1	SENATE BILL NO. 348
2	INTRODUCED BY R. WEBB
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4	A BILL FOR AN ACT ENTITLED: "AN ACT REVISING LAWS RELATED TO SCHEDULE II DRUGS; PROVIDING
5	FOR A FEE OF 0.01 CENT PER DOSE OF TAX ON ANY SCHEDULE II DRUG FOR USE IN MAINTAINING
6	THE PRESCRIPTION DRUG REGISTRY AND PROVIDING DRUG EDUCATION; AND SOLD BY A
7	WHOLESALE DRUG DISTRIBUTOR; PROVIDING FOR ASSESSMENT AND COLLECTION OF THE TAX BY
8	THE DEPARTMENT OF REVENUE; ESTABLISHING A STATE SPECIAL REVENUE ACCOUNT ADMINISTERED
9	BY THE DEPARTMENT OF JUSTICE; PROVIDING FOR THE DISTRIBUTION OF REVENUE FOR MEDICAL
10	EDUCATION, DRUG PREVENTION, AND TEAM-BUILDING PROGRAMS; PROVIDING RULEMAKING
11	AUTHORITY; AMENDING SECTIONS 37-7-1511, 37-7-604 AND 37-7-605, MCA; AND PROVIDING
12	AN APPLICABILITY DATE."
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14	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
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16	Section 1. Section 37-7-1511, MCA, is amended to read:
17	"37-7-1511. Prescription drug registry funding fees. (1) Each person licensed under Title 37 who
18	is authorized to prescribe, dispense, or distribute controlled substances shall pay to the board a nonrefundable
19	fee that is set by rule commensurate with costs, not to exceed \$30.
20	(2) The board may apply for any available grants and may accept gifts, grants, or donations to assist in
21	establishing and maintaining the registry.
22	(3) Funds collected pursuant to this part must be deposited into a state special revenue account to the
23	credit of the department. The money must be used to defray the expenses of the board in establishing and
24	maintaining the registry and in discharging its administrative and regulatory duties under this part.
25	(4) (a) For each dose of a Schedule II drug, as designated in 50-32-224, that is prescribed by a person
26	licensed under Title 37 who is authorized to prescribe, dispense, or distribute Schedule II drugs, the patient shall
27	pay a nonrefundable fee of 0.01 cent per dose.
28	(b) Funds collected pursuant to this subsection (4) must be deposited in the state special revenue
29	account established in subsection (3) and used to defray the expenses of the board in maintaining the registry
30	under this part. Once the expenses necessary to maintain the registry are met, the board may use any remaining

1 funds to pay for drug education programs. (Subsection (1) terminates June 30, 2017--sec. 2, Ch. 357, L. 2015.)" 2 3 NEW SECTION. Section 1. Definitions. As used in [sections 1 through 8], the following definitions 4 APPLY: 5 (1) "DEPARTMENT" MEANS THE DEPARTMENT OF REVENUE PROVIDED FOR IN 2-15-1301. (2) "WHOLESALE DRUG DISTRIBUTION" HAS THE MEANING PROVIDED IN 37-7-602. 6 7 (3) "Wholesale drug distributor" has the meaning provided in 37-7-602. 8 9 NEW SECTION. Section 2. Schedule II drug tax -- wholesaler. A tax of 1/10 of 1% of the 10 WHOLESALE PRICE IS IMPOSED ON SALES OF ALL SCHEDULE II DRUGS IN THIS STATE. THE TAX IS IMPOSED ON THE 11 WHOLESALE DRUG DISTRIBUTOR FOR WHOLESALE DRUG DISTRIBUTION SALES AND IS PAYABLE TO THE DEPARTMENT. 12 13 NEW SECTION. Section 3. Quarterly statement and payment of tax -- recordkeeping. (1) Each WHOLESALE DRUG DISTRIBUTOR SHALL, WITHIN 30 DAYS AFTER THE END OF EACH QUARTER, FILE A RETURN ON A FORM 14 15 PROVIDED BY THE DEPARTMENT AND PAY THE TAX DUE UNDER [SECTION 2]. THE DEPARTMENT MAY ADMINISTER 16 COLLECTION OF THE TAX THROUGH AN ELECTRONIC FORM, INCLUDING PAYMENT OF THE TAX BY AN ELECTRONIC FUNDS 17 TRANSFER. 18 (2) THE TAX MUST BE PAID IN QUARTERLY INSTALLMENTS FOR THE QUARTERS ENDING MARCH 31, JUNE 30, 19 SEPTEMBER 30, AND DECEMBER 31 OF EACH YEAR. 20 (3) EACH WHOLESALE DRUG DISTRIBUTOR SHALL KEEP A RECORD IN THE FORM REQUIRED BY THE DEPARTMENT 21 OF ALL SCHEDULE II DRUGS SOLD IN THIS STATE. THE RECORDS ARE SUBJECT TO INSPECTION BY THE DEPARTMENT. 22 (4) THE DEPARTMENT MAY GRANT A REASONABLE EXTENSION OF TIME FOR FILING STATEMENTS AND PAYMENT 23 OF TAXES DUE UPON GOOD CAUSE SHOWN. 24 25 NEW SECTION. Section 4. Procedure to estimate tax on failure to file return -- penalty and 26 INTEREST. (1) IF A WHOLESALE DRUG DISTRIBUTOR FAILS TO FILE A FORM OR FAILS TO PAY THE TAX REQUIRED BY 27 [SECTIONS 2 AND 3] ON OR BEFORE THE DATE THE PAYMENT IS DUE, THE DEPARTMENT SHALL, IMMEDIATELY AFTER THE 28 TIME HAS EXPIRED, DETERMINE THE AMOUNT OF SCHEDULE II DRUGS SOLD BY THE WHOLESALE DRUG DISTRIBUTOR IN THIS 29 STATE. 30 (2) THE DEPARTMENT SHALL ADD PENALTIES AND INTEREST TO THE AMOUNT OF DELINQUENT TAXES AS PROVIDED Legislative

1	<u>IN 15-1-216.</u>
2	(3) THE DEPARTMENT SHALL MAIL TO THE WHOLESALE DRUG DISTRIBUTOR REQUIRED TO FILE A QUARTERLY
3	STATEMENT AND PAY THE TAX A LETTER SETTING FORTH THE AMOUNT OF TAX, PENALTY, AND INTEREST DUE. THE LETTER
4	MUST CONTAIN A STATEMENT THAT IF PAYMENT IS NOT MADE, A WARRANT FOR DISTRAINT MAY BE FILED.
5	(4) A PENALTY IMPOSED BY 15-1-216 MAY BE WAIVED BY THE DEPARTMENT PURSUANT TO 15-1-206.
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7	NEW SECTION. Section 5. Warrant for distraint. If all or part of the tax imposed by [sections
8	2 AND 3] IS NOT PAID WHEN DUE, THE DEPARTMENT MAY ISSUE A WARRANT FOR DISTRAINT AS PROVIDED IN TITLE 15
9	CHAPTER 1, PART 7. THE RESULTING LIEN HAS PRECEDENCE OVER ANY OTHER CLAIM, LIEN, OR DEMAND FILED AND
10	RECORDED AFTER THE WARRANT FOR DISTRAINT IS ISSUED.
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12	NEW SECTION. Section 6. Deposit of taxes. All taxes collected under the provisions of [sections
13	1 THROUGH 8] MUST, IN ACCORDANCE WITH THE PROVISIONS OF 17-2-124, BE DEPOSITED IN THE DRUG PREVENTION AND
14	MEDICAL EDUCATION ACCOUNT PROVIDED FOR IN [SECTION 9].
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16	NEW SECTION. Section 7. Rulemaking. The department may adopt rules to administer and
17	ENFORCE THE PROVISIONS OF [SECTIONS 1 THROUGH 8].
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19	NEW SECTION. Section 8. Drug prevention and medical education account. (1) There is a drug
20	PREVENTION AND MEDICAL EDUCATION ACCOUNT IN THE STATE SPECIAL REVENUE FUND ESTABLISHED IN 17-2-102.
21	(2) ALL MONEY COLLECTED UNDER [SECTIONS 1 THROUGH 8] MUST, IN ACCORDANCE WITH THE PROVISIONS OF
22	17-2-124, BE DEPOSITED IN THE ACCOUNT TO THE CREDIT OF THE DEPARTMENT OF JUSTICE TO BE USED AS FOLLOWS
23	(A) 30% FOR THE WWAMI REGIONAL MEDICAL EDUCATION PROGRAM; AND
24	(B) 70% FOR GRANTS BY THE DEPARTMENT OF JUSTICE TO DRUG PREVENTION AND TEAM-BUILDING PROGRAMS
25	(3) FOR THE PURPOSES OF THIS SECTION, "DRUG PREVENTION AND TEAM-BUILDING PROGRAMS" MEANS:
26	(A) DRUG PREVENTION EDUCATION TO PROVIDE INFORMATION RELATING TO THE USE OF ANY CHEMICAL
27	SUBSTANCE, LEGAL OR ILLEGAL, THAT CREATES BEHAVIORAL OR HEALTH PROBLEMS;
28	(B) AFTER-SCHOOL CARE FOR CHILDREN;
29	(C) GROUP PROGRAMS THAT PREPARE CHILDREN TO MAKE ETHICAL AND MORAL CHOICES OVER THEIR LIFETIMES
30	AND BECOME RESPONSIBLE CITIZENS; AND

1 (D) GROUP PROGRAMS THAT PROVIDE CHILDREN WITH THE OPPORTUNITY TO BUILD COURAGE, CONFIDENCE, AND 2 CHARACTER WHILE PROMOTING PERSONAL GROWTH AND LEADERSHIP DEVELOPMENT. 3 4 **SECTION 9.** SECTION 37-7-604, MCA, IS AMENDED TO READ: 5 "37-7-604. 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 6 7 board and paying the license fee. 8 (2) A license may not be issued or renewed for a wholesale drug distributor to operate in this state unless 9 the applicant: 10 (a) agrees to abide by federal and state law and to comply with the rules adopted by the board; and 11 (b) pays the license fee set by the board; and 12 (c) is in compliance with Schedule II drug tax payments to the department of revenue under [sections 13 2 and 31. 14 (3) The board in its discretion may require that a separate license be obtained for: 15 (a) each facility directly or indirectly owned or operated by the same business entity within the state; or 16 (b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted 17 at more than one location and joint ownership and control exists among all entities. 18 (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 19 20 maintain: 21 (a) adequate storage conditions and facilities; 22 (b) minimum liability and other insurance that may be required by applicable federal or state law; 23 (c) a functioning security system that includes: 24 (i) an after hours central alarm or comparable entry detection system; 25 (ii) restricted access to the premises; 26 (iii) comprehensive employee applicant screening; and 27 (iv) safeguards against employee theft; 28 (d) a system of records setting forth all activities of wholesale drug distribution as defined in 37-7-602 29 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.

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(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;
- 12 (iii) insufficient inspections for all incoming and outgoing product shipments;
- 13 (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."

**SECTION 10.** SECTION 37-7-605, MCA, IS AMENDED TO READ:

"37-7-605. Out-of-state wholesale drug distributor licensing requirements. (1) An out-of-state wholesale drug distributor may not 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 an approved form.
- (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.



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1	(4) A person acting as principal or agent for an out-of-state wholesale drug distributor may not sell or
2	distribute drugs in this state unless the distributor has obtained a license and complies with the Schedule II drug
3	tax payment obligations under [sections 2 and 3]."
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5	NEW SECTION. Section 11. Codification instruction. (1) [Sections 1 through 8] are intended to
6	BE CODIFIED AS AN INTEGRAL PART OF TITLE 15, AND THE PROVISIONS OF TITLE 15 APPLY TO [SECTIONS 1 THROUGH 8].
7	(2) [SECTION 9] IS INTENDED TO BE CODIFIED AS AN INTEGRAL PART OF TITLE 44, CHAPTER 4, AND THE
8	PROVISIONS OF TITLE 44, CHAPTER 4, APPLY TO [SECTION 9].
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10	NEW SECTION. SECTION 12. APPLICABILITY. [THIS ACT] APPLIES TO SCHEDULE II DRUG SALES BY A
11	WHOLESALE DRUG DISTRIBUTOR AFTER DECEMBER 31, 2017.
12	- END -

