

HOUSE BILL 692

Introduced by Gould, et al.

2/08	Introduced
2/08	Referred to Business & Economic Development
2/08	First Reading
2/08	Fiscal Note Requested
2/09	Rereferred to Appropriations
2/15	Fiscal Note Received
2/18	Fiscal Note Printed
3/05	Hearing
3/25	Committee Report--Bill Passed as Amended
3/27	2nd Reading Passed
3/28	3rd Reading Passed
	Transmitted to Senate
3/28	First Reading
3/28	Referred to Finance & Claims
4/03	Hearing
4/13	Committee Report--Bill Not Passed
4/13	Adverse Committee Report Adopted

1 HOUSE BILL NO. 692
 2 INTRODUCED BY [Signature]
 3 [Signature]

4 A BILL FOR AN ACT ENTITLED: "AN ACT CONDITIONALLY
 5 INCREASING OR IMPOSING VARIOUS LICENSING AND REGISTRATION
 6 FEES IN THE PHARMACEUTICAL PROFESSION AND WITH REGARD TO THE
 7 MARKETING OF PHARMACEUTICAL PRODUCTS; REQUIRING THE
 8 LICENSURE OF PHARMACEUTICAL MANUFACTURERS AND RETAILERS OF
 9 OVER-THE-COUNTER DRUGS; REQUIRING PHARMACEUTICAL WHOLESALERS
 10 TO PAY ANNUAL FEES; DEDICATING REVENUE TO PROGRAM
 11 ENHANCEMENTS AT THE SCHOOL OF PHARMACY AT THE UNIVERSITY OF
 12 MONTANA AND APPROPRIATING THE INITIAL COLLECTIONS; MAKING
 13 THE FEES CONDITIONAL UPON THE CONTINUED ACCREDITATION OF THE
 14 SCHOOL OF PHARMACY AT THE UNIVERSITY OF MONTANA; AMENDING
 15 SECTIONS 37-7-101, 37-7-303, 37-7-321, AND 37-7-324, MCA;
 16 AND PROVIDING AN EFFECTIVE DATE AND A CONDITIONAL
 17 TERMINATION DATE."

18
 19 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

20 **Section 1.** Section 37-7-101, MCA, is amended to read:

21 "37-7-101. **Definitions.** Unless the context requires
 22 otherwise, in parts 1 through 3 of this chapter the
 23 following definitions apply:

- 24 (1) "Board" means the board of pharmacy provided for in
 25 2-15-1843.

1 (2) "Chemical" means medicinal or industrial
 2 substances, whether simple, compound, or obtained through
 3 the process of the science and art of chemistry, whether of
 4 organic or inorganic origin.

5 (3) "Commercial purposes" means the ordinary purposes
 6 of trade, agriculture, industry, and commerce, exclusive of
 7 the practices of medicine and pharmacy.

8 (4) "Continuing education" means professional
 9 pharmaceutical postgraduate education in the following
 10 areas:

- 11 (a) the socioeconomic and legal aspects of health care;
- 12 (b) the properties and actions of drugs and dosage
 13 forms; and
- 14 (c) the etiology, characteristics, and therapeutics of
 15 the disease state.

16 (5) "Department" means the department of commerce
 17 provided for in Title 2, chapter 15, part 18.

- 18 (6) (a) "Drug" means:
- 19 (i) articles recognized in the official United States
 20 Pharmacopoeia/National Formulary or a supplement to them;
- 21 (ii) articles intended for use in diagnosis, cure,
 22 mitigation, treatment, or prevention of disease in man or
 23 other animals;
- 24 (iii) articles (other than food) intended to affect the
 25 structure or function of the body of man or other animals;



1 and

2 (iv) articles intended for use as a component of an
3 article specified in subsection (i), (ii), or (iii).

4 (b) "Drug" does not include devices or their
5 components, parts, or accessories.

6 (7) "Intern" means a natural person licensed by the
7 department to prepare, compound, dispense, and sell drugs,
8 medicines, chemicals, and poisons under the supervision of a
9 registered and licensed pharmacist.

10 (8) "Medicine" means a remedial agent which has the
11 property of curing, preventing, treating, or mitigating
12 diseases or which is used for this purpose.

13 (9) "Over-the-counter drug" means any substance listed
14 in the national drug code authorized under 21 U.S.C. 360,
15 that does not require a prescription.

16 ~~(9)~~(10) "Person" includes an individual, partnership,
17 corporation, or association.

18 ~~(10)~~(11) "Pharmacist" means a natural person licensed by
19 the department to prepare, compound, dispense, and sell
20 drugs, medicines, chemicals, and poisons and who may affix
21 to his name the term "R.Ph."

22 ~~(11)~~(12) "Pharmacy" means an established place
23 registered by the department of commerce in which
24 prescriptions, drugs requiring a prescription, medicines,
25 chemicals, and poisons are compounded, dispensed, vended, or

1 sold.

2 ~~(12)~~(13) "Poison" means a substance which, when
3 introduced into the system, either directly or by
4 absorption, produces violent, morbid, or fatal changes or
5 which destroys living tissue with which it comes in contact.

6 ~~(13)~~(14) "Prescription" means an order given
7 individually for the person for whom prescribed, directly
8 from the prescriber to the furnisher or indirectly to the
9 furnisher, by means of an order signed by the prescriber and
10 bearing the name and address of the prescriber, his license
11 classification, the name of the patient, the name and the
12 quantity of the drug or drugs prescribed, the directions for
13 use and the date of its issue. These stipulations apply to
14 both written and telephoned prescriptions.

15 (15) "School" means the school of pharmacy at the
16 university of Montana.

17 ~~(14)~~(16) "Wholesale" means a sale for the purpose of
18 resale."

19 NEW SECTION. Section 2. Legislative findings and
20 intent. (1) The legislature finds and declares that:

21 (a) the education of pharmacists is an essential
22 function of government in Montana and that the school's
23 faculty provides vital information and continuing
24 educational services to practicing pharmacists in Montana;

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1 pharmacists which will mitigate the anticipated shortage of
2 personnel in the profession in the near future;

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4 an accredited pharmacy curriculum and to keep pace with the
5 rapid growth in information about pharmaceutical products
6 marketed in Montana; and

7 (d) the closing of the school through the loss of
8 accreditation would be a serious threat to the delivery of
9 adequate health care to Montanans.

10 (2) Based on these findings, it is the legislature's
11 intent to assist the school in maintaining an accredited
12 status. Further, to accomplish this goal, it is the
13 legislature's intent that [sections 2 through 4 and 7
14 through 11] provide that all segments of the pharmaceutical
15 industry and profession be licensed on a basis that
16 generates revenue commensurate with the benefits that the
17 pharmaceutical industry and its customers are receiving from
18 the school.

19 NEW SECTION. **Section 3. Account established in special**
20 **revenue fund -- administrative costs.** An account is
21 established in the special revenue fund into which the
22 revenue from all fees imposed consistent with provisions of
23 37-7-303(3), 37-7-321(4), and [sections 8, 9, and 10] are to
24 be paid, and all administrative costs for the registration,
25 licensure, and collection of the fees imposed by 37-7-303,

1 37-7-321, and [sections 8, 9, and 10] must be paid from this
2 account.

3 NEW SECTION. **Section 4. Purpose and use of account.**

4 (1) Except as provided in [section 3], funds in the account
5 established in [section 3] are to be used solely for the
6 purposes of expanding the faculty and instituting additional
7 services and courses at the school in order to restore and
8 maintain the school's accreditation and to provide the
9 services described in [sections 7 and 9].

10 (2) The funds in the account may not be used to replace
11 funding allocated by the board of regents to the school.

12 **Section 5.** Section 37-7-303, MCA, is amended to read:

13 **"37-7-303. Annual renewal fee.** (1) A person licensed
14 and registered by the department shall annually pay to the
15 department before June 30 a renewal of registration fee
16 prescribed by the board. A default in the payment of a
17 renewal fee after the date it is due increases the renewal
18 fee as prescribed by the board. It is unlawful for a person
19 who refuses or fails to pay the renewal fee to practice
20 pharmacy in this state. A certificate and renewal expires at
21 the time prescribed, not later than 1 year from its date. A
22 defaulter in a renewal fee may be reinstated within 1 year
23 of the default without examination on payment of the arrears
24 and compliance with the continuing education provisions of
25 this chapter.

1 (2) The board may charge an additional fee for such
2 license renewal to be used in administering the continuing
3 education provisions of this chapter.

4 (3) In addition to the registration renewal fee imposed
5 in subsection (1), the board shall charge \$25 for each
6 license renewal and shall deposit all revenue collected from
7 the additional fee into the account established in [section
8 3]."

9 **Section 6.** Section 37-7-321, MCA, is amended to read:

10 "37-7-321. Certified pharmacy license and annual
11 renewal fees -- suspension or revocation. (1) The board
12 shall provide for the original certification and annual
13 renewal by the department of every pharmacy doing business
14 in this state: as follows:

15 (a) On presentation of evidence satisfactory to the
16 board and on application on a form prescribed by the board
17 and on the payment of an original certification fee
18 prescribed by the board, the department shall issue a
19 license to a pharmacy as a certified pharmacy.

20 (b) ~~However,--the~~ The license may be granted only to
21 pharmacies operated by registered pharmacists qualified
22 under this chapter.

23 (c) The annual renewal fee for a pharmacy ~~shall~~ must be
24 set by the board. Any default in the payment of ~~such~~ the
25 renewal fee after the date ~~the same~~ it is due ~~shall increase~~

1 increases the renewal fee as prescribed by the board.

2 (d) The license must be displayed in a conspicuous
3 place in the pharmacy for which it is issued and expires on
4 June 30 following the date of issue. It is unlawful for a
5 person to conduct a pharmacy, use the word "pharmacy" to
6 identify his business, or use the word "pharmacy" in
7 advertising unless a license has been issued and is in
8 effect.

9 (2) The board may suspend, revoke, or refuse to renew a
10 pharmacy license:

11 (a) obtained by false representation or fraud;

12 (b) when the pharmacy for which the license is issued
13 is kept open for the transaction of business without a
14 pharmacist in charge;

15 (c) when the person to whom the license is granted has
16 been convicted of:

17 (i) a violation of parts 1 through 3 of this chapter;

18 or

19 (ii) a violation of the Federal Food, Drug, and Cosmetic
20 Act (Title 21, chapter 9, U.S.C.); chapter 2 or 7 of Title
21 37, chapter 9 or 10 of Title 45, or chapter 31 or 32 of
22 Title 50, MCA; or rules adopted under such act or chapters;

23 (d) when the person to whom the license is granted is a
24 natural person whose pharmacist license has been revoked; or

25 (e) when the pharmacy is conducted in violation of

1 parts 1 through 3 of this chapter.

2 (3) Before a license can be revoked, the holder is
3 entitled to a hearing by the board.

4 (4) In addition to the fee established by the board in
5 subsection (1), the board shall charge \$50 for each license
6 renewal and shall deposit the revenue from the additional
7 fee into the account established in [section 3]."

8 **NEW SECTION. Section 7. Drug information center.** The
9 board of regents shall establish a drug information center
10 within the school that shall rapidly respond to inquiries
11 from pharmacists practicing in Montana about the qualities
12 and effects of the various drugs they dispense.

13 **NEW SECTION. Section 8. Licensure of stores selling**
14 **over-the-counter drugs -- registration, fees, and renewal.**
15 (1) A store or other business not licensed as a pharmacy
16 that sells over-the-counter drugs and medications shall
17 register with and be licensed by the board to sell
18 over-the-counter drugs.

19 (2) The fee for initial and renewed registration and
20 licensure is \$25 per year, payable to the board. The board
21 shall deposit 5% of all fees it collects under this section
22 into the account created pursuant to 37-7-324 and shall
23 deposit the balance of the fees collected into the account
24 established in [section 3].

25 (3) Money collected under this section and paid into

1 the account established under [section 3] must be used to
2 support an accredited pharmacy program at the school that
3 includes:

4 (a) one or more courses of instruction in
5 over-the-counter drugs for students who are not pursuing a
6 degree in pharmacy;

7 (b) an over-the-counter drug information center; and

8 (c) a periodic publication that contains information
9 about current or significant developments in the area of
10 over-the-counter drugs and that is disseminated to the
11 stores or other businesses licensed under the provisions of
12 this section.

13 **NEW SECTION. Section 9. Licensure of pharmaceutical**
14 **manufacturers -- intent, registration, fees, and renewal.**

15 (1) The licensure requirements and fees imposed in this
16 section are to provide the school with compensation
17 commensurate with the burden placed on the school by
18 manufacturers of pharmaceutical products listed in the
19 national drug code who actively promote the sale or use of
20 these products in Montana. Promotional and marketing efforts
21 are contributing to the rapid increase in data and other
22 information about legal drugs within the state, are
23 affecting public safety and welfare, and impose a burden on
24 the school to educate pharmacy students to accurately assess
25 and apply this great quantity of information.

(2) Each manufacturer of pharmaceutical products listed in the national drug code who actively promotes the sale or use of its products in Montana shall register with and be licensed annually by the board. The annual fee for the initial and annual licensure is \$1,000 for each manufacturer of pharmaceutical products. This fee is in addition to any registration fee required by 50-32-301 for manufacturers of controlled substances.

(3) The board shall deposit 5% of all fees collected under this section in the account created pursuant to 37-7-324 and shall deposit the balance of the fees into the account established in [section 3].

(4) A manufacturer may take, as a credit against the fees imposed by this section, 25% of any donation or grant made during the preceding year by the manufacturer or by a foundation affiliated with the manufacturer to the university of Montana for the purpose of pharmaceutical research or instruction.

NEW SECTION. Section 10. Pharmaceutical wholesalers -- fees. (1) In addition to the registration fees required in [Senate Bill No. 135, pharmaceutical wholesalers shall pay to the board an annual fee based on the number of pharmacies in Montana served by the wholesaler. The fees are as follows:

(a) \$200 if nine or fewer pharmacies are served;

(b) \$500 if 10 to 25 pharmacies are served; and

(c) \$1,000 if 26 or more pharmacies are served.

(2) All fees collected under the provisions of subsection (1) must be deposited in the account established in [section 3].

NEW SECTION. Section 11. Sanctions -- pharmaceutical manufacturers and stores selling over-the-counter drugs. (1) An unlicensed store that sells an over-the-counter drug bears the burden of proving that it was not negligent in any tort action by the purchaser of an over-the-counter drug.

(2) Upon a petition to the department by the board, any pharmaceutical manufacturer that actively promotes the sale or use of its products in the state without possessing a license as required in [section 9] must have its products deleted by the department of social and rehabilitation services from the list of drugs and medications covered by the medicaid program.

Section 12. Section 37-7-324, MCA, is amended to read:

"37-7-324. Deposit of fees and fines. Fines Except as provided in 37-7-303, 37-7-321, and [sections 8, 9, and 10], fines paid under this chapter, except those paid to a justice's court, and fees collected by the department for registration and licenses issued under this chapter shall must be deposited in the state special revenue fund for the use of the board, subject to 37-1-101(6)."

1 NEW SECTION. **Section 13.** **Appropriation.** All money in
2 the account established by [section 3] in the biennium
3 ending June 30, 1993, is appropriated to the university of
4 Montana for the continued accreditation of the university's
5 school of pharmacy.

6 NEW SECTION. **Section 14.** **Codification** instruction.
7 [Sections 2 through 4 and 7 through 11] are intended to be
8 codified as an integral part of Title 37, chapter 7, and the
9 provisions of Title 37, chapter 7, apply to [sections 2
10 through 4 and 7 through 11].

11 NEW SECTION. **Section 15.** **Coordination instruction.** If
12 Senate Bill No. 135 is not passed and approved, then
13 [section 10 of this act] must read as follows:

14 "NEW SECTION. **Section 10.** **Pharmaceutical wholesalers**
15 -- fees. (1) Except as provided in subsection (3),
16 pharmaceutical wholesalers shall pay to the board an annual
17 fee based on the number of pharmacies in Montana served by
18 the wholesaler. The fees are as follows:

- 19 (a) \$200 if nine or fewer pharmacies are served;
20 (b) \$500 if 10 to 25 pharmacies are served; and
21 (c) \$1,000 if 26 or more pharmacies are served.

22 (2) All fees collected under the provisions of
23 subsection (1) must be deposited in the account established
24 in [section 3].

25 (3) The board may not collect the fees imposed by

1 subsection (1) unless it certifies to the governor that:

2 (a) the university of Montana has an accredited program
3 of pharmacy instruction;

4 (b) the duties of at least one faculty member in the
5 school encompass the supervision of the drug information
6 center established in [section 7]; and

7 (c) the school pharmacy program has adequate faculty to
8 keep abreast of and instruct students about the advances in
9 pharmacy being developed and introduced by pharmaceutical
10 manufacturers."

11 NEW SECTION. **Section 16.** **Saving clause.** [This act]
12 does not affect rights and duties that matured, penalties
13 that were incurred, or proceedings that were begun before
14 [the effective date of this act].

15 NEW SECTION. **Section 17.** **Effective date.** [This act] is
16 effective July 1, 1991.

17 NEW SECTION. **Section 18.** **Conditional** termination.
18 [This act] terminates at the end of the calendar year in
19 which accreditation is withdrawn from the school of pharmacy
20 of the university of Montana.

-End-

STATE OF MONTANA - FISCAL NOTE

Form BD-15


In compliance with a written request, there is hereby submitted a Fiscal Note for HB0692, as introduced.

DESCRIPTION OF PROPOSED LEGISLATION:

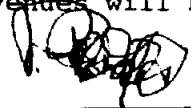
An act conditionally increasing or imposing various licensing and registration fees in the pharmaceutical profession and with regard to the marketing of pharmaceutical products; requiring the licensure of pharmaceutical manufacturers and retailers of over-the counter drugs; requiring pharmaceutical wholesalers to pay annual fees; dedicating revenue to program enhancements at the school of pharmacy at the University of Montana and appropriating the initial collections; making the fees conditional upon the continued accreditation of the school of pharmacy at the University of Montana, effective July 1, 1991.

ASSUMPTIONS:DEPARTMENT OF COMMERCE - BOARD OF PHARMACISTS:

1. Licensing, renewal and registration fees would be collected as follows: a) 1,478 Pharmacists renewal fees @ \$25 = \$36,950 (100% to UM); b) 275 pharmacies license renewal fees @ \$50 = \$13,750 (100% to UM); c) 35 manufacturer's registration fees @ \$1,000 = \$35,000 (95% or \$33,250 to UM; 5% or \$1,750 to Commerce); d) 1,800 over-the-counter registration fees @ \$25 = \$45,000 (95% or \$42,750 to UM; 5% or \$2,250 to Commerce); e) 3 pharmaceutical wholesaler's serving 26+ pharmacies each @ \$1,000 = \$3,000 (100% to UM); f) 6 minor wholesalers @ \$200 or \$1,200 (100% to UM).
2. From fees collected above, UM would receive \$130,900 per annum for the pharmacy program and \$4,000 would go to the Board of Pharmacy in the Department of Commerce.
3. The Board of Pharmacy will need to establish and monitor an account on behalf of the UM. This will require the POL Bureau to add additional staff to carry out the added workload.
4. For purposes of this fiscal note, revenues generated from SB0135 (requiring licensing of wholesale drug distributors) are not included (net impact would be \$0).
5. The Board of Pharmacy's recharges will appear in both the board budget and the POL Bureau budget.
6. The board will require two additional one-day meetings per year @ \$500 travel costs per meeting.
7. The proposed fee schedule contained in this bill is not sufficient to cover board costs. An increase in regular license fees will be necessary to cover board costs.
8. The University of Montana will hire one additional faculty member (\$45,000) and one secretary (\$15,000) for the Drug Information Center. The Drug Information Center will require an operating budget of \$19,000 per year.
9. The University of Montana will use the remaining revenues generated from the fees imposed by this bill toward meeting its accreditation requirements. One faculty member will be hired at \$45,000 per year. The balance of \$6,900 will be used for operations.
10. The revenues raised from this bill will not be sufficient to meet all of UM's accreditation requirements. Additional revenue from other sources will be required.
11. In cases where revenue is insufficient to meet Board of Pharmacy expenditures, the board will draw on its reserves. When the Board of Pharmacy revenues exceed expenditures, excess revenues will be deposited in the reserve fund.


 ROD SUNDSTED, BUDGET DIRECTOR
 Office of Budget and Program Planning

2-16-91
 DATE


 BUDD R. GOULD, PRIMARY SPONSOR

2-18-91
 DATE

Fiscal Note for HB0692, as introduced

HB 692

FISCAL IMPACT:

Department of Commerce, Board of Pharmacists:

Expenditures:

	FY '92			FY '93		
	Current Law	Proposed Law	Difference	Current Law	Proposed Law	Difference
Personal Services	47,111	47,611	500	47,007	47,507	500
Operations	89,296	124,390	35,094	88,785	120,564	31,779
Transfers to UM	0	130,900	130,900	0	130,900	130,900
Total	136,407	302,901	166,494	135,792	298,971	163,179
<u>Funding:</u>						
State Special Revenue	136,407	302,861	166,454	135,792	302,246	166,454
Board Reserves	0	40	40	0	(3,275)	(3,275)
Total	136,407	302,901	166,494	135,792	298,971	163,179

Revenue:

Pharmacists Fees	136,407	302,861	166,494	135,792	302,246	166,454
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University of Montana, School of Pharmacy:

Expenditures:

FTE	0.00	3.00	3.00	0.00	3.00	3.00
Personal Services	0	105,000	105,000	0	105,000	105,000
Operating Costs	0	25,900	25,900	0	25,900	25,900
Capital Outlay	0	0	0	0	0	0
Local Assistance	0	0	0	0	0	0
Total	0	130,900	130,900	0	130,900	130,900

Funding:

Current Restricted	0	130,900	130,900	0	130,900	130,900
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Revenues:

Transfers from Licensing and Reg	0	130,900	130,900	0	130,900	130,900
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TECHNICAL NOTES:

The university system accounts for funds in the CUBA fund structure. Monies collected would be deposited in the Current Restricted Fund, rather than the "special revenue fund" identified in new section 3.

RE-REFERRED AND
APPROVED BY COMMITTEE
ON APPROPRIATIONS
AS AMENDED

HOUSE BILL NO. 692

INTRODUCED BY GOULD, KADAS, PECK

A BILL FOR AN ACT ENTITLED: "AN ACT CONDITIONALLY INCREASING OR IMPOSING VARIOUS LICENSING AND REGISTRATION FEES IN THE PHARMACEUTICAL PROFESSION AND WITH REGARD TO THE MARKETING OF PHARMACEUTICAL PRODUCTS; REQUIRING THE LICENSURE OF PHARMACEUTICAL MANUFACTURERS AND RETAILERS OF OVER-THE-COUNTER DRUGS; REQUIRING PHARMACEUTICAL WHOLESALERS TO PAY ANNUAL FEES; DEDICATING REVENUE TO PROGRAM ENHANCEMENTS AT THE SCHOOL OF PHARMACY AT THE UNIVERSITY OF MONTANA AND APPROPRIATING THE INITIAL COLLECTIONS; MAKING THE FEES CONDITIONAL UPON THE CONTINUED ACCREDITATION OF THE SCHOOL OF PHARMACY AT THE UNIVERSITY OF MONTANA; AMENDING SECTIONS 37-7-101, 37-7-303, 37-7-321, AND 37-7-324, MCA; AND PROVIDING AN EFFECTIVE DATE, A TERMINATION DATE, AND A CONDITIONAL TERMINATION DATE."

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10 bearing the name and address of the prescriber, his license
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12 quantity of the drug or drugs prescribed, the directions for
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19 **NEW SECTION. Section 3. Account established in special**
20 **revenue fund -- administrative costs.** An account is
21 established in the special-revenue RESTRICTED SUBFUND OF THE
22 CURRENT fund into which the revenue from all fees imposed
23 consistent with provisions of 37-7-303(3), 37-7-321(4), and
24 [sections 8, 9, and 10] are to be paid, and all
25 administrative costs for the registration, licensure, and

1 collection of the fees imposed by 37-7-303, 37-7-321, and
2 [sections 8, 9, and 10] must be paid from this account.

3 **NEW SECTION. Section 4. Purpose and use of account.**

4 (1) Except as provided in [section 3], funds in the account
5 established in [section 3] are to be used solely for the
6 purposes of expanding the faculty and instituting additional
7 services and courses at the school in order to restore and
8 maintain the school's accreditation and to provide the
9 services described in [sections 7 and 9].

10 (2) The funds in the account may not be used to replace
11 funding allocated by the board of regents to the school.

12 **Section 5. Section 37-7-303, MCA, is amended to read:**

13 ***37-7-303. Annual renewal fee.** (1) A person licensed
14 and registered by the department shall annually pay to the
15 department before June 30 a renewal of registration fee
16 prescribed by the board. A default in the payment of a
17 renewal fee after the date it is due increases the renewal
18 fee as prescribed by the board. It is unlawful for a person
19 who refuses or fails to pay the renewal fee to practice
20 pharmacy in this state. A certificate and renewal expires at
21 the time prescribed, not later than 1 year from its date. A
22 defaulter in a renewal fee may be reinstated within 1 year
23 of the default without examination on payment of the arrears
24 and compliance with the continuing education provisions of
25 this chapter.

1 (2) The board may charge an additional fee for such
2 license renewal to be used in administering the continuing
3 education provisions of this chapter.

4 (3) In addition to the registration renewal fee imposed
5 in subsection (1), the board shall charge \$25 for each
6 license renewal and shall deposit all revenue collected from
7 the additional fee into the account established in [section
8 3]."

9 **Section 6.** Section 37-7-321, MCA, is amended to read:

10 "37-7-321. Certified pharmacy license and annual
11 renewal fees — suspension or revocation. (1) The board
12 shall provide for the original certification and annual
13 renewal by the department of every pharmacy doing business
14 in this state; as follows:

15 (a) On presentation of evidence satisfactory to the
16 board and on application on a form prescribed by the board
17 and on the payment of an original certification fee
18 prescribed by the board, the department shall issue a
19 license to a pharmacy as a certified pharmacy.

20 (b) However, the license may be granted only to
21 pharmacies operated by registered pharmacists qualified
22 under this chapter.

23 (c) The annual renewal fee for a pharmacy shall ~~must~~ be
24 set by the board. Any default in the payment of such ~~the~~
25 renewal fee after the date ~~the same~~ it is due ~~shall increase~~

1 increases the renewal fee as prescribed by the board.

2 (d) The license must be displayed in a conspicuous
3 place in the pharmacy for which it is issued and expires on
4 June 30 following the date of issue. It is unlawful for a
5 person to conduct a pharmacy, use the word "pharmacy" to
6 identify his business, or use the word "pharmacy" in
7 advertising unless a license has been issued and is in
8 effect.

9 (2) The board may suspend, revoke, or refuse to renew a
10 pharmacy license:

11 (a) obtained by false representation or fraud;

12 (b) when the pharmacy for which the license is issued
13 is kept open for the transaction of business without a
14 pharmacist in charge;

15 (c) when the person to whom the license is granted has
16 been convicted of:

17 (i) a violation of parts 1 through 3 of this chapter;
18 or

19 (ii) a violation of the Federal Food, Drug, and Cosmetic
20 Act (Title 21, chapter 9, U.S.C.); chapter 2 or 7 of Title
21 37, chapter 9 or 10 of Title 45, or chapter 31 or 32 of
22 Title 50, MCA; or rules adopted under such act or chapters;

23 (d) when the person to whom the license is granted is a
24 natural person whose pharmacist license has been revoked; or

25 (e) when the pharmacy is conducted in violation of

1 parts 1 through 3 of this chapter.

2 (3) Before a license can be revoked, the holder is
3 entitled to a hearing by the board.

4 (4) In addition to the fee established by the board in
5 subsection (1), the board shall charge \$50 for each license
6 renewal and shall deposit the revenue from the additional
7 fee into the account established in [section 3]."

8 NEW SECTION. Section 7. Drug information center. The
9 board of regents shall establish a drug information center
10 within the school that shall rapidly respond to inquiries
11 from pharmacists practicing in Montana about the qualities
12 and effects of the various drugs they dispense.

13 NEW SECTION. Section 8. Licensure of stores selling
14 over-the-counter drugs -- registration, fees, and renewal.

15 (1) A store or other business not licensed as a pharmacy
16 that sells over-the-counter drugs and medications shall
17 register with and be licensed by the board to sell
18 over-the-counter drugs.

19 (2) The fee for initial and renewed registration and
20 licensure is \$25 per year, payable to the board. The board
21 ~~shall deposit 5% of all fees it collects under this section~~
22 ~~into the account created pursuant to 37-7-324 and shall~~
23 deposit the ~~balance of the~~ fees collected into the account
24 established in [section 3].

25 (3) Money collected under this section and paid into

1 the account established under [section 3] must be used to
2 support an accredited pharmacy program at the school that
3 includes:

4 (a) one or more courses of instruction in
5 over-the-counter drugs for students who are not pursuing a
6 degree in pharmacy;

7 (b) an over-the-counter drug information center; and

8 (c) a periodic publication that contains information
9 about current or significant developments in the area of
10 over-the-counter drugs and that is disseminated to the
11 stores or other businesses licensed under the provisions of
12 this section.

13 NEW SECTION. Section 9. Licensure of pharmaceutical
14 manufacturers -- intent, registration, fees, and renewal.

15 (1) The licensure requirements and fees imposed in this
16 section are to provide the school with compensation
17 commensurate with the burden placed on the school by
18 manufacturers of pharmaceutical products listed in the
19 national drug code who actively promote the sale or use of
20 these products in Montana. Promotional and marketing efforts
21 are contributing to the rapid increase in data and other
22 information about legal drugs within the state, are
23 affecting public safety and welfare, and impose a burden on
24 the school to educate pharmacy students to accurately assess
25 and apply this great quantity of information.

1 (2) Each manufacturer of pharmaceutical products listed
 2 in the national drug code who actively promotes the sale or
 3 use of its products in Montana shall register with and be
 4 licensed annually by the board. The annual fee for the
 5 initial and annual licensure is \$1,000 for each manufacturer
 6 of pharmaceutical products. This fee is in addition to any
 7 registration fee required by 50-32-301 for manufacturers of
 8 controlled substances.

9 (3) The board shall ~~deposit 5% of all fees collected~~
 10 ~~under this section in the account created pursuant to~~
 11 ~~37-7-324 and shall~~ deposit the balance of the fees into the
 12 account established in [section 3].

13 (4) A manufacturer may take, as a credit against the
 14 fees imposed by this section, 25% of any donation or grant
 15 made during the preceding year by the manufacturer or by a
 16 foundation affiliated with the manufacturer to the
 17 university of Montana for the purpose of pharmaceutical
 18 research or instruction.

19 NEW SECTION. Section 10. Pharmaceutical wholesalers --
 20 fees. (1) In addition to the registration fees required in
 21 [Senate Bill No. 135], pharmaceutical wholesalers shall pay
 22 to the board an annual fee based on the number of pharmacies
 23 in Montana served by the wholesaler. The fees are as
 24 follows:

25 (a) \$200 if nine or fewer pharmacies are served;

1 (b) \$500 if 10 to 25 pharmacies are served; and

2 (c) \$1,000 if 26 or more pharmacies are served.

3 (2) All fees collected under the provisions of
 4 subsection (1) must be deposited in the account established
 5 in [section 3].

6 NEW SECTION. Section 11. Sanctions -- pharmaceutical
 7 manufacturers and stores WHOLESALERS selling
 8 over-the-counter drugs TO UNLICENSED RETAILERS. (1) An
 9 unlicensed store that sells an over-the-counter drug bears
 10 the burden of proving that it was not negligent in any tort
 11 action by the purchaser of an over-the-counter drug. A
 12 MANUFACTURER LICENSED UNDER [SECTION 9] OR A WHOLESALER
 13 LICENSED UNDER [SENATE BILL NO. 135 OR SECTION 10 OF THIS
 14 ACT] MAY NOT SELL AN OVER-THE-COUNTER DRUG TO A RETAILER WHO
 15 IS NOT LICENSED BY THE BOARD AS A PHARMACY OR AN
 16 OVER-THE-COUNTER STORE. THE BOARD MAY SUSPEND OR REVOKE,
 17 SUBJECT TO THE OPPORTUNITY FOR A CONTESTED CASE HEARING, THE
 18 LICENSE OF ANY MANUFACTURER OR WHOLESALER THAT IT FINDS HAS
 19 SOLD ONE OR MORE OVER-THE-COUNTER DRUGS TO AN UNLICENSED
 20 RETAILER.

21 (2) Upon a petition to the department by the board, any
 22 pharmaceutical manufacturer that actively promotes the sale
 23 or use of its products in the state without possessing a
 24 license as required in [section 9] must have its products
 25 deleted by the department of social and rehabilitation

1 services from the list of drugs and medications covered by
 2 the medicaid program.

3 **Section 12.** Section 37-7-324, MCA, is amended to read:
 4 "37-7-324. Deposit of fees and fines. Fines Except as
 5 provided in 37-7-303, 37-7-321, and [sections 8, 9, and 10],
 6 fines paid under this chapter, except those paid to a
 7 justice's court, and fees collected by the department for
 8 registration and licenses issued under this chapter ~~shall~~
 9 must be deposited in the state special revenue fund for the
 10 use of the board, subject to 37-1-101(6)."

11 NEW SECTION. **Section 13.** Appropriation. All money in
 12 the account established by [section 3] in the biennium
 13 ending June 30, 1993, is appropriated to the university of
 14 Montana for the continued accreditation of the university's
 15 school of pharmacy.

16 NEW SECTION. **Section 14.** Codification instruction.
 17 [Sections 2 through 4 and 7 through 11] are intended to be
 18 codified as an integral part of Title 37, chapter 7, and the
 19 provisions of Title 37, chapter 7, apply to [sections 2
 20 through 4 and 7 through 11].

21 ~~NEW SECTION.--Section 15.--Coordination--instruction--if~~
 22 ~~Senate Bill--No--135--is--not--passed--and--approved--then~~
 23 ~~{section 10 of this act} must read as follows:~~

24 ~~NEW SECTION.--Section 10.--Pharmaceutical--wholesalers~~
 25 ~~---fees--{1}--Except--as--provided--in--subsection--{3}--~~

1 ~~pharmaceutical wholesalers shall pay to the board an annual~~
 2 ~~fee--based--on--the--number--of--pharmacies--in--Montana--served--by~~
 3 ~~the wholesaler--The fees are as follows:~~

- 4 ~~{a}--\$200--if--nine--or--fewer--pharmacies--are--served;~~
- 5 ~~{b}--\$500--if--10--to--25--pharmacies--are--served--and~~
- 6 ~~{c}--\$1,000--if--26--or--more--pharmacies--are--served--~~
- 7 ~~{2}--All--fees--collected--under--the--provisions--of~~

8 ~~subsection--{1}--must--be--deposited--in--the--account--established~~
 9 ~~in--{section 3}--~~

10 ~~{3}--The board may not collect the fees imposed by~~
 11 ~~subsection--{1}--unless--it--certifies--to--the--governor--that:~~

12 ~~{a}--the university of Montana has an accredited program~~
 13 ~~of pharmacy instruction;~~

14 ~~{b}--the--duties--of--at--least--one--faculty--member--in--the~~
 15 ~~school--encompass--the--supervision--of--the--drug--information~~
 16 ~~center--established--in--{section 7}--and~~

17 ~~{c}--the school pharmacy program has adequate faculty to~~
 18 ~~keep--abreast--of--and--instruct--students--about--the--advances--in~~
 19 ~~pharmacy--being--developed--and--introduced--by--pharmaceutical~~
 20 ~~manufacturers."~~

21 NEW SECTION. **Section 15.** Saving clause. [This act]
 22 does not affect rights and duties that matured, penalties
 23 that were incurred, or proceedings that were begun before
 24 [the effective date of this act].

25 NEW SECTION. **Section 16.** Effective date. [This act] is

1 effective July 1, 1991.

2 NEW SECTION. Section 17. -CONDITIONAL TERMINATION --
3 CONDITIONAL termination. [This act] terminates at the end of
4 the calendar year in which accreditation is withdrawn from
5 the school of pharmacy of the university of Montana OR JULY
6 1, 1993, WHICHEVER OCCURS FIRST.

-End-

1 HOUSE BILL NO. 692

2 INTRODUCED BY GOULD, KADAS, PECK

3
4 A BILL FOR AN ACT ENTITLED: "AN ACT CONDITIONALLY
5 INCREASING OR IMPOSING VARIOUS LICENSING AND REGISTRATION
6 FEES IN THE PHARMACEUTICAL PROFESSION AND WITH REGARD TO THE
7 MARKETING OF PHARMACEUTICAL PRODUCTS; REQUIRING THE
8 LICENSURE OF PHARMACEUTICAL MANUFACTURERS AND RETAILERS OF
9 OVER-THE-COUNTER DRUGS; REQUIRING PHARMACEUTICAL WHOLESALERS
10 TO PAY ANNUAL FEES; DEDICATING REVENUE TO PROGRAM
11 ENHANCEMENTS AT THE SCHOOL OF PHARMACY AT THE UNIVERSITY OF
12 MONTANA AND APPROPRIATING THE INITIAL COLLECTIONS; MAKING
13 THE FEES CONDITIONAL UPON THE CONTINUED ACCREDITATION OF THE
14 SCHOOL OF PHARMACY AT THE UNIVERSITY OF MONTANA; AMENDING
15 SECTIONS 37-7-101, 37-7-303, 37-7-321, AND 37-7-324, MCA;
16 AND PROVIDING AN EFFECTIVE DATE, A TERMINATION DATE, AND A
17 CONDITIONAL TERMINATION DATE."
18

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

20 **Section 1.** Section 37-7-101, MCA, is amended to read:

21 "37-7-101. **Definitions.** Unless the context requires
22 otherwise, in parts 1 through 3 of this chapter the
23 following definitions apply:

24 (1) "Board" means the board of pharmacy provided for in
25 2-15-1843.

There are no changes in this bill,
and will not be reprinted. Please
refer to yellow copy for complete
text.