SENATE BILL NO. 135

INTRODUCED BY KENNEDY
BY REQUEST OF THE DEPARTMENT OF COMMERCE

IN THE SENATE

JANUARY 18, 1991	INTRODUCED AND REFERRED TO COMMITTEE ON PUBLIC HEALTH, WELFARE, & SAFETY.
	FIRST READING.
JANUARY 28, 1991	COMMITTEE RECOMMEND BILL DO PASS. REPORT ADOPTED.
JANUARY 29, 1991	PRINTING REPORT.
	SECOND READING, DO PASS.
JANUARY 30, 1991	ENGROSSING REPORT.
	THIRD READING, PASSED. AYES, 48; NOES, 0.
	TRANSMITTED TO HOUSE.

IN THE HOUSE

JANUARY 30, 1991	INTRODUCED AND REFERRED TO COMMITTEE ON HUMAN SERVICES & AGING.
JANUARY 31, 1991	FIRST READING.
FEBRUARY 14, 1991	COMMITTEE RECOMMEND BILL BE CONCURRED IN. REPORT ADOPTED.
MARCH 8, 1991	SECOND READING, CONCURRED IN.
MARCH 11, 1991	THIRD READING, CONCURRED IN. AYES, 98; NOES, 0.
	RETURNED TO SENATE.

IN THE SENATE

MARCH 12, 1991	RECEIVED FROM HOUSE.
	SENT TO ENROLLING.
	REPORTED CORRECTLY ENROLLED.

SENATE BILL NO. 135

INTRODUCED BY Kennedy

BY REQUEST OF THE DEPARTMENT OF COMMERCE

A BILL FOR AN ACT ENTITLED: "AN ACT REQUIRING THE LICENSING OF WHOLESALE DRUG DISTRIBUTORS; PROVIDING FOR LICENSE FEES; PROVIDING PENALTIES FOR VIOLATIONS; AMENDING SECTION 37-7-201, MCA; AND PROVIDING AN EFFECTIVE DATE AND AN APPLICABILITY DATE."

STATEMENT OF INTENT

A statement of intent is required for this bill because it is anticipated that promulgation of administrative rules will be necessary to implement this bill. This bill is proposed solely to bring Montana standards on licensing wholesale drug distributors into compliance with rules of the federal food and drug administration (FDA). Unless state law complies with FDA requirements by September 1992, federal law would prohibit the distribution of drugs by manufacturers and wholesalers in Montana. In adopting administrative rules, the department of commerce shall implement the federal Prescription Drug Marketing Act of 1987 as well as guidelines developed by the FDA.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

LC 0567/01

Section 1. Section 37-7-201, MCA, is amended to read:

"**37-7-201. Organization -- powers and duties.** (1) The board shall meet at least once a year to transact its business. The board shall annually elect from its members a president, vice-president, and secretary.

(2) The board shall:

(a) regulate the practice of pharmacy in this state subject to this chapter;

(b) determine the minimum equipment necessary in and for a pharmacy;

(c) regulate, under therapeutic classification, the sale of drugs, medicines, chemicals, and poisons and their labeling;

(d) regulate the quality of drugs and medicines dispensed in this state, using the United States Pharmacopoeia/National Formulary or revisions thereof as the standards;

(e) request the department to enter and inspect, at reasonable times, places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

(f) regulate the practice of interns under national standards;

INTRODUCED BILL
SB 135

(g) make rules for the conduct of its business;

(h) perform other duties and exercise other powers as this chapter requires;

(i) adopt and authorize the department to publish rules for carrying out and enforcing parts 1 through 3 of this chapter.

(3) The department shall:

(a) license, register, and examine, subject to 37-1-101, applicants whom the board considers qualified under this chapter;

(b) license pharmacies and certain stores under this chapter; and

(c) license wholesale drug distributors;

~~(c)~~(d) issue certificates of "certified pharmacy" under this chapter; and

(e) establish and collect license fees."

NEW SECTION. **Section 2.** Scope and purpose. [Sections 2 through 11] apply to a person or entity engaged in the wholesale distribution of prescription drugs in this state. The purpose of [sections 2 through 11] is to implement the federal Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for licensing by the department of persons or entities engaged in wholesale distributions of prescription drugs.

NEW SECTION. **Section 3.** Definitions. As used in

[sections 2 through 11] the following definitions apply:

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

(2) "Blood component" means that part of blood separated by physical or mechanical means.

(3) "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.

(4) "Manufacturer" means a person or entity engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(5) "Prescription drug" means any drug for humans that is 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 (21 U.S.C.S. 353).

(6) "Wholesale drug distribution" means distribution of prescription drugs to persons other than a consumer or patient. The term does not include:

(a) intracompany sales;

(b) 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 group purchasing organizations;

(c) 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;

(d) 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 subsection (d), "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, contract, or otherwise.

(e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection (e), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

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

(g) the distribution of drug samples by manufacturers'

representatives or distributors' representatives; or

(h) the sale, purchase, or trade of blood and blood components intended for transfusion.

(7) "Wholesale drug distributor" means a person or entity 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.

NEW SECTION. **Section 4. Prohibited purchase or receipt of drugs -- restrictions on wholesale drug distributors -- penalty.** (1) Except as otherwise provided, it is unlawful for a person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under [sections 2 through 11].

(2) Licensed wholesale drug distributors other than pharmacies may not dispense or distribute prescription drugs directly to patients.

(3) A person who violates the provisions of this section is guilty of a misdemeanor.

NEW SECTION. **Section 5. Wholesale drug distributor licensing requirements -- fee -- federal compliance.** (1) A

person or distribution outlet may not act as a wholesale drug distributor without first obtaining a license from the board and paying the license fee.

(2) A license may not be issued or renewed for a wholesale drug distributor to operate in this state unless the applicant:

(a) agrees to abide by federal and state law and to comply with the rules adopted by the board; and

(b) pays the license fee set by the board.

(3) The board in its discretion may require that a separate license be obtained for:

(a) each facility directly or indirectly owned or operated by the same business entity within the state; or

(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted at more than one location and joint ownership and control exists among all entities.

(4) In order to obtain and maintain a wholesale drug distributorship in this state, an applicant shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale drug distribution as defined in [section 3] for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) principals, including officers, directors, primary shareholders, and management executives, who shall at all times demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices as well as state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, pertaining to each wholesale drug distributor to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that assures preparation by the wholesale drug distributor for

the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;

(iv) lack of control of outdated or other unauthorized products;

(v) inappropriate disposition of returned goods; and

(vi) failure to promptly comply with product recalls; and

(h) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(5) An agent or employee of a licensed wholesale drug distributor need not be licensed as a wholesale drug distributor.

(6) For purposes of this section, all rules and regulations promulgated by the board must conform to the wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. If a conflict arises between a food and drug administration guideline and a rule or regulation of the board, the former controls.

NEW SECTION. **Section 6.** **Out-of-state wholesale drug**

distributor licensing requirements. (1) It is unlawful for an out-of-state wholesale drug distributor to conduct business in this state without first obtaining a license from the board and paying the license fee established by the board.

(2) Application for a license under this section must be made on a form furnished by the board.

(3) The issuance of a license may not affect tax liability imposed by the department of revenue on any out-of-state wholesale drug distributor.

(4) A person acting as principal or agent for an out-of-state wholesale drug distributor may not sell or distribute drugs in this state unless the distributor has obtained a license.

NEW SECTION. **Section 7.** **Issuance of licenses.** The license for wholesale drug distributors is effective from April 1 to March 31 of the following year. An application for renewal of a license must be mailed to each licensee on or before March 1, and if the renewal application and the fee are not mailed by March 31, the license is void upon its expiration date.

NEW SECTION. **Section 8.** **Qualifications for licensure -- denial of license application -- notice and hearing.** (1) The board shall consider the following factors in determining the qualifications of applicants to engage in

wholesale distribution of prescription drugs in this state:

(a) any conviction of the applicant under federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(b) any felony conviction of the applicant under federal, state, or local law;

(c) the applicant's previous experience in the manufacture or distribution of prescription drugs, including controlled substances;

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

(e) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) compliance with licensing requirements under any previously granted licenses;

(g) compliance with requirements to maintain or to make available to the board or to enforcement officers of the federal government or other states records required to be maintained under this section; and

(h) any other factors the board determines necessary to protect the public interest.

(2) The board may deny a license to an applicant that in the board's discretion fails to meet the qualifications outlined in this section. The board shall give the applicant notice of the proposed action and an opportunity for a hearing pursuant to Title 2, chapter 4.

NEW SECTION. **Section 9. License discipline -- grounds for revocation, suspension, or refusal to renew license -- penalty -- notice and hearing.** (1) The board may suspend, revoke, or refuse to renew a wholesale drug distribution license:

(a) obtained by misrepresentation or fraud;

(b) upon conviction of a violation of federal, state, or local drug laws;

(c) upon conviction of a violation of:

(i) the Federal Food, Drug, and Cosmetic Act (Title 21, chapter 9, U.S.C.);

(ii) Title 37, chapter 2 or 7;

(iii) Title 45, chapter 9 or 10;

(iv) Title 50, chapter 31 or 32; or rules adopted under subsections (1)(c)(i) through (1)(c)(iv);

(d) upon suspension or revocation by a state or territory of a license to conduct wholesale distribution of prescription drugs; or

(e) upon conviction of a violation of a provision listed in subsection (1) or [section 4, 5, or 6] or the

rules implementing them.

(2) It is a misdemeanor punishable by a fine of not more than $500 for a person or entity to distribute wholesale prescription drugs in violation of a provision of subsection (1) or [section 4, 5, or 6] or the rules implementing them.

(3) Before a license can be revoked or suspended, the holder of the license is entitled to notice and the opportunity for a hearing pursuant to Title 2, chapter 4.

NEW SECTION. **Section 10.** **Board access to wholesale drug records.** Wholesale drug distributors may keep records at a central location apart from the principal office of the wholesale drug distributor or the location where the drugs are stored and from where they are shipped, provided that the records must be available for inspection within 2 working days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drug recordkeeping.

NEW SECTION. **Section 11.** **Rulemaking authority.** The board shall adopt rules and regulations necessary to carry out the purpose and enforce the provisions of [sections 2 through 11]. If the rules and regulations conflict with the wholesale drug distribution guidelines promulgated by the United States food and drug administration, the latter control.

NEW SECTION. **Section 12.** **Codification instruction.** [Sections 2 through 11] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 2 through 11].

NEW SECTION. **Section 13.** **Applicability.** (1) The provisions of [section 1 through 11] are applicable to activities that occur on or after April 1, 1992.

(2) Rulemaking by the board may commence on July 1, 1991, to be applicable on April 1, 1992.

NEW SECTION. **Section 14.** **Effective date.** [This act] is effective July 1, 1991.

-End-

STATE OF MONTANA - FISCAL NOTE
Form BD-15
In compliance with a written request, there is hereby submitted a Fiscal Note for SB0135, as introduced.

DESCRIPTION OF PROPOSED LEGISLATION:

An act requiring the licensing of wholesale drug distributors; providing for license fees; providing penalties for violations; amending section 37-7-201, MCA; and providing an effective date and an applicability date.

ASSUMPTIONS:

1. Approximately 85 wholesale drug distributors reside within the State of Montana.
2. Current law is represented by the executive budget recommendation for the Board of Pharmacy of the Department of Commerce.
3. Licensing wholesale drug distributors will require one additional board meeting per year.
4. The increased cost to administer licensure of wholesale drug distributors will increase the administrative overhead expenses of the Board of Pharmacy which will likewise be reflected in the operating expenses of the Professional and Occupational Licensing Bureau of the Department of Commerce.

FISCAL IMPACT:

Board of Pharmacy:	FY 92			FY 93		
	Current Law	Proposed Law	Difference	Current Law	Proposed Law	Difference
Expenditures:						
FTE	1.00	1.00	0	1.00	1.00	0
Personal Services	47,111	47,361	250	47,007	47,257	250
Operating Costs	89,296	94,046	4,750	88,785	92,663	3,878
Equipment	0	0	0	0	0	0
Total	136,407	141,407	5,000	135,792	139,920	4,128
Funding:						
State Special	136,407	141,407	5,000	135,792	139,920	4,128
Revenues:						
Licenses Fees (02)	127,925	133,025	5,100	127,925	133,025	5,100

Rod Sundsted 1-22-91
ROD SUNDSTED, BUDGET DIRECTOR DATE
Office of Budget and Program Planning

John Ed Kennedy Jr. 1-24-91
JOHN "ED" KENNEDY, JR., PRIMARY SPONSOR DATE

Fiscal Note for SB0135, as introduced. SB 135

APPROVED BY COMMITTEE
ON PUBLIC HEALTH, WELFARE
& SAFETY

Senate BILL NO. 135

INTRODUCED BY Kennedy

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(c) regulate, under therapeutic classification, the sale of drugs, medicines, chemicals, and poisons and their labeling;

(d) regulate the quality of drugs and medicines dispensed in this state, using the United States Pharmacopoeia/National Formulary or revisions thereof as the standards;

(e) request the department to enter and inspect, at reasonable times, places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

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SECOND READING
SB 135

(g) make rules for the conduct of its business;

(h) perform other duties and exercise other powers as this chapter requires;

(i) adopt and authorize the department to publish rules for carrying out and enforcing parts 1 through 3 of this chapter.

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(b) 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 group purchasing organizations;

(c) 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;

(d) 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 subsection (d), "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, contract, or otherwise.

(e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection (e), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

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

(g) the distribution of drug samples by manufacturers'

representatives or distributors' representatives; or

(h) the sale, purchase, or trade of blood and blood components intended for transfusion.

(7) "Wholesale drug distributor" means a person or entity 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.

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(2) Licensed wholesale drug distributors other than pharmacies may not dispense or distribute prescription drugs directly to patients.

(3) A person who violates the provisions of this section is guilty of a misdemeanor.

NEW SECTION. **Section 5. Wholesale drug distributor licensing requirements -- fee -- federal compliance.** (1) A

person or distribution outlet may not act as a wholesale drug distributor without first obtaining a license from the board and paying the license fee.

(2) A license may not be issued or renewed for a wholesale drug distributor to operate in this state unless the applicant:

(a) agrees to abide by federal and state law and to comply with the rules adopted by the board; and

(b) pays the license fee set by the board.

(3) The board in its discretion may require that a separate license be obtained for:

(a) each facility directly or indirectly owned or operated by the same business entity within the state; or

(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted at more than one location and joint ownership and control exists among all entities.

(4) In order to obtain and maintain a wholesale drug distributorship in this state, an applicant shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale drug distribution as defined in [section 3] for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) principals, including officers, directors, primary shareholders, and management executives, who shall at all times demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices as well as state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, pertaining to each wholesale drug distributor to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that assures preparation by the wholesale drug distributor for

the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;

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(v) inappropriate disposition of returned goods; and

(vi) failure to promptly comply with product recalls; and

(h) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(5) An agent or employee of a licensed wholesale drug distributor need not be licensed as a wholesale drug distributor.

(6) For purposes of this section, all rules and regulations promulgated by the board must conform to the wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. If a conflict arises between a food and drug administration guideline and a rule or regulation of the board, the former controls.

NEW SECTION. **Section 6.** Out-of-state wholesale drug

distributor licensing requirements. (1) It is unlawful for an out-of-state wholesale drug distributor to conduct business in this state without first obtaining a license from the board and paying the license fee established by the board.

(2) Application for a license under this section must be made on a form furnished by the board.

(3) The issuance of a license may not affect tax liability imposed by the department of revenue on any out-of-state wholesale drug distributor.

(4) A person acting as principal or agent for an out-of-state wholesale drug distributor may not sell or distribute drugs in this state unless the distributor has obtained a license.

NEW SECTION. **Section 7.** Issuance of licenses. The license for wholesale drug distributors is effective from April 1 to March 31 of the following year. An application for renewal of a license must be mailed to each licensee on or before March 1, and if the renewal application and the fee are not mailed by March 31, the license is void upon its expiration date.

NEW SECTION. **Section 8.** Qualifications for licensure -- denial of license application -- notice and hearing. (1) The board shall consider the following factors in determining the qualifications of applicants to engage in

wholesale distribution of prescription drugs in this state:

(a) any conviction of the applicant under federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(b) any felony conviction of the applicant under federal, state, or local law;

(c) the applicant's previous experience in the manufacture or distribution of prescription drugs, including controlled substances;

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

(e) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) compliance with licensing requirements under any previously granted licenses;

(g) compliance with requirements to maintain or to make available to the board or to enforcement officers of the federal government or other states records required to be maintained under this section; and

(h) any other factors the board determines necessary to protect the public interest.

(2) The board may deny a license to an applicant that in the board's discretion fails to meet the qualifications outlined in this section. The board shall give the applicant notice of the proposed action and an opportunity for a hearing pursuant to Title 2, chapter 4.

NEW SECTION. **Section 9. License discipline -- grounds for revocation, suspension, or refusal to renew license -- penalty -- notice and hearing.** (1) The board may suspend, revoke, or refuse to renew a wholesale drug distribution license:

(a) obtained by misrepresentation or fraud;

(b) upon conviction of a violation of federal, state, or local drug laws;

(c) upon conviction of a violation of:

(i) the Federal Food, Drug, and Cosmetic Act (Title 21, chapter 9, U.S.C.);

(ii) Title 37, chapter 2 or 7;

(iii) Title 45, chapter 9 or 10;

(iv) Title 50, chapter 31 or 32; or rules adopted under subsections (1)(c)(i) through (1)(c)(iv);

(d) upon suspension or revocation by a state or territory of a license to conduct wholesale distribution of prescription drugs; or

(e) upon conviction of a violation of a provision listed in subsection (1) or [section 4, 5, or 6] or the

rules implementing them.

(2) It is a misdemeanor punishable by a fine of not more than $500 for a person or entity to distribute wholesale prescription drugs in violation of a provision of subsection (1) or [section 4, 5, or 6] or the rules implementing them.

(3) Before a license can be revoked or suspended, the holder of the license is entitled to notice and the opportunity for a hearing pursuant to Title 2, chapter 4.

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NEW SECTION. **Section 12. Codification instruction.** [Sections 2 through 11] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 2 through 11].

NEW SECTION. **Section 13. Applicability.** (1) The provisions of [section 1 through 11] are applicable to activities that occur on or after April 1, 1992.

(2) Rulemaking by the board may commence on July 1, 1991, to be applicable on April 1, 1992.

NEW SECTION. **Section 14. Effective date.** [This act] is effective July 1, 1991.

-End-

Senate BILL NO. 135

INTRODUCED BY Kennedy

BY REQUEST OF THE DEPARTMENT OF COMMERCE

A BILL FOR AN ACT ENTITLED: "AN ACT REQUIRING THE LICENSING OF WHOLESALE DRUG DISTRIBUTORS; PROVIDING FOR LICENSE FEES; PROVIDING PENALTIES FOR VIOLATIONS; AMENDING SECTION 37-7-201, MCA; AND PROVIDING AN EFFECTIVE DATE AND AN APPLICABILITY DATE."

STATEMENT OF INTENT

A statement of intent is required for this bill because it is anticipated that promulgation of administrative rules will be necessary to implement this bill. This bill is proposed solely to bring Montana standards on licensing wholesale drug distributors into compliance with rules of the federal food and drug administration (FDA). Unless state law complies with FDA requirements by September 1992, federal law would prohibit the distribution of drugs by manufacturers and wholesalers in Montana. In adopting administrative rules, the department of commerce shall implement the federal Prescription Drug Marketing Act of 1987 as well as guidelines developed by the FDA.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 37-7-201, MCA, is amended to read:

"37-7-201. Organization -- powers and duties. (1) The board shall meet at least once a year to transact its business. The board shall annually elect from its members a president, vice-president, and secretary.

(2) The board shall:

(a) regulate the practice of pharmacy in this state subject to this chapter;

(b) determine the minimum equipment necessary in and for a pharmacy;

(c) regulate, under therapeutic classification, the sale of drugs, medicines, chemicals, and poisons and their labeling;

(d) regulate the quality of drugs and medicines dispensed in this state, using the United States Pharmacopoeia/National Formulary or revisions thereof as the standards;

(e) request the department to enter and inspect, at reasonable times, places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

(f) regulate the practice of interns under national standards;

THIRD READING
SB 135

(g) make rules for the conduct of its business;

(h) perform other duties and exercise other powers as this chapter requires;

(i) adopt and authorize the department to publish rules for carrying out and enforcing parts 1 through 3 of this chapter.

(3) The department shall:

(a) license, register, and examine, subject to 37-1-101, applicants whom the board considers qualified under this chapter;

(b) license pharmacies and certain stores under this chapter; and

(c) license wholesale drug distributors;

~~(c)~~(d) issue certificates of "certified pharmacy" under this chapter; and

(e) establish and collect license fees."

NEW SECTION. **Section 2.** Scope and purpose. [Sections 2 through 11] apply to a person or entity engaged in the wholesale distribution of prescription drugs in this state. The purpose of [sections 2 through 11] is to implement the federal Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for licensing by the department of persons or entities engaged in wholesale distributions of prescription drugs.

NEW SECTION. **Section 3.** Definitions. As used in

[sections 2 through 11] the following definitions apply:

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

(2) "Blood component" means that part of blood separated by physical or mechanical means.

(3) "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.

(4) "Manufacturer" means a person or entity engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(5) "Prescription drug" means any drug for humans that is 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 (21 U.S.C.S. 353).

(6) "Wholesale drug distribution" means distribution of prescription drugs to persons other than a consumer or patient. The term does not include:

(a) intracompany sales;

(b) 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 group purchasing organizations;

(c) 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;

(d) 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 subsection (d), "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, contract, or otherwise.

(e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection (e), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

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

(g) the distribution of drug samples by manufacturers'

representatives or distributors' representatives; or

(h) the sale, purchase, or trade of blood and blood components intended for transfusion.

(7) "Wholesale drug distributor" means a person or entity 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.

NEW SECTION. **Section 4.** **Prohibited purchase or receipt of drugs -- restrictions on wholesale drug distributors -- penalty.** (1) Except as otherwise provided, it is unlawful for a person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under [sections 2 through 11].

(2) Licensed wholesale drug distributors other than pharmacies may not dispense or distribute prescription drugs directly to patients.

(3) A person who violates the provisions of this section is guilty of a misdemeanor.

NEW SECTION. **Section 5.** **Wholesale drug distributor licensing requirements -- fee -- federal compliance.** (1) A

person or distribution outlet may not act as a wholesale drug distributor without first obtaining a license from the board and paying the license fee.

(2) A license may not be issued or renewed for a wholesale drug distributor to operate in this state unless the applicant:

(a) agrees to abide by federal and state law and to comply with the rules adopted by the board; and

(b) pays the license fee set by the board.

(3) The board in its discretion may require that a separate license be obtained for:

(a) each facility directly or indirectly owned or operated by the same business entity within the state; or

(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted at more than one location and joint ownership and control exists among all entities.

(4) In order to obtain and maintain a wholesale drug distributorship in this state, an applicant shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale drug distribution as defined in [section 3] for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) principals, including officers, directors, primary shareholders, and management executives, who shall at all times demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices as well as state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, pertaining to each wholesale drug distributor to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that assures preparation by the wholesale drug distributor for

the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;

(iv) lack of control of outdated or other unauthorized products;

(v) inappropriate disposition of returned goods; and

(vi) failure to promptly comply with product recalls; and

(h) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(5) An agent or employee of a licensed wholesale drug distributor need not be licensed as a wholesale drug distributor.

(6) For purposes of this section, all rules and regulations promulgated by the board must conform to the wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. If a conflict arises between a food and drug administration guideline and a rule or regulation of the board, the former controls.

NEW SECTION. **Section 6.** Out-of-state wholesale drug

distributor licensing requirements. (1) It is unlawful for an out-of-state wholesale drug distributor to conduct business in this state without first obtaining a license from the board and paying the license fee established by the board.

(2) Application for a license under this section must be made on a form furnished by the board.

(3) The issuance of a license may not affect tax liability imposed by the department of revenue on any out-of-state wholesale drug distributor.

(4) A person acting as principal or agent for an out-of-state wholesale drug distributor may not sell or distribute drugs in this state unless the distributor has obtained a license.

NEW SECTION. **Section 7.** Issuance of licenses. The license for wholesale drug distributors is effective from April 1 to March 31 of the following year. An application for renewal of a license must be mailed to each licensee on or before March 1, and if the renewal application and the fee are not mailed by March 31, the license is void upon its expiration date.

NEW SECTION. **Section 8.** Qualifications for licensure -- denial of license application -- notice and hearing. (1) The board shall consider the following factors in determining the qualifications of applicants to engage in

wholesale distribution of prescription drugs in this state:

(a) any conviction of the applicant under federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(b) any felony conviction of the applicant under federal, state, or local law;

(c) the applicant's previous experience in the manufacture or distribution of prescription drugs, including controlled substances;

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

(e) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) compliance with licensing requirements under any previously granted licenses;

(g) compliance with requirements to maintain or to make available to the board or to enforcement officers of the federal government or other states records required to be maintained under this section; and

(h) any other factors the board determines necessary to protect the public interest.

(2) The board may deny a license to an applicant that in the board's discretion fails to meet the qualifications outlined in this section. The board shall give the applicant notice of the proposed action and an opportunity for a hearing pursuant to Title 2, chapter 4.

NEW SECTION. **Section 9.** License discipline -- grounds for revocation, suspension, or refusal to renew license -- penalty -- notice and hearing. (1) The board may suspend, revoke, or refuse to renew a wholesale drug distribution license:

(a) obtained by misrepresentation or fraud;

(b) upon conviction of a violation of federal, state, or local drug laws;

(c) upon conviction of a violation of:

(i) the Federal Food, Drug, and Cosmetic Act (Title 21, chapter 9, U.S.C.);

(ii) Title 37, chapter 2 or 7;

(iii) Title 45, chapter 9 or 10;

(iv) Title 50, chapter 31 or 32; or rules adopted under subsections (1)(c)(i) through (1)(c)(iv);

(d) upon suspension or revocation by a state or territory of a license to conduct wholesale distribution of prescription drugs; or

(e) upon conviction of a violation of a provision listed in subsection (1) or [section 4, 5, or 6] or the

rules implementing them.

(2) It is a misdemeanor punishable by a fine of not more than $500 for a person or entity to distribute wholesale prescription drugs in violation of a provision of subsection (1) or [section 4, 5, or 6] or the rules implementing them.

(3) Before a license can be revoked or suspended, the holder of the license is entitled to notice and the opportunity for a hearing pursuant to Title 2, chapter 4.

NEW SECTION. **Section 10.** Board access to wholesale drug records. Wholesale drug distributors may keep records at a central location apart from the principal office of the wholesale drug distributor or the location where the drugs are stored and from where they are shipped, provided that the records must be available for inspection within 2 working days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drug recordkeeping.

NEW SECTION. **Section 11.** Rulemaking authority. The board shall adopt rules and regulations necessary to carry out the purpose and enforce the provisions of [sections 2 through 11]. If the rules and regulations conflict with the wholesale drug distribution guidelines promulgated by the United States food and drug administration, the latter control.

NEW SECTION. **Section 12.** Codification instruction. [Sections 2 through 11] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 2 through 11].

NEW SECTION. **Section 13.** Applicability. (1) The provisions of [section 1 through 11] are applicable to activities that occur on or after April 1, 1992.

(2) Rulemaking by the board may commence on July 1, 1991, to be applicable on April 1, 1992.

NEW SECTION. **Section 14.** Effective date. [This act] is effective July 1, 1991.

-End-

SENATE BILL NO. 135

INTRODUCED BY KENNEDY

BY REQUEST OF THE DEPARTMENT OF COMMERCE

A BILL FOR AN ACT ENTITLED: "AN ACT REQUIRING THE LICENSING OF WHOLESALE DRUG DISTRIBUTORS; PROVIDING FOR LICENSE FEES; PROVIDING PENALTIES FOR VIOLATIONS; AMENDING SECTION 37-7-201, MCA; AND PROVIDING AN EFFECTIVE DATE AND AN APPLICABILITY DATE."

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(2) The board shall:

(a) regulate the practice of pharmacy in this state subject to this chapter;

(b) determine the minimum equipment necessary in and for a pharmacy;

(c) regulate, under therapeutic classification, the sale of drugs, medicines, chemicals, and poisons and their labeling;

(d) regulate the quality of drugs and medicines dispensed in this state, using the United States Pharmacopoeia/National Formulary or revisions thereof as the standards;

(e) request the department to enter and inspect, at reasonable times, places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

(f) regulate the practice of interns under national standards;

REFERENCE BILL

(g) make rules for the conduct of its business;

(h) perform other duties and exercise other powers as this chapter requires;

(i) adopt and authorize the department to publish rules for carrying out and enforcing parts 1 through 3 of this chapter.

(3) The department shall:

(a) license, register, and examine, subject to 37-1-101, applicants whom the board considers qualified under this chapter;

(b) license pharmacies and certain stores under this chapter; and

(c) license wholesale drug distributors;

~~(c)~~(d) issue certificates of "certified pharmacy" under this chapter; and

(e) establish and collect license fees."

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(6) "Wholesale drug distribution" means distribution of prescription drugs to persons other than a consumer or patient. The term does not include:

(a) intracompany sales;

(b) 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 group purchasing organizations;

(c) 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;

(d) 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 subsection (d), "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, contract, or otherwise.

(e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection (e), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

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

(g) the distribution of drug samples by manufacturers'

representatives or distributors' representatives; or

(h) the sale, purchase, or trade of blood and blood components intended for transfusion.

(7) "Wholesale drug distributor" means a person or entity 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.

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(2) Licensed wholesale drug distributors other than pharmacies may not dispense or distribute prescription drugs directly to patients.

(3) A person who violates the provisions of this section is guilty of a misdemeanor.

NEW SECTION. **Section 5.** Wholesale drug distributor licensing requirements -- fee -- federal compliance. (1) A

person or distribution outlet may not act as a wholesale drug distributor without first obtaining a license from the board and paying the license fee.

(2) A license may not be issued or renewed for a wholesale drug distributor to operate in this state unless the applicant:

(a) agrees to abide by federal and state law and to comply with the rules adopted by the board; and

(b) pays the license fee set by the board.

(3) The board in its discretion may require that a separate license be obtained for:

(a) each facility directly or indirectly owned or operated by the same business entity within the state; or

(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted at more than one location and joint ownership and control exists among all entities.

(4) In order to obtain and maintain a wholesale drug distributorship in this state, an applicant shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale drug distribution as defined in [section 3] for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) principals, including officers, directors, primary shareholders, and management executives, who shall at all times demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices as well as state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, pertaining to each wholesale drug distributor to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that assures preparation by the wholesale drug distributor for

the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;

(iv) lack of control of outdated or other unauthorized products;

(v) inappropriate disposition of returned goods; and

(vi) failure to promptly comply with product recalls; and

(h) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(5) An agent or employee of a licensed wholesale drug distributor need not be licensed as a wholesale drug distributor.

(6) For purposes of this section, all rules and regulations promulgated by the board must conform to the wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. If a conflict arises between a food and drug administration guideline and a rule or regulation of the board, the former controls.

NEW SECTION. **Section 6.** Out-of-state wholesale drug

distributor licensing requirements. (1) It is unlawful for an out-of-state wholesale drug distributor to conduct business in this state without first obtaining a license from the board and paying the license fee established by the board.

(2) Application for a license under this section must be made on a form furnished by the board.

(3) The issuance of a license may not affect tax liability imposed by the department of revenue on any out-of-state wholesale drug distributor.

(4) A person acting as principal or agent for an out-of-state wholesale drug distributor may not sell or distribute drugs in this state unless the distributor has obtained a license.

NEW SECTION. **Section 7.** Issuance of licenses. The license for wholesale drug distributors is effective from April 1 to March 31 of the following year. An application for renewal of a license must be mailed to each licensee on or before March 1, and if the renewal application and the fee are not mailed by March 31, the license is void upon its expiration date.

NEW SECTION. **Section 8.** Qualifications for licensure -- denial of license application -- notice and hearing. (1) The board shall consider the following factors in determining the qualifications of applicants to engage in

wholesale distribution of prescription drugs in this state:

(a) any conviction of the applicant under federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(b) any felony conviction of the applicant under federal, state, or local law;

(c) the applicant's previous experience in the manufacture or distribution of prescription drugs, including controlled substances;

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

(e) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) compliance with licensing requirements under any previously granted licenses;

(g) compliance with requirements to maintain or to make available to the board or to enforcement officers of the federal government or other states records required to be maintained under this section; and

(h) any other factors the board determines necessary to protect the public interest.

(2) The board may deny a license to an applicant that in the board's discretion fails to meet the qualifications outlined in this section. The board shall give the applicant notice of the proposed action and an opportunity for a hearing pursuant to Title 2, chapter 4.

NEW SECTION. **Section 9. License discipline -- grounds for revocation, suspension, or refusal to renew license -- penalty -- notice and hearing.** (1) The board may suspend, revoke, or refuse to renew a wholesale drug distribution license:

(a) obtained by misrepresentation or fraud;

(b) upon conviction of a violation of federal, state, or local drug laws;

(c) upon conviction of a violation of:

(i) the Federal Food, Drug, and Cosmetic Act (Title 21, chapter 9, U.S.C.);

(ii) Title 37, chapter 2 or 7;

(iii) Title 45, chapter 9 or 10;

(iv) Title 50, chapter 31 or 32; or rules adopted under subsections (1)(c)(i) through (1)(c)(iv);

(d) upon suspension or revocation by a state or territory of a license to conduct wholesale distribution of prescription drugs; or

(e) upon conviction of a violation of a provision listed in subsection (1) or [section 4, 5, or 6] or the

rules implementing them.

(2) It is a misdemeanor punishable by a fine of not more than $500 for a person or entity to distribute wholesale prescription drugs in violation of a provision of subsection (1) or [section 4, 5, or 6] or the rules implementing them.

(3) Before a license can be revoked or suspended, the holder of the license is entitled to notice and the opportunity for a hearing pursuant to Title 2, chapter 4.

NEW SECTION. **Section 10. Board access to wholesale drug records.** Wholesale drug distributors may keep records at a central location apart from the principal office of the wholesale drug distributor or the location where the drugs are stored and from where they are shipped, provided that the records must be available for inspection within 2 working days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drug recordkeeping.

NEW SECTION. **Section 11. Rulemaking authority.** The board shall adopt rules and regulations necessary to carry out the purpose and enforce the provisions of [sections 2 through 11]. If the rules and regulations conflict with the wholesale drug distribution guidelines promulgated by the United States food and drug administration, the latter control.

NEW SECTION. **Section 12. Codification instruction.** [Sections 2 through 11] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 2 through 11].

NEW SECTION. **Section 13. Applicability.** (1) The provisions of [section 1 through 11] are applicable to activities that occur on or after April 1, 1992.

(2) Rulemaking by the board may commence on July 1, 1991, to be applicable on April 1, 1992.

NEW SECTION. **Section 14. Effective date.** [This act] is effective July 1, 1991.

-End-