# 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 INTRODUCED AND REFERRED TO COMMITTEE JANUARY 30, 1991 ON HUMAN SERVICES & AGING. FIRST READING. JANUARY 31, 1991

FEBRUARY 14, 1991 COMMITTEE RECOMMEND BILL BE CONCURRED IN. REPORT ADOPTED.

SECOND READING, CONCURRED IN. MARCH 8, 1991

THIRD READING, CONCURRED IN. MARCH 11, 1991

AYES, 98; NOES, 0.

RETURNED TO SENATE.

IN THE SENATE

RECEIVED FROM HOUSE. MARCH 12, 1991

SENT TO ENROLLING.

REPORTED CORRECTLY ENROLLED.

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BY REQUEST OF THE DEPARTMENT OF COMMERCE

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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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#### 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 quidelines developed by the FDA.

232425

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



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

- 2 "37-7-201. Organization -- powers and duties. (1) The
- 3 board shall meet at least once a year to transact its
- 4 business. The board shall annually elect from its members a
- 5 president, vice-president, and secretary.
- 6 (2) The board shall:
- 7 (a) regulate the practice of pharmacy in this state
- 8 subject to this chapter;
- 9 (b) determine the minimum equipment necessary in and
- 10 for a pharmacy:
- 11 (c) regulate, under therapeutic classification, the
- 12 sale of drugs, medicines, chemicals, and poisons and their
- 13 labeling:
- 14 (d) regulate the quality of drugs and medicines
- 15 dispensed in this state, using the United States
- 16 Pharmacopoeia/National Pormulary or revisions thereof as the
- 17 standards:
- 18 (e) request the department to enter and inspect, at
- 19 reasonable times, places where drugs, medicines, chemicals,
- 20 or poisons are sold, vended, given away, compounded,
- 21 dispensed, or manufactured. It is a misdemeanor for a person
- 22 to refuse to permit or otherwise prevent the department from
- 23 entering these places and making an inspection.
- 24 (f) regulate the practice of interns under national
- 25 standards;

INTRODUCED BILL SB 135

-2-

- (g) make rules for the conduct of its business;
- 2 (h) perform other duties and exercise other powers as 3 this chapter requires;
- 4 (i) adopt and authorize the department to publish rules 5 for carrying out and enforcing parts 1 through 3 of this
- (3) The department shall:

chapter.

- 8 (a) license, register, and examine, subject to 9 37-1-101, applicants whom the board considers qualified 10 under this chapter;
- (b) license pharmacies and certain stores under this chapter; and
- (c) license wholesale drug distributors;
- (e) establish and collect license fees."
- NEW SECTION. Section 2. Scope and purpose. [Sections 2
- 18 through 11] apply to a person or entity engaged in the
- 19 wholesale distribution of prescription drugs in this state.
- 20 The purpose of [sections 2 through 11] is to implement the
- 21 federal Prescription Drug Marketing Act of 1987 by providing
- 22 minimum standards, terms, and conditions for licensing by
- 23 the department of persons or entities engaged in wholesale
- 24 distributions of prescription drugs.
- 25 NEW SECTION. Section 3. Definitions. As used in

- [sections 2 through 11] the following definitions apply:
- 2 (1) "Blood" means whole blood collected from a single 3 donor and processed either for transfusion or for further
- 4 manufacturing.

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- 5 (2) "Blood component" means that part of blood 6 separated by physical or mechanical means.
- 7 (3) "Drug sample" means a unit of a prescription drug 8 that is not intended to be sold and is intended to promote 9 the sale of the drug.
- 10 (4) "Manufacturer" means a person or entity engaged in
  11 the manufacturing, preparing, propagating, compounding,
  12 processing, packaging, repackaging, or labeling of a
  13 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).
- 19 (6) "Wholesale drug distribution" means distribution of 20 prescription drugs to persons other than a consumer or 21 patient. The term does not include:
  - (a) intracompany sales;
- 23 (b) the purchase or other acquisition, by a hospital or 24 other health care entity that is a member of a group 25 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;
- 4 (c) the sale, purchase, or trade of a drug or an offer 5 to sell, purchase, or trade a drug by a charitable 6 organization described in section 501(c)(3) of the Internal 7 Revenue Code of 1954 to a nonprofit affiliate of the 8 organization to the extent otherwise permitted by law;

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- (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'

- l representatives or distributors' representatives; or
- 2 (h) the sale, purchase, or trade of blood and blood 3 components intended for transfusion.
- 4 (7) "Wholesale drug distributor" means a person or 5 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 9 10 warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail pharmacies that conduct 11
  - 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].
- 19 (2) Licensed wholesale drug distributors other than
  20 pharmacies may not dispense or distribute prescription drugs
  21 directly to patients.
- 22 (3) A person who violates the provisions of this
- 23 section is guilty of a misdemeanor.

wholesale distributions.

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- 24 NEW SECTION. Section 5. Wholesale drug distributor
- 25 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:
- 7 (a) agrees to abide by federal and state law and to 8 comply with the rules adopted by the board; and
  - (b) pays the license fee set by the board.

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- 10 (3) The board in its discretion may require that a
  11 separate license be obtained for:
- 12 (a) each facility directly or indirectly owned or 13 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;
- 23 (b) minimum liability and other insurance that may be 24 required by applicable federal or state law;
- 25 (c) a functioning security system that includes:

- 1 (i) an after hours central alarm or comparable entry
  2 detection system;
- 3 (ii) restricted access to the premises;

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- (iii) comprehensive employee applicant screening; and
- 5 (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;
- 16 (f) complete, updated information, to be provided to
  17 the board as a condition for obtaining and retaining a
  18 license, pertaining to each wholesale drug distributor to be
  19 licensed, including but not limited to:
- 20 (i) all pertinent corporate license information, if 21 applicable; and
- (ii) other information regarding ownership, principals,key personnel, and facilities;
- 24 (g) a written protocol of procedures and policies that
  25 assures preparation by the wholesale drug distributor for

LC 0567/01 LC 0567/01

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

- 3 (i) natural disaster or government emergency;
- 4 (ii) inventory inaccuracies or product shipping and 5 receiving:
- (iii) insufficient inspections for all incoming and
   outgoing product shipments;
- 8 (iv) lack of control of outdated or other unauthorized
  9 products;
- 10 (v) inappropriate disposition of returned goods; and
- 11 (vi) failure to promptly comply with product recalls;
  12 and
- 13 (h) operations in compliance with all federal 14 requirements applicable to wholesale drug distribution.
- 15 (5) An agent or employee of a licensed wholesale drug 16 distributor need not be licensed as a wholesale drug

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distributor.

- 18 (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.

  21 If a conflict arises between a food and drug administration guideline and a rule or regulation of the board, the former
- 24 controls.
- 25 NEW SECTION. Section 6. Out-of-state wholesale drug

1 distributor licensing requirements. (1) It is unlawful for

- 2 an out-of-state wholesale drug distributor to conduct
- 3 business in this state without first obtaining a license
- 4 from the board and paying the license fee established by the
- board.
- 6 (2) Application for a license under this section must 7 be made on a form furnished by the board.
- 8 (3) The issuance of a license may not affect tax
  9 liability imposed by the department of revenue on any
  10 out-of-state wholesale drug distributor.
- 11 (4) A person acting as principal or agent for an 12 out-of-state wholesale drug distributor may not sell or 13 distribute drugs in this state unless the distributor has
- 14 obtained a license.
- 15 NEW SECTION. Section 7. Issuance of licenses. The
- 16 license for wholesale drug distributors is effective from
- 17 April 1 to March 31 of the following year. An application
- 18 for renewal of a license must be mailed to each licensee on
- 19 or before March 1, and if the renewal application and the
- 20 fee are not mailed by March 31, the license is void upon its
- 21 expiration date.
- 22 NEW SECTION. Section 8. Qualifications for licensure
- 23 -- denial of license application -- notice and hearing. (1)
- 24 The board shall consider the following factors in
- 25 determining the qualifications of applicants to engage in

- 1 wholesale distribution of prescription drugs in this state:
- 2 (a) any conviction of the applicant under federal,
- 3 state, or local law relating to drug samples, wholesale or
- 4 retail drug distribution, or distribution of controlled
- 5 substances;
- 6 (b) any felony conviction of the applicant under
- 7 federal, state, or local law;
- 8 (c) the applicant's previous experience in the
- 9 manufacture or distribution of prescription drugs, including
- 10 controlled substances;
- ll (d) the furnishing by the applicant of false or
- 12 fraudulent material in any application made in connection
- 13 with drug distribution or manufacturing;
- (e) suspension or revocation by federal, state, or
- 15 local government of a license currently or previously held
- 16 by the applicant for the manufacture or distribution of any
- 17 drugs, including controlled substances;
- 18 (f) compliance with licensing requirements under any
- 19 previously granted licenses:
- 20 (g) compliance with requirements to maintain or to make
- 21 available to the board or to enforcement officers of the
- 22 federal government or other states records required to be
- 23 maintained under this section; and
- 24 (h) any other factors the board determines necessary to
- 25 protect the public interest.

- 1 (2) The board may deny a license to an applicant that
- 2 in the board's discretion fails to meet the qualifications
- 3 outlined in this section. The board shall give the applicant
- 4 notice of the proposed action and an opportunity for a
- 5 hearing pursuant to Title 2, chapter 4.
- 6 NEW SECTION. Section 9. License discipline -- grounds
- 7 for revocation, suspension, or refusal to renew license --
- 8 penalty -- notice and hearing. (1) The board may suspend,
- 9 revoke, or refuse to renew a wholesale drug distribution
- 10 license:
- 11 (a) obtained by misrepresentation or fraud;
- 12 (b) upon conviction of a violation of federal, state,
- 13 or local drug laws;
- 14 (c) upon conviction of a violation of:
- 15 (i) the Federal Food, Drug, and Cosmetic Act (Title 21,
- 16 chapter 9, U.S.C.);
- 17 (ii) Title 37, chapter 2 or 7:
- 18 (iii) Title 45, chapter 9 or 10;
- 19 (iv) Title 50, chapter 31 or 32; or rules adopted under
- 20 subsections (1)(c)(i) through (1)(c)(iv);
- 21 (d) upon suspension or revocation by a state or
- 22 territory of a license to conduct wholesale distribution of
- 23 prescription drugs; or
- 24 (e) upon conviction of a violation of a provision
- 25 listed in subsection (1) or [section 4, 5, or 6] or the

1 rules implementing them.

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- 2 (2) It is a misdemeanor punishable by a fine of not 3 more than \$500 for a person or entity to distribute 4 wholesale prescription drugs in violation of a provision of 5 subsection (1) or [section 4, 5, or 6] or the rules 6 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.

- 1 NEW SECTION. Section 12. Codification instruction.
- 2 [Sections 2 through 11] are intended to be codified as an
- 3 integral part of Title 37, chapter 7, and the provisions of
- 4 Title 37, chapter 7, apply to [sections 2 through 11].
- 5 NEW SECTION. Section 13. Applicability. (1) The
- 6 provisions of [section 1 through 11] are applicable to
- 7 activities that occur on or after April 1, 1992.
- 8 (2) Rulemaking by the board may commence on July 1,
- 9 1991, to be applicable on April 1, 1992.
- 10 NEW SECTION. Section 14. Effective date. [This act] is
- 11 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			
	<u>Current Law</u>	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, BUDGET DIRECTOR

DATE

Office of Budget and Program Planning

JOHN "ED" KENNEDY, JR., PRIMARY SPONSOR

DATE

DATE

Fiscal Note for SB0135, as introduced.

SB 135

# APPROVED BY COMMITTEE ON PUBLIC HEALTH, WELFARE & SAFETY

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INTRODUCED BY

BY REQUEST OF THE DEPARTMENT OF COMMERCE

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232425

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



- Section 1. Section 37-7-201, MCA, is amended to read:
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- 3 board shall meet at least once a year to transact its
- 4 business. The board shall annually elect from its members a
- 5 president, vice-president, and secretary.
  - (2) The board shall:
- 7 (a) regulate the practice of pharmacy in this state
- 8 subject to this chapter;
- 9 (b) determine the minimum equipment necessary in and
- 10 for a pharmacy;
- 11 (c) regulate, under therapeutic classification, the
- 12 sale of drugs, medicines, chemicals, and poisons and their
- 13 labeling;

- 14 (d) regulate the quality of drugs and medicines
  - dispensed in this state, using the United States
- 16 Pharmacopoeia/National Formulary or revisions thereof as the
- 17 standards:
- 18 (e) request the department to enter and inspect, at
- reasonable times, places where drugs, medicines, chemicals,
- 20 or poisons are sold, vended, given away, compounded,
- 21 dispensed, or manufactured. It is a misdemeanor for a person
- 22 to refuse to permit or otherwise prevent the department from
- 23 entering these places and making an inspection.
- 24 (f) regulate the practice of interns under national
- 25 standards;

- 1 (g) make rules for the conduct of its business;
- 2 (h) perform other duties and exercise other powers as 3 this chapter requires;
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- 8 (a) license, register, and examine, subject to 9 37-1-101, applicants whom the board considers qualified 10 under this chapter;
- (b) license pharmacies and certain stores under this chapter; and
- 13 (c) license wholesale drug distributors;
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- 19 wholesale distribution of prescription drugs in this state.
- 20 The purpose of [sections 2 through 11] is to implement the
- 21 federal Prescription Drug Marketing Act of 1987 by providing
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- 23 the department of persons or entities engaged in wholesale
- 24 distributions of prescription drugs.
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- 5 (2) "Blood component" means that part of blood 6 separated by physical or mechanical means.
- 7 (3) "Drug sample" means a unit of a prescription drug 8 that is not intended to be sold and is intended to promote 9 the sale of the drug.
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  18 Food, Drug, and Cosmetic Act (21 U.S.C.S. 353).
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- 22 (a) intracompany sales;
- 23 (b) the purchase or other acquisition, by a hospital or 24 other health care entity that is a member of a group 25 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;

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- (c) the sale, purchase, or trade of a drug or an offer 5 to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal 7 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.
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- 25 (q) the distribution of drug samples by manufacturers'

- 1 representatives or distributors' representatives; or
- 2 (h) the sale, purchase, or trade of blood and blood 3 components intended for transfusion.
- (7) "Wholesale drug distributor" means a person or 4 entity engaged in wholesale distribution of prescription drugs, including but not limited to manufacturers, 7 repackers. own-label distributors. private-label distributors, jobbers, brokers, warehouses (including manufacturers' and distributors' warehouses, chain drug q 10 warehouses, and wholesale drug warehouses), independent 11 wholesale drug traders, and retail pharmacies that conduct 12 wholesale distributions.
- 13 NEW SECTION. Section 4. Prohibited purchase or receipt 14 of drugs -- restrictions on wholesale drug distributors --15 penalty. (1) Except as otherwise provided, it is unlawful 16 for a person to knowingly purchase or receive a prescription 17 drug from a source other than a person or entity licensed 18 under [sections 2 through 11].
- 19 (2) Licensed wholesale drug distributors other than 20 pharmacies may not dispense or distribute prescription drugs 21 directly to patients.
- 22 (3) A person who violates the provisions of this 23 section is guilty of a misdemeanor.
- 24 NEW SECTION. Section 5. Wholesale drug distributor
- 25 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.

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- 10 (3) The board in its discretion may require that a
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  - (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:

- 1 (i) an after hours central alarm or comparable entry
  2 detection system;
- 3 (ii) restricted access to the premises;
- 4 (iii) comprehensive employee applicant screening; and
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  9 records must be accessible, as defined by board regulations,
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- 11 (e) principals, including officers, directors, primary
  12 shareholders, and management executives, who shall at all
  13 times demonstrate and maintain their responsibility for
  14 conducting the business in conformity with sound financial
  15 practices as well as state and federal law;
- 16 (f) complete, updated information, to be provided to
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  19 licensed, including but not limited to:
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- 24 (g) a written protocol of procedures and policies that
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LC 0567/01 LC 0567/01

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controls.

- 4 (ii) inventory inaccuracies or product shipping and 5 receiving;
  - (iii) insufficient inspections for all incoming and outgoing product shipments;
- 8 (iv) lack of control of outdated or other unauthorized9 products;
  - (v) inappropriate disposition of returned goods; and
- (vi) failure to promptly comply with product recalls;
  and
- (h) operations in compliance with all federalrequirements 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
- 25 NEW SECTION. Section 6. Out-of-state wholesale drug

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

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expiration date.

- 6 (2) Application for a license under this section must 7 be made on a form furnished by the board.
- 8 (3) The issuance of a license may not affect tax
  9 liability imposed by the department of revenue on any
  10 out-of-state wholesale drug distributor.
- 11 (4) A person acting as principal or agent for an 12 out-of-state wholesale drug distributor may not sell or 13 distribute drugs in this state unless the distributor has 14 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
- 22 <u>NEW SECTION.</u> Section 8. Qualifications for licensure
- 23 -- denial of license application -- notice and hearing. (1)
- 24 The board shall consider the following factors in
- 25 determining the qualifications of applicants to engage in

- wholesale distribution of prescription drugs in this state:
- 2 (a) any conviction of the applicant under federal,
- 3 state, or local law relating to drug samples, wholesale or
  - retail drug distribution, or distribution of controlled
- 5 substances;

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- 6 (b) any felony conviction of the applicant under
- 7 federal, state, or local law;
- 8 (c) the applicant's previous experience in the
- 9 manufacture or distribution of prescription drugs, including
- 10 controlled substances;
- ll (d) the furnishing by the applicant of false or
- 12 fraudulent material in any application made in connection
- 13 with drug distribution or manufacturing;
- 14 (e) suspension or revocation by federal, state, or
- 15 local government of a license currently or previously held
- 16 by the applicant for the manufacture or distribution of any
  - drugs, including controlled substances;
- 18 (f) compliance with licensing requirements under any
- 19 previously granted licenses;
- 20 (g) compliance with requirements to maintain or to make
- 21 available to the board or to enforcement officers of the
- 22 federal government or other states records required to be
- 23 maintained under this section; and
- 24 (h) any other factors the board determines necessary to
- 25 protect the public interest.

- 1 (2) The board may deny a license to an applicant that
- 2 in the board's discretion fails to meet the qualifications
- 3 outlined in this section. The board shall give the applicant
- 4 notice of the proposed action and an opportunity for a
- 5 hearing pursuant to Title 2, chapter 4.
- 6 NEW SECTION. Section 9. License discipline -- grounds
- 7 for revocation, suspension, or refusal to renew license --
- 8 penalty -- notice and hearing. (1) The board may suspend,
- 9 revoke, or refuse to renew a wholesale drug distribution
- 10 license:
- 11 (a) obtained by misrepresentation or fraud;
- (b) upon conviction of a violation of federal, state,
- 13 or local drug laws;
- 14 (c) upon conviction of a violation of:
- 15 (i) the Federal Food, Drug, and Cosmetic Act (Title 21,
- 16 chapter 9, U.S.C.);
- 17 (ii) Title 37, chapter 2 or 7;
- 18 (iii) Title 45, chapter 9 or 10;
- 19 (iv) Title 50, chapter 31 or 32; or rules adopted under
- 20 subsections (1)(c)(i) through (1)(c)(iv);
- 21 (d) upon suspension or revocation by a state or
- 22 territory of a license to conduct wholesale distribution of
- 23 prescription drugs; or
- (e) upon conviction of a violation of a provision
- 25 listed in subsection (1) or [section 4, 5, or 6] or the

1 rules implementing them.

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- 2 (2) It is a misdemeanor punishable by a fine of not 3 more than \$500 for a person or entity to distribute 4 wholesale prescription drugs in violation of a provision of 5 subsection (1) or [section 4, 5, or 6] or the rules 6 implementing them.
- 7 (3) Before a license can be revoked or suspended, the 8 holder of the license is entitled to notice and the 9 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.
- 2 [Sections 2 through 11] are intended to be codified as an
- 3 integral part of Title 37, chapter 7, and the provisions of
- 4 Title 37, chapter 7, apply to [sections 2 through 11].
- 5 NEW SECTION. Section 13. Applicability. (1) The
- 6 provisions of [section 1 through 11] are applicable to
- 7 activities that occur on or after April 1, 1992.
- 8 (2) Rulemaking by the board may commence on July 1,
- 9 1991, to be applicable on April 1, 1992.
- NEW SECTION. Section 14. Effective date. [This act] is
- 11 effective July 1, 1991.

-End-

1	Sente BILL NO. 135
2	INTRODUCED BY Comely
3	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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#### 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.

232425

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

Montana Legistative Council

- 1 Section 1. Section 37-7-201, MCA, is amended to read:
- 2 "37-7-201. Organization -- powers and duties. (1) The
- 3 board shall meet at least once a year to transact its
- 4 business. The board shall annually elect from its members a
- 5 president, vice-president, and secretary.
  - (2) The board shall:
- 7 (a) regulate the practice of pharmacy in this state
- 8 subject to this chapter;
- 9 (b) determine the minimum equipment necessary in and
- 10 for a pharmacy;
- 11 (c) regulate, under therapeutic classification, the
- 12 sale of drugs, medicines, chemicals, and poisons and their
- 13 labeling;
- 14 (d) regulate the quality of drugs and medicines
- 15 dispensed in this state, using the United States
- 16 Pharmacopoeia/National Formulary or revisions thereof as the
- 17 standards:
- 18 (e) request the department to enter and inspect, at
- 19 reasonable times, places where drugs, medicines, chemicals,
- 20 or poisons are sold, vended, given away, compounded,
- 21 dispensed, or manufactured. It is a misdemeanor for a person
- 22 to refuse to permit or otherwise prevent the department from
- 23 entering these places and making an inspection.
- 24 (f) regulate the practice of interns under national
- 25 standards;

THIRD READING

- 1 (g) make rules for the conduct of its business;
- (h) perform other duties and exercise other powers asthis chapter requires;
  - (i) adopt and authorize the department to publish rules for carrying out and enforcing parts 1 through 3 of this chapter.
- 7 (3) The department shall:

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- (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 thischapter; and
- 13 (c) license wholesale drug distributors;
- - (e) establish and collect license fees."
- NEW SECTION. Section 2. Scope and purpose. [Sections 2 17 18 through 11) apply to a person or entity engaged in the 19 wholesale distribution of prescription drugs in this state. 20 The purpose of [sections 2 through 11] is to implement the 21 federal Prescription Drug Marketing Act of 1987 by providing 22 minimum standards, terms, and conditions for licensing by 23 the department of persons or entities engaged in wholesale distributions of prescription drugs. 24
- 25 NEW SECTION. Section 3. Definitions. As used in

- 1 (sections 2 through 11) the following definitions apply:
- 2 (1) "Blood" means whole blood collected from a single
  3 donor and processed either for transfusion or for further
  4 manufacturing.
- 5 (2) "Blood component" means that part of blood 6 separated by physical or mechanical means.
- 7 (3) "Drug sample" means a unit of a prescription drug
  8 that is not intended to be sold and is intended to promote
  9 the sale of the drug.
- 10 (4) "Manufacturer" means a person or entity engaged in
  11 the manufacturing, preparing, propagating, compounding,
  12 processing, packaging, repackaging, or labeling of a
  13 prescription drug.
- 14 (5) "Prescription drug" means any drug for humans that
  15 is required by federal law or regulation to be dispensed
  16 only by a prescription, including finished dosage forms and
  17 active ingredients subject to section 503(b) of the Federal
  18 Food, Drug, and Cosmetic Act (21 U.S.C.S. 353).
- 19 (6) "Wholesale drug distribution" means distribution of
  20 prescription drugs to persons other than a consumer or
  21 patient, The term does not include:
- 22 (a) intracompany sales;
- 23 (b) the purchase or other acquisition, by a hospital or 24 other health care entity that is a member of a group 25 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:

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- (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;
- 25 (g) the distribution of drug samples by manufacturers'

- representatives or distributors' representatives; or
- 2 (h) the sale, purchase, or trade of blood and blood3 components intended for transfusion.
- (7) "Wholesale drug distributor" means a person or 5 entity engaged in wholesale distribution of prescription drugs, including but not limited to manufacturers. 7 repackers. own-label distributors. private-label distributors, jobbers, brokers, warehouses (including manufacturers' and distributors' warehouses, chain drug 10 warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail pharmacies that conduct 11 12 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 111.
- (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 thissection is guilty of a misdemeanor.
- NEW SECTION. Section 5. Wholesale drug distributor
  licensing requirements -- fee -- federal compliance. (1) A

LC 0567/01

- 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.
- 4 (2) A license may not be issued or renewed for a 5 wholesale drug distributor to operate in this state unless 6 the applicant:
  - (a) agrees to abide by federal and state law and to comply with the rules adopted by the board; and
- 9 (b) pays the license fee set by the board.

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- 10 (3) The board in its discretion may require that a
  11 separate license be obtained for:
- (a) each facility directly or indirectly owned oroperated 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 berequired by applicable federal or state law;
- 25 (c) a functioning security system that includes:

- 1 (i) an after hours central alarm or comparable entry
  2 detection system;
- 3 (ii) restricted access to the premises;
- 4 (iii) comprehensive employee applicant screening; and
- 5 (iv) safequards against employee theft;
- 6 (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.
- 11 (e) principals, including officers, directors, primary
  12 shareholders, and management executives, who shall at all
  13 times demonstrate and maintain their responsibility for
  14 conducting the business in conformity with sound financial
  15 practices as well as state and federal law;
- 16 (f) complete, updated information, to be provided to
  17 the board as a condition for obtaining and retaining a
  18 license, pertaining to each wholesale drug distributor to be
  19 licensed, including but not limited to:
- (i) all pertinent corporate license information, ifapplicable; 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

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- the handling of security or operational problems, including
  but not limited to those caused by:
- 3 (i) natural disaster or government emergency;
- 4 (ii) inventory inaccuracies or product shipping and 5 receiving;
- 6 (iii) insufficient inspections for all incoming and
   7 outgoing product shipments;
- 8 (iv) lack of control of outdated or other unauthorized9 products;
- 10 (v) inappropriate disposition of returned goods; and
- (vi) failure to promptly comply with product recalls;and
- (h) operations in compliance with all federalrequirements 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.
- 22 If a conflict arises between a food and drug administration
- $\,$  guideline and a rule or regulation of the board, the  $\,$  former
- 24 controls.

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

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

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- 6 (2) Application for a license under this section must 7 be made on a form furnished by the board.
- 8 (3) The issuance of a license may not affect tax
  - liability imposed by the department of revenue on any
- 10 out-of-state wholesale drug distributor.
- 11 (4) A person acting as principal or agent for an
- 12 out-of-state wholesale drug distributor may not sell or
  - distribute drugs in this state unless the distributor has
- 14 obtained a license.
- 15 NEW SECTION. Section 7. Issuance of licenses. The
- 16 license for wholesale drug distributors is effective from
- 17 April 1 to March 31 of the following year. An application
- 18 for renewal of a license must be mailed to each licensee on
- 19 or before March 1, and if the renewal application and the
- 20 fee are not mailed by March 31, the license is void upon its
- 21 expiration date.
- 22 NEW SECTION. Section 8. Qualifications for licensure
- 23 -- denial of license application -- notice and hearing. (1)
- 24 The board shall consider the following factors in
- 25 determining the qualifications of applicants to engage in

- 1 wholesale distribution of prescription drugs in this state:
- 2 (a) any conviction of the applicant under federal,
- 3 state, or local law relating to drug samples, wholesale or
- 4 retail drug distribution, or distribution of controlled
- 5 substances:

- 6 (b) any felony conviction of the applicant under
- 7 federal, state, or local law;
- 8 (c) the applicant's previous experience in the
- 9 manufacture or distribution of prescription drugs, including
- 10 controlled substances:
- (d) the furnishing by the applicant of false or
- 12 fraudulent material in any application made in connection
- 13 with drug distribution or manufacturing:
- (e) suspension or revocation by federal, state, or
  - local government of a license currently or previously held
- 16 by the applicant for the manufacture or distribution of any
- 17 drugs, including controlled substances;
- (f) compliance with licensing requirements under any
- 19 previously granted licenses:
- 20 (q) compliance with requirements to maintain or to make
- 21 available to the board or to enforcement officers of the
- 22 federal government or other states records required to be
- 23 maintained under this section; and
- 24 (h) any other factors the board determines necessary to
- 25 protect the public interest.

- 1 (2) The board may deny a license to an applicant that
- 2 in the board's discretion fails to meet the qualifications
- 3 outlined in this section. The board shall give the applicant
- 4 notice of the proposed action and an opportunity for a
- 5 hearing pursuant to Title 2, chapter 4.
- 6 NEW SECTION. Section 9. License discipline -- grounds
- 7 for revocation, suspension, or refusal to renew license --
- penalty -- notice and hearing. (1) The board may suspend,
- g revoke, or refuse to renew a wholesale drug distribution
- 10 license:
- 11 (a) obtained by misrepresentation or fraud;
- 12 (b) upon conviction of a violation of federal, state,
- 13 or local drug laws;
- 14 (c) upon conviction of a violation of:
- 15 (i) the Federal Food, Drug, and Cosmetic Act (Title 21,
- 16 chapter 9, U.S.C.);
- 17 (ii) Title 37, chapter 2 or 7;
- 18 (iii) Title 45, chapter 9 or 10;
- 19 (iv) Title 50, chapter 31 or 32; or rules adopted under
- 20 subsections (1)(c)(i) through (1)(c)(iv);
- 21 (d) upon suspension or revocation by a state or
- 22 territory of a license to conduct wholesale distribution of
- 23 prescription drugs; or
- 24 (e) upon conviction of a violation of a provision
- 25 listed in subsection (1) or [section 4, 5, or 6] or the

rules implementing them.

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- (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.

- 1 NEW SECTION. Section 12. Codification instruction.
- 2 [Sections 2 through 11] are intended to be codified as an
- 3 integral part of Title 37, chapter 7, and the provisions of
- 4 Title 37, chapter 7, apply to [sections 2 through 11].
- 5 NEW SECTION. Section 13. Applicability. (1) The
- 6 provisions of [section 1 through 11] are applicable to
- 7 activities that occur on or after April 1, 1992.
- 8 (2) Rulemaking by the board may commence on July 1,
- 9 1991, to be applicable on April 1, 1992.
- 10 NEW SECTION. Section 14. Effective date. [This act] is
- 11 effective July 1, 1991.

-End-

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2	INTRODUCED BY KENNEDY
3	BY REQUEST OF THE DEPARTMENT OF COMMERCE
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5	A BILL FOR AN ACT ENTITLED: "AN ACT REQUIRING THE LICENSING
6	OF WHOLESALE DRUG DISTRIBUTORS; PROVIDING FOR LICENSE FEES;
7	PROVIDING PENALTIES FOR VIOLATIONS; AMENDING SECTION
8	37-7-201, MCA; AND PROVIDING AN EFFECTIVE DATE AND AN
9	APPLICABILITY DATE."
10	
11	STATEMENT OF INTENT
12	A statement of intent is required for this bill because
13	it is anticipated that promulgation of administrative rules
14	will be necessary to implement this bill. This bill is
15	proposed solely to bring Montana standards on licensing
16	wholesale drug distributors into compliance with rules of
17	the federal food and drug administration (FDA). Unless state
18	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

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

1987 as well as guidelines developed by the FDA.

SENATE BILL NO. 135

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Lontana	Legislative	Council

1	Section 1.	Section	37-7-201,	MCA, i	s ame	n <b>ded</b> to	read:	
2	*37-7-201.	Organiz	ation	powers	and	duties	. (1) 7	Che

- board shall meet at least once a year to transact its business. The board shall annually elect from its members a
- 5 president, vice-president, and secretary.
  - (2) The board shall:
- 7 (a) regulate the practice of pharmacy in this state8 subject to this chapter;
- 9 (b) determine the minimum equipment necessary in and 10 for a pharmacy;
- 11 (c) regulate, under therapeutic classification, the 12 sale of drugs, medicines, chemicals, and poisons and their 13 labeling;
- 14 (d) regulate the quality of drugs and medicines
  15 dispensed in this state, using the United States
  16 Pharmacopoeia/National Formulary or revisions thereof as the
  17 standards;
- 18 (e) request the department to enter and inspect, at
  19 reasonable times, places where drugs, medicines, chemicals,
  20 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
- 23 entering these places and making an inequation
- 23 entering these places and making an inspection.
- 24 (f) regulate the practice of interns under national
- 25 standards;

SB 0135/02 SB 0135/02

- 1 (g) make rules for the conduct of its business;
- 2 (h) perform other duties and exercise other powers as 3 this chapter requires;
- 4 (i) adopt and authorize the department to publish rules 5 for carrying out and enforcing parts 1 through 3 of this 6 chapter.
- 7 (3) The department shall:
- 8 (a) license, register, and examine, subject to 9 37-1-101, applicants whom the board considers qualified 10 under this chapter;
- (b) license pharmacies and certain stores under this chapter; and
- 13 (c) license wholesale drug distributors;
- - (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.
- 25 NEW SECTION. Section 3. Definitions. As used in

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- 1 [sections 2 through 11] the following definitions apply:
- 2 (1) "Blood" means whole blood collected from a single 3 donor and processed either for transfusion or for further 4 manufacturing.
- 5 (2) "Blood component" means that part of blood
  6 separated by physical or mechanical means.
- 7 (3) "Drug sample" means a unit of a prescription drug 8 that is not intended to be sold and is intended to promote 9 the sale of the drug.
- 10 (4) "Manufacturer" means a person or entity engaged in
  11 the manufacturing, preparing, propagating, compounding,
  12 processing, packaging, repackaging, or labeling of a
  13 prescription drug.
- 14 (5) "Prescription drug" means any drug for humans that
  15 is required by federal law or regulation to be dispensed
  16 only by a prescription, including finished dosage forms and
  17 active ingredients subject to section 503(b) of the Federal
  18 Food, Drug, and Cosmetic Act (21 U.S.C.S. 353).
- 19 (6) "Wholesale drug distribution" means distribution of 20 prescription drugs to persons other than a consumer or 21 patient. The term does not include:
  - (a) intracompany sales;

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23 (b) the purchase or other acquisition, by a hospital or
24 other health care entity that is a member of a group
25 purchasing organization, of a drug for its own use from the

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group purchasing organization or from other hospitals or health care entities that are members of group purchasing organizations:

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- (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.
- 22 (f) the sale, purchase, or trade of a drug or an offer 23 to sell, purchase, or trade a drug, or the dispensing of a 24 drug pursuant to a prescription;
- 25 (g) the distribution of drug samples by manufacturers'

- representatives or distributors' representatives; or
- 2 (h) the sale, purchase, or trade of blood and blood3 components intended for transfusion.
- 4 (7) "Wholesale drug distributor" means a person or 5 entity engaged in wholesale distribution of prescription 6 drugs, including but not limited to manufacturers, 7 repackers, own-label distributors, private-label 8 distributors, jobbers, brokers, warehouses (including 9 manufacturers' and distributors' warehouses, chain drug 10 warehouses, and wholesale drug warehouses), independent 11 wholesale drug traders, and retail pharmacies that conduct 12 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].
- 19 (2) Licensed wholesale drug distributors other than 20 pharmacies may not dispense or distribute prescription drugs 21 directly to patients.
- 22 (3) A person who violates the provisions of this 23 section is guilty of a misdemeanor.
- NEW SECTION. Section 5. Wholesale drug distributor
  licensing requirements -- fee -- federal compliance. (1) A

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SB 0135/02 SB 0135/02

person or distribution outlet may not act as a wholesale 1 drug distributor without first obtaining a license from the 2 board and paying the license fee. 3

- (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.

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- (3) The board in its discretion may require that a 10 separate license be obtained for: 11
  - (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: 21
  - (a) adequate storage conditions and facilities;
- (b) minimum liability and other insurance that may be 23 required by applicable federal or state law; 24

-7-

(c) a functioning security system that includes: 25

- 1 (i) an after hours central alarm or comparable entry detection system;
- 3 (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,
- 10 for inspections authorized by the board.
- 11 (e) principals, including officers, directors, primary 12 shareholders, and management executives, who shall at all 13
- times demonstrate and maintain their responsibility for 14 conducting the business in conformity with sound financial
- 15 practices as well as state and federal law:
- 16 (f) complete, updated information, to be provided to
- 17 the board as a condition for obtaining and retaining a
- 18 license, pertaining to each wholesale drug distributor to be
- 19 licensed, including but not limited to:
- 20 (i) all pertinent corporate license information, if 21 applicable; and
- 22 (ii) other information regarding ownership, principals,
- 23 key personnel, and facilities;
- 24 (9) a written protocol of procedures and policies that
- 25 assures preparation by the wholesale drug distributor for

-8-

SB 135

SB 0135/02 SB 0135/02

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

- 3 (i) natural disaster or government emergency;
- 4 (ii) inventory inaccuracies or product shipping and 5 receiving;
- 6 (iii) insufficient inspections for all incoming and
   7 outgoing product shipments;
- 8 (iv) lack of control of outdated or other unauthorized
  9 products;
- 10 (v) inappropriate disposition of returned goods; and
- 11 (vi) failure to promptly comply with product recalls;
- 12 and

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- 13 (h) operations in compliance with all federal
  14 requirements applicable to wholesale drug distribution.
- 15 (5) An agent or employee of a licensed wholesale drug
  16 distributor need not be licensed as a wholesale drug
  17 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
- 24 controls.
- 25 NEW SECTION. Section 6. Out-of-state wholesale drug

- distributor licensing requirements. (1) It is unlawful for
- 2 an out-of-state wholesale drug distributor to conduct
- 3 business in this state without first obtaining a license
- 4 from the board and paying the license fee established by the
- 5 board.
- 6 (2) Application for a license under this section must
  7 be made on a form furnished by the board.
- 8 (3) The issuance of a license may not affect tax
  9 liability imposed by the department of revenue on any
  10 out-of-state wholesale drug distributor.
- 11 (4) A person acting as principal or agent for an 12 out-of-state wholesale drug distributor may not sell or 13 distribute drugs in this state unless the distributor has
- 14 obtained a license.
- NEW SECTION. Section 7. Issuance of licenses. The
- 16 license for wholesale drug distributors is effective from
- 17 April 1 to March 31 of the following year. An application
- 18 for renewal of a license must be mailed to each licensee on
- 19 or before March 1, and if the renewal application and the
- 20 fee are not mailed by March 31, the license is void upon its
- 21 expiration date.
- NEW SECTION. Section 8. Qualifications for licensure
- 23 -- denial of license application -- notice and hearing. (1)
- 24 The board shall consider the following factors in
- 25 determining the qualifications of applicants to engage in

-10-

-9- SB 135

SB 135

SB 0135/02 SB 0135/02

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
- 4 retail drug distribution, or distribution of controlled
- 5 substances;

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- 6 (b) any felony conviction of the applicant under
- 7 federal, state, or local law;
- 8 (c) the applicant's previous experience in the
- 9 manufacture or distribution of prescription drugs, including
- 10 controlled substances;
- 11 (d) the furnishing by the applicant of false or
- 12 fraudulent material in any application made in connection
- 13 with drug distribution or manufacturing;
- 14 (e) suspension or revocation by federal, state, or
- 15 local government of a license currently or previously held
- 16 by the applicant for the manufacture or distribution of any
- 17 drugs, including controlled substances;
- 18 (f) compliance with licensing requirements under any
- 19 previously granted licenses;
- 20 (q) compliance with requirements to maintain or to make
- 21 available to the board or to enforcement officers of the
- 22 federal government or other states records required to be
- 23 maintained under this section; and
- 24 (h) any other factors the board determines necessary to

-11-

25 protect the public interest.

- 1 (2) The board may deny a license to an applicant that
- 2 in the board's discretion fails to meet the qualifications
- 3 outlined in this section. The board shall give the applicant
  - notice of the proposed action and an opportunity for a
- 5 hearing pursuant to Title 2, chapter 4.
- 6 NEW SECTION. Section 9. License discipline -- grounds
- 7 for revocation, suspension, or refusal to renew license --
- 8 penalty -- notice and hearing. (1) The board may suspend,
  - revoke, or refuse to renew a wholesale drug distribution
- 10 license:
- 11 (a) obtained by misrepresentation or fraud;
- (b) upon conviction of a violation of federal, state,
- 13 or local drug laws:
- (c) upon conviction of a violation of:
- 15 (i) the Federal Food, Drug, and Cosmetic Act (Title 21,
- 16 chapter 9, U.S.C.):
- 17 (ii) Title 37, chapter 2 or 7;
- 18 (iii) Title 45, chapter 9 or 10;
- 19 (iv) Title 50, chapter 31 or 32; or rules adopted under
- 20 subsections (1)(c)(i) through (1)(c)(iv);
- 21 (d) upon suspension or revocation by a state or
- 22 territory of a license to conduct wholesale distribution of
- 23 prescription drugs; or
- 24 (e) upon conviction of a violation of a provision
- 25 listed in subsection (1) or [section 4, 5, or 6] or the

SB 135

-12-

SB 0135/02

SB 0135/02

rules implementing them.

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- (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.
- 2 [Sections 2 through 11] are intended to be codified as an
- 3 integral part of Title 37, chapter 7, and the provisions of
- 4 Title 37, chapter 7, apply to [sections 2 through 11].
- 5 NEW SECTION. Section 13. Applicability. (1) The
- 6 provisions of [section 1 through 11] are applicable to
- 7 activities that occur on or after April 1, 1992.
- 8 (2) Rulemaking by the board may commence on July 1,
- 9 1991, to be applicable on April 1, 1992.
- 10 NEW SECTION. Section 14. Effective date. [This act] is
- 11 effective July 1, 1991.

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