

Ladies and Gentleman of the Committee, I thank you for the opportunity to testify before you today concerning the Resolution supporting the state application for participation in the federal Essential Access Community Hospital (EACH) Demonstration Program.

In 1989 the United States Congress passed legislation creating the EACH Demonstration Project. The EACH project proposes to provide incentives for restructuring rural delivery systems with the goal of creating more effective rural health networking and better integrated services. Seven states will be picked to participate in this demonstration project.

In the spring of 1990, the Kansas Department of Health and Environment, the Kansas Hospital Association and the Kansas Board of Emergency Medical Services jointly presented an application for grant funding to the Wesley Foundation. This public/private partnership requested funding to study the applicability of the EACH federal demonstration project for Kansas. In June of 1990 the Wesley Foundation awarded this unique public private partnership a grant of $263,000 for "The EACH Concept: A Study of Applicability in Kansas". At the heart of the study was the development of the Technical Advisory Group. A 30 member body comprised of representatives of hospitals, physicians, nurses, public health officials, rural citizens, and health financial experts. This group was facilitated by national consultants to explore in depth the needs for change in the rural health delivery system and specifically to examine and recommend whether or not the state of Kansas should pursue participation in the federal EACH demonstration project. After ten months of work the Technical Advisory Group has recommended that the state make application to be one of the seven demonstration sites for the EACH project.

Senate P H&W
Attachment #4
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Our public/private partnership believes that the rural health delivery system must be restructured to adapt to the rapidly changing health care environment. We are committed to ideas that allow change to be controlled at the local level. The EACH project allows for local planning, local networking and local decision making. More than 20 communities in Kansas have examined this project and have made application to the Office of Rural Health for participation in this project. Your support of this project by passing the proposed Resolution will provide the Health Care Financing Administration with evidence that the state of Kansas is firmly committed to participation in this Rural Health Networking Demonstration Project.

KANSAS HOSPITAL ASSOCIATION

Memorandum

Donald A. Wilson
President

April 9, 1991

TO: Senate Public Health and Welfare

FROM: Kansas Hospital Association

SUBJECT: SENATE CONCURRENT RESOLUTION 1623

In 1990, the federal government funded a new concept referred to as the Essential Access Community Hospital (EACH). The legislation established small, Rural Primary Care Hospitals (RPCHs or PCHs pronounced "peach") and linked them with larger, supporting facilities called EACHs. The legislation established a federal program of grants to states and individual hospitals within those states for the purpose of implementing this concept, along with special reimbursement arrangements. While the legislation also described the concept and the basic requirements for these facilities, it did not go into any detail about their specific services or relationships.

To determine how these types of facilities might be configured in Kansas, the Wesley Foundation funded a public-private partnership between KDHE, BEMS and KHA which took on the task of designing a Kansas-specific system. A broad-based Technical Advisory Group (TAG) was appointed and began their work in the summer of 1990.

The federal legislation established two components. The first is an ongoing program to designate EACHs and RPCHs. The second is a program of grants to be awarded to seven states. Only the seven states who are awarded grants will be able to implement the ongoing program designating EACHs and RPCHs.

We would like KDHE to apply on behalf of the partnership to be one of the seven grant states and establish a program designating EACHs and RPCHs. SCR 1623 asks for the Legislature's support in this effort.

TLB:mkc

Senate P H&W
Attachment 5
4-10-91

1263 Topeka Avenue • P.O. Box 2308 • Topeka, Kansas 66601 • (913) 233-7436 • FAX (913) 233-6955

Testimony before the Senate Public Health & Welfare Committee
Re: HCR 5008
April 10, 1991
Orville L. Voth, Speaker, Kansas Silver Haired Legislature

I appreciate the opportunity to appear as a proponent of Concurrent Resolution 5008, representing the Silver Haired Legislature.

Support for this resolution rests on a very simple premise, namely, that the federal government should be the major enabler of any comprehensive health care system so that there will be broad universal policy parameters to guide the system. Such a system should, however, be administered by state authorities and I note that the original version of HCR 5008 has been amended to include that stipulation.

I am fully aware of SB 205 and the fact that there are other state-initiated programs in this area of concern. It should be noted, however, that many proponents of such programs across the country argue that state-based health care systems should serve as pilot or model programs for a national system. I submit that lack of such models is not the problem. The problems are inertia at the federal level, oppositon by special interest groups (e.g., there is an alleged coalition of Congress, the president and the health care industry), and a mind-set that it can't be done or that voters don't really want it. It is worth noting that an NBC 1989 poll showed that 67 percent of Americans prefer a comprehensive national health plan that covers all Americans and is paid for by federal tax revenues. One may also cite public statements supporting a national health program by such groups as the AARP, Citizens Action (a national grassroots group), Gray Panthers, the Heritage Foundation, Physicians for a National Health Plan, the National Insurance Organization and the Kansas Silver Haired Legislature, representing over 400,000 senior citizens in Kansas.

Therefore, I urge that Concurrent Resolution 5008 be passed as a signal to the federal Congress that universal health care is a priority concern for all Kansans and a responsibility of both national and state government.

Thank you

Senate P H&W
Attachment #6
4-10-91

KANSAS NASW

National Association of Social Workers, Inc.
Chapter Office
817 West Sixth Street
Topeka, Kansas 66603

Telephone: 913-354-4804

April 10, 1991

TESTIMONY IN SUPPORT OF HCR 5008

By: Gigi Felix, LMSW
Executive Director

Senator Ehrlich and members of the Senate Committee on Public Health and Welfare. I am Gigi Felix, the Executive Director of the Kansas Chapter of the National Association of Social Workers.

Thank you for giving me the opportunity to submit written testimony in support of HCR5008. Our National Office has been pursuing the goal of federal legislation for National Health Insurance for several years. Attached for your information are copies of several documents:

- a summary of NASW proposed National Health Care components.
- a sample resolution as developed by the National Office for use by Chapters of the organization which embodies our "dream" plan, and
- a copy of a news article which appeared in the NASW national newsletter in February 1991 showing a cost analysis of such a plan.

We are working with Sen. Walker for SB205 - now scheduled for Summer Interim Committee study - so at least residents of our state can have accessible, affordable, quality health care, and business can afford to continue covering employees, and their dependants.

Again, we can not say strongly enough that this issue is of great concern to NASW at every level, especially here in Kansas.

Thank you for your time. PLease contact me at our Chapter Office if I can be of any help in answering any questions you may have.

Senate P H&W
Attachment #7
4-10-91

NASW National Health Care Plan

In response to our nation's severe health care crisis, the NASW developed a National Health Care (NHC) plan that fundamentally restructures our costly and inefficient health system and provides every American with comprehensive health and mental health services, including long-term care.

The basic components of the NHC Plan include:

- A single-payer health system administered by the states under federal guidelines.
- Universal access for all U.S. residents regardless of race, national origin, income, religion, age, sex, sexual preference, language, or geographic residence.
- Freedom to choose from among any of the participating public and private providers.
- Expansion of public health functions for disease prevention and health promotion.
- Care coordination services to ensure appropriate and cost-efficient health care.
- No cost-sharing, except for a modest room and board fee based on income for nursing home care. The plan allows limited cost-sharing based on income, if necessary, to control excess utilization.
- Global budgeting for states with expenditure targets by category of services.
- Global budgeting for hospitals and prospective payment options for other health facilities, with state regulated funds for capital expansion and purchase of highly-specialized equipment.
- Negotiated fee schedules for physicians and other health care practitioners.
- Emphasis on community-based health and mental health services, including home health care for those in need of long-term care, regardless of age.
- Health planning at all levels to ensure more efficient utilization and equitable distribution of health resources.
- Financing primarily through a dedicated federal tax on personal income and a federal employer payroll tax. Additional sources of revenue include state contributions, earmarked estate taxes, and higher taxes on alcohol and cigarettes.
- Quality assurance standards for all health care providers with federal and state responsibility for data collection, evaluation and monitoring of appropriate treatment and utilization.
- Targeting of essential health and mental health services for underserved populations.
- Expanded federal support for training/education of health/mental health professionals and allied personnel.
- Continued support for basic biomedical and mental health research, and research efforts that will improve the delivery of cost-conscious, quality health care.
- Support for medical malpractice reform.

SAMPLE RESOLUTION ON NATIONAL HEALTH CARE

(May be used by chapters to get a resolution passed on national health care by state legislatures, state or local political organizations, professional organizations or coalitions where the NASW chapter is a member.)

Whereas the health of the nation is short of what can be achieved;

Whereas the cost of health care in the U.S. has reached an unacceptable level with no end in sight;

Whereas thirty-seven million people have no health insurance and fifty million people lack adequate insurance coverage;

Whereas the burden of providing health care for the uninsured falls disproportionately on those employers that do provide insurance to their own employees and in the process subsidize uncompensated care;

Whereas the U.S. spends $600 billion a year on health care constituting almost twelve percent of the Gross National Product;

Whereas this expenditure is larger than that of any other nation;

Whereas the health status of our citizens is worse than that of many other nations that spend relatively less than we do for health care;

Whereas health care costs are rising at a faster rate than those in other sectors of the economy;

Whereas cost containment measures by a single organization, business, or state are only marginally effective in containing costs;

Whereas piecemeal approaches to the health care crisis have been unsuccessful;

Whereas all citizens are entitled to comprehensive community and personal health programs that emphasize health promotion and disease prevention and provide efficient, high quality services;

Now, therefore, be it resolved that it is the sense of the **(name of organization)** that the **(organization)** should advocate, and the U.S. should enact, a National Health Care program with the following characteristics:

- Universal access and delivery of services regardless of income, age, race, gender, health status, or geographic location;
- Comprehensive health and mental health benefits, including long-term care;
- Progressive financing with little or no consumer cost-sharing;
- A single-payer health system administered by the states under federal guidelines;
- Freedom to choose among any of the participating public and private providers;
- Incentives and safeguards to assure effective and cost efficient organization and delivery of services and high quality care;

- Technology assessment and practice guidelines that encourage appropriate utilization by consumers;
- Fair payment to providers using negotiated fee schedules, global budgeting for hospitals and prospective payment options for other facilities with regulation of capital expenditures;
- Ongoing evaluation and planning to improve the delivery of health services and promote efficient utilization and equitable distribution of health resources;
- Community based disease prevention and health promotion programs; and
- Consumer access to adequate information on the quality and costs of health care services.

NOTE: This resolution is based on a resolution developed by the NASW New Hampshire Chapter.

NASW NEWS

National Association of Social Workers • Silver Spring, Maryland • Volume 36, Number 2 • February 1991

National Health Care Proposal by NASW Would Save U.S. Billions, Analysts Find

By M. Scott Moss
NASW NEWS Managing Editor

THE NATIONAL HEALTH care plan NASW unveiled last spring would save the United States $200 billion to $300 billion a year at the turn of the century, independent economic analysts confirmed on Jan. 8.

In releasing the analysts' projection of the plan's cost at a Capitol Hill press conference, NASW became the first national organization in the country to go on record with a detailed cost estimate for a health care plan that would cover all U.S. residents and rely on a single payment source.

"We expect this proposal to be introduced as a bill in Congress very shortly, and we will work to move that bill through Congress," NASW President Richard L. Edwards told reporters from the national news media.

"We call upon Congress and the president to responsibly address the health care needs of all Americans and to courageously expend the resources needed now in order to save later," he urged.

President Richard L. Edwards (right), with economist Zachary Dyckman and NASW's Judy A. Hall, briefs reporters at Capitol Hill press conference.

Edwards said that the association will mobilize its 135,000 members and 55 chapters to lobby for the plan's enactment.

The proposal, based on the 1979 Delegate Assembly's "National Health" policy statement and shaped by NASW's Legislative Affairs Department in concert with numerous social work experts and the NASW Health and Mental Health Commission, underwent the independent cost analysis after it was announced in the May 1990 *NASW NEWS*.

"In the long run, we project that the NASW plan, with expanded coverage for the entire population, will cost less than maintaining current systems of care," said Zachary Dyckman, executive vice-president of the Center for Health Policy Studies, who analyzed the proposal in consultation with the Actuarial Research Corporation.

Dyckman acknowledged that in the plan's first full year of implementation, it would cost about $40 billion to $77 billion more than is currently spent on health care, depending on whether a system of nominal, income-based copayments were used.

But by the year 2002, if the co,

(See HEALTH, page 14)

Health Plan's Costs, Advantages Analyzed

HEALTH

CONT'D FROM P. 1

ments were applied, the plan would reduce health care spending by $308 billion, he said.

The annual savings would amount to nearly $200 billion even if a long-term care benefit were added at a price tag of $46.5 billion.

The study projected the long-term care benefit's cost separately because, "for the most part, [long-term care costs] are not reflected in current health care expenditures," Dyckman noted.

Under the copayment system, persons with incomes below 150 percent of the federal poverty line would pay nothing out-of-pocket for outpatient visits and prescription drugs. Others would pay from $5 to $15 for visits and from $1 to $5 for prescriptions, with those who earn more than $100,000 paying the highest amounts. Yearly out-of-pocket spending would be subject to caps ranging from $1,000 to $3,000, also geared to income.

For the long-term care benefit, consumers' share of the costs would range from $5 to $10 per service for in-home and community-based services, and from 10 percent to 30 percent of nursing home room-and-board costs, depending on income and on the length of stay.

The analysts did not estimate what the entire plan's cost would be in the year 2002 if no copayments were required.

They also did not attempt to gauge additional savings that would accrue as a result of the plan's nationwide coverage of preventive care and its promotion of widespread health education.

According to Dyckman, the plan's reliance on a uniform package of comprehensive benefits and a single payment source—the states, under federal guidelines—would reduce the amount currently spent on health care administrative costs by $9.6 billion, or 30 percent.

In addition, its prospective budgeting and other reforms would cut the cost of hospital care by $2.4 billion, or nearly 1 percent, he said.

Dyckman acknowledged that the plan's expansion of benefits for dental care and other professional services, including mental health services, would "very substantially" increase their costs over current levels. About $23 billion more would be spent for dental care, and about $18 billion more for other professional services.

But these services, he noted, "are not well covered under most insurance programs now," keeping current spending low because many consumers forgo the services as a result.

"I would like to stress that our cost estimates are based on a benefit package that far exceeds most private insurance coverage—and is extended to the entire population," Dyckman said.

At least 13.5 percent of the U.S. population is excluded from service by the current health care system, on which the nation now spends 12 percent of its gross national product (GNP), according to NASW's figures. By 2002, if health care costs increase at an average annual rate of 9.5 percent, the current system's bite out of the GNP would be 15.5 percent, Dyckman estimated.

But under NASW's plan, with copayments, only 13.1 percent of the GNP would be consumed in 2002 (14 percent if the long-term care benefit were included), while all U.S. residents would be served, he said.

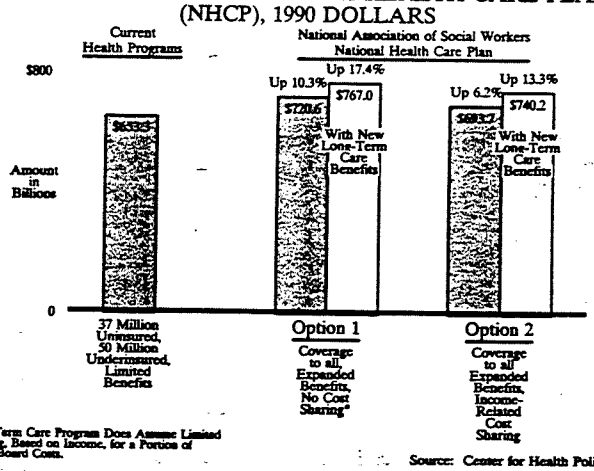
The plan would be funded by an earmarked federal personal-income tax and an employer payroll tax.

Dyckman said he anticipated that individuals would pay, on average, about the same amount in taxes as they now spend on premiums, deductibles and out-of-pocket costs.

"Consumers may not be asked to pay substantially more than they do now—just to change the *way* they pay," he said.

Each state would also contribute an amount based on its previous level of health care spending, incidence of health problems and other demographic factors.

PROJECTED ANNUAL NATIONAL HEALTH EXPENDITURES UNDER THE NASW NATIONAL HEALTH CARE PLAN (NHCP), 1990 DOLLARS



* The Long-Term Care Program Does Assume Limited Cost Sharing, Based on Income, for a Portion of Room and Board Costs.

Source: Center for Health Policy Studies

The new system would be run by an independent National Health Board, which would set federal guidelines.

States would get a lump sum annually to use in paying for all covered services. They would pay physicians and other health care practitioners directly on a fee-for-service basis at negotiated rates, comparable to rates paid under what is now the Medicare program.

Hospitals would be given a lump sum yearly for operating expenses. Separate, state-regulated funds would be available for capital expansion and for purchasing high-tech equipment.

Private insurers would be prohibited from covering services provided under the national plan, but could offer additional benefits.

Consumers would remain free to choose their health care providers.

"While this plan is a radical departure from the current system, we believe that the American people—as indicated by numerous opinion polls—want this kind of change," said NASW Deputy Executive Director Judy A. Hall.

Recent surveys by national polling organizations found that 89 percent of the public wants fundamental change in the health care system and that 66 percent favors a national health insurance system similar to Canada's, according to figures cited by NASW.

A Jan. 9 *Washington Post* report on the association's proposal predicted that the current state of the health care system "could become a major point in the 1992 presidential election, with Democrats likely to push for some form of comprehensive national coverage." ■

Copies of NASW's national health care proposal and the Center for Health Policy Studies' cost analysis are available for $5 each/$10 both (NASW members), or $7.50 each/$15 both (nonmembers), from: Legislative Affairs Department, NASW, 7981 Eastern Ave., Silver Spring, MD 20910; (301) 565-0333, ext. 284, or toll-free 1-800-638-8799, ext. 284.

Plan Highlights: Inclusiveness, Simplicity

NASW's proposed national health care plan includes these basic components:

- Negotiated fee schedules for physicians and other practitioners.
- Emphasis on community-based health and mental health services

As Amended by House Committee

Session of 1991

HOUSE BILL No. 2104

By Committee on Public Health and Welfare

2-1

AN ACT providing for licensure of speech-language pathologists and audiologists; establishing a speech-language pathology and audiology ~~commission~~ **board** and prescribing the powers and duties thereof; prohibiting certain acts and prescribing penalties for violations thereof.

Be it enacted by the Legislature of the State of Kansas:

Section 1. As used in this act, the following words and phrases shall have the meanings respectively ascribed to them in this section:

(a) "Secretary" means the secretary of health and environment.

(b) "Speech-language pathology" means the application of principles, methods and procedures related to the development and disorders of human communication. Disorders include any and all conditions, whether of organic or nonorganic origin, that impede the normal process of human communication including disorders and ~~relative~~ **related** disorders of speech, articulation, fluency, voice, verbal and written language, auditory comprehension, ~~cognition/communication, and oral pharyngeal and/or~~ **cognition/communication, and oral pharyngeal or** laryngeal sensorimotor competencies, **or both. Speech-language pathology does not mean diagnosis or treatment of medical conditions as defined by K.S.A. 65-2869 and amendments thereto.**

(c) "Practice of speech-language pathology" means:

(1) Rendering or offering to render to individuals or groups of individuals who have or are suspected of having disorders of communication, any service in speech-language pathology including prevention, identification, evaluation, consultation, habilitation~~,~~ and rehabilitation, ~~instruction and research~~;

(2) determining the need for personal augmentative communication systems, recommending such systems and providing training in utilization of such systems; and

(3) planning, directing, conducting or supervising such services.

(d) "Speech-language pathologist" means a person who engages in the practice of speech-language pathology and who meets the qualifications set forth in this act.

April 8, 1991

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Attachment #8
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(c) "Audiology" means the application of principles, methods and procedures related to hearing and the disorders of hearing and to related language and speech disorders. Disorders include any and all conditions, whether of organic or nonorganic origin, peripheral or central, that impede the normal process of human communication including, but not limited to, disorders ~~or~~ of auditory sensitivity, acuity, function or processing. **Audiology does not mean diagnosis or treatment of medical conditions as defined by K.S.A. 65-2869 and amendments thereto.**

(f) "Practice of audiology" means:

(1) Rendering or offering to render to individuals or groups of individuals who have or are suspected of having disorders of hearing, any service in audiology, including prevention, identification, evaluation, consultation~~,~~ and habilitation or rehabilitation (other than hearing aid or other assistive listening device dispensing)~~, instruction and research~~;

(2) participating in hearing conservation;

(3) providing auditory training and speech reading;

(4) conducting tests of vestibular function;

(5) evaluating tinnitus; and

(6) planning, directing, conducting or supervising services.

(g) "Audiologist" means any person who engages in the practice of audiology and who meets the qualifications set forth in this act.

(h) "Speech-language pathology assistant" means an individual who meets minimum qualifications established by the secretary which are less than those established by this act as necessary for licensing as a speech-language pathologist; does not act independently; and works under the direction and supervision of a speech-language pathologist licensed under this act.

(i) "Audiology assistant" means an individual who meets minimum qualifications established by the secretary, which are less than those established by this act as necessary for licensing as an audiologist; does not act independently; and works under the direction and supervision of an audiologist licensed under this act.

Sec. 2. (a) There is hereby established a speech-language pathology and audiology ~~commission~~ **board**. Such ~~commission~~ **board** shall be advisory to the secretary of health and environment in all matters concerning standards, rules and regulations and all matters relating to this act.

(b) The ~~commission~~ **board** shall be composed of five persons appointed by the secretary who have been residents of this state for at least two years ~~and who are actively engaged in the practice~~ of audiology. Two members shall be licensed, or initially eligible

for licensure, as speech-language pathologists; one member shall be licensed, or initially eligible for licensure, as an audiologist; one member shall be a licensed physician; and one member shall be a member of the general public who is not a health care provider. The secretary may make appointments from a list submitted by professional organizations representing speech pathologists and audiologists. ~~The commission shall be composed of at least three members licensed, or initially eligible for licensure, under this act.~~

(c) Members of the commission board attending meetings of such commission board or attending a subcommittee meeting thereof authorized by such commission board shall be paid ~~compensation, subsistence allowances, mileage and other expenses as~~ provided in K.S.A. 75-3223 and amendments thereto.

(d) ~~Commission~~ Board members shall be appointed for a term of three two years and until their successors are appointed and qualified, except that of the initial appointments, which shall be made within 60 days after the effective date of this act, ~~one member shall be appointed for a term of one year, two members shall be appointed for terms of two years and two members shall be appointed for terms of three years~~ two members first appointed, as specified by the secretary, shall serve on the board for terms of one year and thereafter, upon expiration of such one-year terms, successors shall be appointed in the same manner as the original appointments. The chairperson of the board shall be elected annually from among the members of the board. Whenever a vacancy occurs on the commission board by reason other than the expiration of a term of office, the secretary shall appoint a successor of like qualifications for the remainder of the unexpired term. No person shall be appointed to serve more than two successive ~~three~~ year two-year terms.

(e) Appointments to fill vacancies shall be made in the same manner as original appointments for the unexpired portion of the term. The secretary may terminate the appointment of any member for cause which in the opinion of the secretary reasonably justifies such termination.

Sec. 3. The secretary shall:

(a) Issue to each person who has met the education and training requirements listed in section 5 and amendments thereto and such other reasonable qualifications as may be established by rules and regulations promulgated by the secretary, the appropriate license as a speech-language pathologist or audiologist;

(b) establish by regulation rules and regulations the methods

KMS

licensed to practice medicine and surgery

amounts provided in subsection (e) of

Note: advisory boards usually do not receive compensation but receive mileage and other expenses under subsection (e) of K.S.A. 75-3223 and amendments thereto.

and procedures for examination of candidates for licensure;

(c) appoint employees necessary to administer this act and fix their compensation within the limits of appropriations made for that purpose;

(d) keep a record of the ~~commission's~~ board's proceedings and a register of all applicants for and recipients of licenses; and

(e) make all such reasonable rules and regulations as deemed necessary to carry out and enforce the provisions of this act.

Sec. 4. ~~It~~ (a) On or after September 1, 1992, it shall be unlawful for any person to engage in the practice of speech-language pathology or audiology ~~for a fee~~ in the state of Kansas unless ~~they have~~ such person has been issued a valid license pursuant to this act or ~~are~~ is specifically exempted from the provisions of this act. It shall be unlawful for any person to hold ~~themselves~~ oneself out to the public as a "speech pathologist," "speech therapist," "speech correctionist," "speech clinician," "language pathologist," "voice therapist," "voice pathologist," "logopedist," "communicologist," "aphasiologist," "phoniatrist," "audiologist," "audiometrist," "hearing therapist," "hearing clinician," "hearing aid audiologist," or any variation, unless ~~they have been appropriately licensed by this act. Notwithstanding the provisions of this act, any person who engages in the practice of dispensing and fitting hearing aids as defined by K.S.A. 74-5807 and amendments thereto must be licensed under and adhere to the provisions of that act.~~ such person is licensed under this act as a speech-language pathologist or audiologist

(b) No person licensed under this act shall be authorized to engage in the practice of dispensing and fitting hearing aids as defined under K.S.A. 74-5807 and amendments thereto unless such person is also licensed or holds a certificate of endorsement under the hearing aid act to engage in the practice of dispensing and fitting hearing aids.

(c) Persons licensed under this act to engage in the practice of speech-language pathology or audiology shall not be deemed to be engaged in the practice of the healing arts when practicing under and in accordance with this act.

Sec. 5. Speech-language pathologists or audiologists shall meet the following qualifications for licensure under this act:

(a) Possess at least a master's degree or equivalent in speech-language pathology or audiology from an educational institution with standards consistent with those of the state universities of Kansas approved by the secretary which consists of ~~coursework~~ a course of study consistent with the standards of the state universities of Kansas approved by the secretary pursuant to the rules and regulations;

(b) complete supervised clinical practicum experiences from an educational institution or its cooperating programs the content of which shall be approved by the secretary and shall be consistent with the standards of the state universities of Kansas and delineated in the rules and regulations;

(c) complete a postgraduate professional experience as approved by the secretary pursuant to the rules and regulations; and

(d) pass an examination in speech-language pathology or audiology approved by the secretary.

Sec. 6. (a) Any applicant for licensure shall submit an application to the secretary upon the forms prescribed and furnished by the secretary and shall pay appropriate fees as established by the secretary, including examination fees if required. ~~Any initial fee shall be for the period of two years following the date of application.~~ All licenses shall expire after two years and may be renewed by submitting an application, showing proof of completing required continuing education and paying a renewal fee to be established and collected by the secretary.

(b) At least 30 days before the expiration of the license, the secretary shall notify the licensee of the expiration by mail addressed to the licensee's last place of residence as noted upon the office records. If the licensee fails to submit an application and fee by the date of expiration of the license, the licensee shall be given a second notice that the license has expired and the license may only be renewed if the application, renewal fee, and late renewal fee are received by the secretary with the thirty-day period following the date of expiration and, if both fees are not received within the thirty-day period, the license shall be considered to have lapsed for failure to renew and shall be reissued only after the applicant has been reinstated under subsection (c).

(c) Any licensee who allows the licensee's license to lapse by failing to renew as herein provided may be reinstated upon payment of the renewal fee and the reinstatement fee, and upon submitting evidence of satisfactory completion of any applicable continuing education requirements established by the secretary. The secretary shall adopt rules and regulations establishing appropriate continuing education requirements for reinstatement of persons whose licenses have lapsed for failure to renew.

~~(b)~~ (d) Upon due application and payment of a licensure fee as established by the secretary within one year subsequent to the effective ~~date of this act~~ September 1, 1992, the secretary may waive the ~~education, practicum, examination and experience~~ requirements and grant a license to all ~~speech-language pathologists~~ or

audiologists any applicant so long as they have been employed in that capacity for at least two of the three years immediately prior to the effective date of this act. Upon payment of such fee and proof of completion of continuing education requirements as established by the secretary, the secretary shall renew such licenses the applicant: (1) Has met the educational, supervised clinical practicum experiences and postgraduate professional experience set forth in this act on or before September 1, 1992; or (2) has a master's degree or equivalent in speech-language pathology or audiology and on the effective date of this act has been actively engaged in the practice of speech-language pathology or audiology for at least two years of the last four years immediately preceding September 1, 1992; or (3) holds a current teaching certificate by the Kansas department of education as a speech-language pathologist or audiologist on the effective date of this act.

(e) (c) The secretary, upon application and payment of the fee fixed by the secretary, may issue a license as a speech-language pathologist or audiologist to any person who holds a valid license or its equivalent issued to such person by another state or country if the requirements for the licensure of the speech-language pathologist or audiologist under which such license or equivalent was issued are equivalent to or exceed the standards of this act.

(d) (f) The secretary, upon application and payment of the ~~fee fixed by the secretary,~~ shall issue to persons meeting the education and experience requirements a temporary license which shall be valid only for the period preceding the first scheduled examination after its issuance and until the date on which the results have been made public the person should have completed the postgraduate experience required by subsection (c) of section 5 and amendments thereto. This temporary license may be renewed by appeal to the secretary if the applicant has failed the examination, but such temporary license shall be renewed no more than two times.

Sec. 7. The secretary may contract with investigative agencies, commissions or consultants to assist the secretary in obtaining information about courses of study and supervised clinical practicum experiences to be approved by the secretary under section 5 and amendments thereto.

Sec. 7 8. The secretary shall deny, revoke, suspend or limit the license provided for in this act for any of the following reasons:

(a) Making a false statement on an application for a license, registration or any other document required by the secretary;

(b) engaging or attempting to engage, or representing oneself as so entitled, to perform procedures not authorized in the license;

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and has been actively engaged in the practice of speech-language pathology or audiology for at least three years of the last five years immediately preceding Secptember 1,1992

temporary licensure

, and submission of evidence of successful completion of the education and supervised clinical practicum experiences, may issue a temporary license, which shall expire 12 months from the date of issuance. The temporary license may be renewed for one period not to exceed 12 months by appeal to the secretary if the applicant has failed the examination or failed to complete the post-graduate professional experience

(c) demonstrating incompetence or making consistent negligent errors in tests or procedures;

(d) engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public;

(e) providing professional services while mentally incompetent, under the influence of alcohol or narcotic or controlled ~~dangerous~~ substance that is in excess of therapeutic amounts or without valid medical indication;

(f) violating or aiding and abetting in a violation of any provisions of this act or any of the rules or regulations adopted under this act.

Sec. ~~8~~ 9. Proceedings under this act shall be conducted in accordance with the Kansas administrative procedure act. Judicial review and civil enforcement of agency actions under this act shall be in accordance with the act for judicial review and civil enforcement of agency actions.

Sec. ~~9~~ 10. Any person who violates any of the provisions of this act shall be guilty of a class C misdemeanor and each day in violation of this act shall be considered a separate offense.

Sec. ~~10~~ 11. The provisions of this act shall not apply to:

(a) Personnel employed by the United States government;

(b) ~~practitioners licensed or registered by the state of Kansas as~~ health care providers as defined by K.S.A. 1990 Supp. 65-4921 and amendments thereto or exempt licensees under the Kansas healing arts act who are providing services within the lawful scope of their authority so long as they do not hold themselves out to the public by a title set forth in section 4 and amendments thereto;

(c) persons duly credentialed by this state as a teacher of the deaf or hearing impaired who are providing services within the lawful scope of their authority so long as they do not hold themselves out to the public by a title set forth in section 4 and amendments thereto;

(d) the activities and services of persons pursuing a course of study leading to a degree in speech-language pathology or audiology at a college or university provided that: (1) These activities and services constitute a part of the organized course of study at that institution; (2) such persons are designated by a title such as intern, trainee, student, or by other such title clearly indicating the status appropriate to their level of education; and (3) such persons work under the supervision of a person licensed by this state to practice speech-language pathology or audiology.

(e) an employee or other person under the supervision of a person licensed to practice medicine and surgery in this state so long as such persons do not hold themselves out to the public by

a title set forth in section 4 and amendments thereto; or

(f) persons licensed or holding a certificate of endorsement to engage in the practice of dispensing and fitting hearing aids under the hearing aid act when practicing under and in accordance with the hearing aid act so long as such persons do not hold themselves out to the public by a title set forth in section 4 and amendments thereto.

Sec. 12. The secretary shall fix by rules and regulations the licensure fee, renewal fee, late renewal fee, reinstatement fee, and examination fee, if necessary, under this act. Such fees shall be fixed in an amount to cover the costs of administering the provisions of the act. The secretary shall remit all monies received from fees, charges or penalties under this act to the state treasurer at least monthly. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount thereof in the state treasury and credit the same to the state general fund.

Sec. ~~11~~ 13. This act shall take effect and be in force from and after January 1, 1992, and its publication in the statute book.

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[temporary licensure fee,