# HOUSE BILL NO. 118

# INTRODUCED BY J. BROWN

	IN THE HOUSE
JANUARY 9, 1991	INTRODUCED AND REFERRED TO COMMITTEE ON HUMAN SERVICES & AGING.
	FIRST READING.
JANUARY 15, 1991	COMMITTEE RECOMMEND BILL DO PASS AS AMENDED. REPORT ADOPTED.
JANUARY 16, 1991	PRINTING REPORT.
JANUARY 17, 1991	SECOND READING, DO PASS AS AMENDED.
JANUARY 18, 1991	ENGROSSING REPORT.
JANUARY 19, 1991	THIRD READING, PASSED. AYES, 91; NOES, 3.
	TRANSMITTED TO SENATE.
	IN THE SENATE
JANUARY 21, 1991	INTRODUCED AND REFERRED TO COMMITTEE ON PUBLIC HEALTH, WELFARE, & SAFETY.
	FIRST READING.
MARCH 7, 1991	COMMITTEE RECOMMEND BILL BE CONCURRED IN AS AMENDED. REPORT ADOPTED.
MARCH 9, 1991	SECOND READING, CONCURRED IN.
MARCH 11, 1991	THIRD READING, CONCURRED IN. AYES, 48; NOES, 1.
	RETURNED TO HOUSE WITH AMENDMENTS.
	IN THE HOUSE
MARCH 16, 1991	RECEIVED FROM SENATE.
	SECOND READING, AMENDMENTS CONCURRED IN.

MARCH 18, 1991

THIRD READING, AMENDMENTS

CONCURRED IN.

SENT TO ENROLLING.

REPORTED CORRECTLY ENROLLED.

18

25.

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

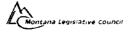
1		LOUSE BILL NO. 1/8
2	INTRODUCED BY	V. Brown
3		

A BILL FOR AN ACT ENTITLED: "AN ACT ALLOWING A LICENSED PHARMACIST TO USE THE SERVICES OF A PHARMACY TECHNICIAN UNDER THE TERMS OF AN APPROVED UTILIZATION PLAN; PROVIDING FOR TRAINING OF PHARMACY TECHNICIANS; PROVIDING FOR FEES AND PENALTIES: AMENDING SECTIONS 37-7-101, 37-7-301, AND 37-7-323, MCA; AND PROVIDING EFFECTIVE DATES."

STATEMENT OF INTENT

It is the intent of the legislature that the board of pharmacy, to implement [sections 3 through 7], adopt rules that, among other issues, describe the functions that a pharmacy technician is permitted to perform, including but not limited to:

- (1) removing a stock bottle from the shelf and counting and pouring the contents into a suitable container under direct supervision of a pharmacist;
- (2) typing a prescription label and affixing it to a prescription bottle, with a final check and any patient counseling performed by the pharmacist;
- (3) entering prescription information into a data 23 24 processing system under supervision of a pharmacist who must 25 be able to check all entries;



- 1 (4) maintaining prescription records, including prescription numbers, refill data, and other information on the patient profile system;
- (5) prepackaging unit dose drugs for internal 4 distribution. These prepackage unit dose drugs must be 5 quarantined together with bulk containers until a pharmacist 6 performs a final check and maintains appropriate records. 7
- (6) selling nonprescription drugs in their original 8 9 containers without engaging in patient counseling;
- pharmaceuticals, (7) receiving and checking in 10 including controlled substances, if the pharmacy technician 11 initials and dates all invoices with the actual date the 12 13 drugs were received;
- 14 (8) participating in the biennial inventory of controlled substances, provided a pharmacist supervises the 15 The supervising pharmacist must cosign the 16 process. inventory list with the participating pharmacist 17 and
- 19 (9) compounding intravenous solutions if a mechanism 20 for verification exists that includes checking of the
- 21 original order, solutions, additives, dosages, and clarity.
- 22 The legislature also intends that the board adopt rules 23 establishing standards for the training required by [section
- 24 5], which must include instruction in:

pharmacy technician.

(1) orientation to the practice of pharmacy;

\_\_\_ INTRODUCED BILL BII BH

month of the first the angle of the angle of

13

1	(2)	pharmacy	terminology	and	basic	pharmaceutics;
•	12/	Pridringer		~		p.i.a.r.maccacacaca

- 2 (3) state and federal laws relating to the practice of 3 pharmacy;
  - (4) pharmaceutical calculations;
  - (5) processing prescription drug orders;
  - (6) telephone procedure and communication;
- (7) pharmaceutical compounding, including intravenous 7 B admixture: and
  - (8) use of pharmacy computer systems, if applicable.
- 10 The legislature further intends that the board's rules allow a supervising pharmacist to use the services of only 11 one technician at a time, except that the pharmacist may use 12 two technicians at a time if both pharmacy technicians are 13 14
  - performing any of the following procedures:
- (1) intravenous admixture and other sterile product 15 preparation; 16
  - (2) filling of unit dose cassettes;
  - (3) prepackaging; and
- (4) bulk compounding. 19

9

17

18

- BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA: 21
- Section 1. Section 37-7-101, MCA, is amended to read: 22
- 23 \*37-7-101. Definitions. Unless the context requires
- otherwise, in parts 1 through 3 of this chapter, the 24
- 25 following definitions apply:

- 1 (1) "Board" means the board of pharmacy provided for in 2-15-1843.
- industrial 3 (2) "Chemical" means medicinal or substances, whether simple, compound, or obtained through 4 the process of the science and art of chemistry, whether of 5 organic or inorganic origin.
- (3) "Commercial purposes" means the ordinary purposes 7 of trade, agriculture, industry, and commerce, exclusive of 8 the practices of medicine and pharmacy. 9
- (4) "Continuing education" means professional 1.0 pharmaceutical postgraduate education in the following 11 12 areas:
  - (a) the socioeconomic and legal aspects of health care;
- (b) the properties and actions of drugs and dosage 14 forms; and 15
- (c) the etiology, characteristics, and therapeutics of 16 17 the disease state.
- (5) "Department" means the department of commerce 18
- 19 provided for in Title 2, chapter 15, part 18.
- (6) (a) "Drug" means: 20
- (i) articles recognized in the official United States 21
- 22 Pharmacopoeia/National Formulary or a supplement to them;
- (ii) articles intended for use in diagnosis, cure, 23
- mitigation, treatment, or prevention of disease in man or 24
- other animals: 25

(iii) articles (other than food) intended to affect the structure or function of the body of man or other animals; and

1

2

3

6

7

В

10

11

12

13

14

15

16

17

18

19

20

21

22

23

- 4 (iv) articles intended for use as a component of an article specified in subsection (i), (ii), or (iii).
  - (b) "Drug" does not include devices or their components, parts, or accessories.
  - (7) "Intern" means a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons under the supervision of a registered and licensed pharmacist.
  - (8) "Medicine" means a remedial agent which has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.
  - (9) "Person" includes an individual, partnership, corporation, or association.
  - (10) "Pharmacist" means a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons and who may affix to his name the term "R.Ph.".
  - (11) "Pharmacy" means an established place registered by the department of commerce in which prescriptions, drugs requiring a prescription, medicines, chemicals, and poisons are compounded, dispensed, vended, or sold.
- 25 (12) "Pharmacy technician" means an individual who

- assists a pharmacist in the practice of pharmacy pursuant to an approved utilization plan.
- 5 absorption, produces violent, morbid, or fatal changes or
  - which destroys living tissue with which it comes in contact.
- 7 (13)(14) "Prescription" means an order given
- 8 individually for the person for whom prescribed, directly
- 9 from the prescriber to the furnisher or indirectly to the
- 10 furnisher, by means of an order signed by the prescriber and
- 11 bearing the name and address of the prescriber, his license
- 12 classification, the name of the patient, the name and the
- 13 quantity of the drug or drugs prescribed, the directions for
- 14 use and the date of its issue. These stipulations apply to
- 15 both written and telephoned prescriptions.
- 16 (15) "Utilization plan" means a plan under which a
- 17 pharmacist may use the services of a pharmacy technician in
- 18 the practice of pharmacy to perform tasks that:
- 19 (a) do not require the exercise of the pharmacist's
- 20 independent professional judgment; and
- (b) are verifiable by the pharmacist.
- 22 (±4)(16) "Wholesale" means a sale for the purpose of
- 23 resale."
- Section 2. Section 37-7-301, MCA, is amended to read:
- 25 "37-7-301. Sale of drugs or medicines unlawful except

the arms about the first of the contraction of the

as provided. Except as provided in {sections 3 through 7],
it is unlawful for a:

1

2

3

4

6

7

9

10

11

12

13 14

15

16

17

18

19

20

21

22

23

24

25

- (1) #t--is--unlawful--for--any person to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons in any place other than a pharmacy, except as hereinafter provided;
- (2) ft--is--unlawful--for--any proprietor, owner, or manager of a pharmacy or any other person to permit the compounding or dispensing of prescriptions or the vending or selling at retail of drugs, medicines, chemicals, or poisons in any pharmacy except by a registered and licensed pharmacist or by an intern registered and licensed by the department, and under the supervision of a registered and licensed pharmacist.
- (3) It--is-unlawful-for-any person to assume or pretend to the title of pharmacist or intern unless such the person has a license as such, issued and in force pursuant to parts 1 through 3 of this chapter;
- (4) It-is-unlawful-for-any person other than a licensed and registered pharmacist or a licensed and registered intern under the supervision of a licensed and registered pharmacist to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons except as provided in parts 1 through 3."
- NEW SECTION. Section 3. Use of services of pharmacy

- 1 technician -- utilization plan required -- contents --
- 2 responsibility of pharmacist. (1) In the practice of
- 3 pharmacy, a pharmacist may use the services of a pharmacy
- 4 technician who is:

- (a) at least 18 years old;
- 6 (b) a high school graduate or has attained an
  7 equivalent degree;
- 8 (c) supervised by the pharmacist; and
- 9 (d) acting pursuant to the provisions of a utilization 10 plan approved by the board or its designee.
- 11 (2) A pharmacy technician utilization plan must set 12 forth:
- (a) the name and qualifications of the supervisingpharmacist or pharmacists;
- 15 (b) the nature and location of the supervising
  16 pharmacist's pharmacy practice;
- 17 (c) the name and qualifications of the pharmacy 18 technician;
- 19 (d) a summary of the tasks performed by the pharmacy
  20 technician and the methods by which a supervising pharmacist
  21 may verify and document the tasks. "Verify" means the
  22 personal confirmation by a supervising pharmacist of the
- 23 correctness of the tasks undertaken by the pharmacy
- 24 technician.
- 25 (e) a description of the training provided by the

- supervising pharmacist to the pharmacy technician that is
  required by [section 5]; and
- 3 (f) any other information the board considers relevant.

6

18

19

20

21

- (3) The board shall approve a utilization plan if it determines that the duties to be delegated to a pharmacy technician are:
- 7 (a) assigned and supervised by the supervising
  8 pharmacist; and
- 9 (b) within the scope of the training and competence of 10 the pharmacy technician.
- 11 (4) A supervising pharmacist is responsible for the 12 actions of a pharmacy technician who performs services for 13 the pharmacist under the terms of a utilization plan.
- NEW SECTION. Section 4. Preparation and approval of
  utilization plan -- revocation of or refusal to renew plan
  -- contested case hearing. (1) A supervising pharmacist
  shall:
  - (a) prepare the utilization plan under which the services of a pharmacy technician are used by the pharmacist and submit a summary of the plan to the board or its designee for approval;
- 22 (b) keep on file in the pharmacy a copy of the 23 utilization plan for inspection by the board or its 24 designee; and
- (c) annually review the utilization plan and provide

- 1 documentation to the board or its designee that the plan  $% \left( 1\right) =\left( 1\right) \left( 1\right) \left$
- 2 accurately reflects the current use of the services of a
- 3 pharmacy technician.

13

19

25

- 4 (2) The board or its designee shall refuse to approve 5 or shall revoke or fail to renew approval of a utilization 6 plan if it does not conform to the provisions of [sections 3 7 through 7] and rules adopted under those sections.
- 8 (3) One year after the board or its designee revokes
  9 approval of a utilization plan, the supervising pharmacist
  10 may reapply for approval by complying with the requirements
  11 of [sections 3 through 7] and with rules adopted under those
  12 sections.
- failing to renew approval of a utilization plan, the board or its designee shall provide the supervising pharmacist a reasonable time in which to supply additional information demonstrating compliance with the requirements of [sections 3 through 7] and with rules adopted under those sections and

(4) Before refusing to approve or before revoking or

- 20 (5) If a supervising pharmacist requests a hearing, the 21 board shall conduct the hearing in accordance with the
- 22 contested case procedures in Title 2, chapter 4, part 6.
- NEW SECTION. Section 5. Training of pharmacy
- 24 technician. (1) A supervising pharmacist shall:

the opportunity to request a hearing.

(a) provide initial training to a pharmacy technician

а

10

11

12

14

16

17

18

19

20

23

that relates to the tasks the pharmacy technician may perform pursuant to a utilization plan;

3

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

- (b) assure the continuing competence of a pharmacy technician through inservice education and training to supplement the initial training; and
- 6 (c) prepare and maintain a written record of initial
  7 and inservice training.
  - (2) An initial training program must include on-the-job practical training and didactic education through a program approved by the board or its designee that is commensurate with the tasks a pharmacy technician may perform, prior to the regular performance of those tasks.
  - NEW SECTION. Section 6. Utilization plan approval fee

    -- renewal of approval -- renewal fee. (1) A pharmacist who
    uses the services of a pharmacy technician under an approved
    utilization plan shall pay to the board a utilization plan
    approval fee in an amount set by the board as provided in
    37-1-134. Payment must be made when the utilization plan is
    submitted to the board and is not refundable.
    - (2) Approval of a pharmacy technician utilization plan expires 1 year from the date of approval. The board shall grant renewal of approval upon payment of a renewal fee in an amount set by the board and documentation as required by [section 4(1)(c)].
      - (3) The board may adopt fees, as provided in 37-1-134,

- for other costs associated with implementation of (sections through 7), including the costs of onsite inspection of the utilization plan and of the record of training required by (section 5) at the participating pharmacy.
  - (4) The board shall deposit fees received in the state special revenue fund for use by the board in administration of [sections 3 through 7], subject to 37-1-101(6).
  - NEW SECTION. Section 7. Auxiliary personnel. To perform clerical tasks, a pharmacist may use the services of auxiliary or support personnel who are not considered to be acting as pharmacy technicians if they do not perform the tasks of pharmacy technicians.
- Section 8. Section 37-7-323, MCA, is amended to read:
  - "37-7-323. Penalty enforcement. (1) Any A person, firm, partnership, or corporation violating any of the provisions of parts 1 through 3 of this chapter shall-be is guilty of a misdemeanor and upon conviction for each violation shall be punished accordingly, and any—thereof convicted shall automatically lose any license issued by the board.
- (2) In addition to the penalty provided in subsection
  (1), the board may withdraw its approval of a utilization

plan previously approved for a supervising pharmacist who:

24 (a) violates any provision of [sections 3 through 7] or 25 rules adopted under those sections;

- 1 (b) obtained the approval of the utilization plan
- 2 through fraud; or
- 3 (c) acts in a manner contrary to the terms of the
- 4 utilization plan.
- 5 (3) The board may seek an injunction to enforce the
- 6 provisions of subsection (2)."
- 7 NEW SECTION. Section 9. Codification instruction.
- 8 [Sections 3 through 7] are intended to be codified as an
- 9 integral part of Title 37, chapter 7, part 3, and the
- 10 provisions of Title 37, chapter 7, part 3, apply to
- 11 [sections 3 through 7].
- NEW SECTION. Section 10. Effective dates. (1) [Section
- 9 and this section) are effective on passage and approval.
- 14 (2) [Sections 1 through 8] are effective January 1,
- 15 1992.

-End-

## STATE OF MONTANA - FISCAL NOTE

#### Form BD-15

In compliance with a written request, there is hereby submitted a Fiscal Note for HB0118, as introduced.

#### DESCRIPTION OF PROPOSED LEGISLATION:

An act allowing a licensed pharmacist to use the services of a pharmacy technician under the terms of an approved utilization plan; providing for training of pharmacy technicians; providing for fees and penalties; and providing effective dates.

#### ASSUMPTIONS:

- 1. The Board of Pharmacy will approve utilization plans for pharmacy technicians.
- 2. If each of the 650 licensed pharmacists practicing in Montana submit two utilization plans, the department will screen, review and process 1,300 plans per year.
- 3. An additional two board members will increase the board to five members. Board members are compensated \$50 per day plus travel cost. Total travel cost for the entire board is approximately \$665 per meeting.
- 4. A screening committee of two board members will meet eight hours per year at a cost of \$50 per day plus travel.
- 5. Statute implementation will require three pages of rules at a cost of \$70 per page.
- 6. Additional cost incurred by the Board of Pharmacy will increase the board's administrative overhead cost of 8.77%.
- 7. The Professional and Occupational Licensing Bureau will need an additional .25 FTE plus operating costs and equipment for the workload increase.
- 8. Current law is represented by the executive budget recommendation for the Professional and Occupational Licensing Bureau of the Department of Commerce.

FISCAL	IMPACT:

POL Bureau		FY 92			FY 93	
<del> </del>	Current Law	Proposed Law	Difference	Current Law	Proposed Law	Difference
Expenditures:						
FTE	25.43	25.68	. 25	25.43	25.68	. 25
Personal Services	665,467	669,906	4,439	664,766	669,295	4,529
Operating Costs	184,593	186,262	1,669	177,083	178,352	1,269
Equipment	5,409	7,809	2,400	5,409	5,409	0
Total	855,469	863,977	8,508	847,258	853,056	5,798
Funding:						
Proprietary Fund	855,469	863,977	8,508	847,258	853,056	5,798
Revenue:						
License Fees (02)	135,809	148,809	13,000	135,210	143,010	7,800
Revenue:	·	,	·		·	·

ROD SUNDSTED, BUDGET DIRECTOR

TE

Office of Budget and Program Planning

JAN BROWN, PRIMARY SPONSOR

DATE

Fiscal Note for <u>HB0118</u>, as introduced.

HB 118

### STATE OF MONTANA - FISCAL NOTE Form BD-15

In compliance with a written request, there is hereby submitted a revised Fiscal Note for HB0118, second reading.

#### DESCRIPTION OF PROPOSED LEGISLATION:

An act allowing a licensed pharmacist to use the services of a pharmacy technician under the terms of an approved utilization plan; providing for training of pharmacy technicians; providing for fees, penalties, and effective dates.

## ASSUMPTIONS:

- The Board of Pharmacy will approve utilization plans for pharmacy technicians.
- 2. Each of the 650 licensed pharmacists practicing in Montana will submit two utilization plans, which will produce approximately 1,300 plans initially and each year thereafter for review and processing.
- 3. The Board of Pharmacy currently consists of five members. Personal services per diem increases because two board members will serve on a screening committee and because there will be at least two additional board meetings in the implementing year, with compensation of \$50 per day for the board members.
- 4. Operating costs increases include three pages of rules at a cost of \$210, board travel of \$665 per meeting, printing of application and license forms and postage of about \$575.
- 5. The Professional and Occupational Licensing Bureau (POL) overhead and supportive services charges will increase as a result of the additional workload, which will require 0.25 FTE added to the bureau. The board has increased authority to pay for these supportive services in the proposed law operating costs listed below and it also will be necessary for the bureau to have increased spending authority.
- 6. Current law is represented by the executive budget recommendation for the Board of Pharmacy located within the Department of Commerce.

## FISCAL IMPACT:

Board of Pharmacy:		FY 92			FY 93	
	Current Law	Proposed Law	Difference	Current Law	Proposed Law	Difference
Expenditures:						-
FTE	1.00	1.00	0.00	1.00	1.00	0.00
Personal Services	47,111	47,861	750	47,007	47,257	250
Operating Costs	<u>89,296</u>	100,907	<u>11,611</u>	<u>88,785</u>	96,102	7,317
Total	136,407	148,768	12,361	135,792	143,859	7,567
Funding:						
State Special Revenue	136,407	148,768	12,361	135,792	143,859	7,567
Revenue:						
License Fees (02)	135,809	148,809	13,000	135,210	143,010	7,800

ROD SUNDSTED BUDGET DIRECTOR

DATE

Office of Budget and Program Planning

AN BROWN PRIMARY SPONSOR

DATE

Revised Fiscal Note for <u>HB0118</u>, second reading

48 118 R

2

3

Montana Legislative Council

# APPROVED BY COMM. ON HUMAN SERVICES AND AGING

-	in Bibb tok his het birtibbe. In het hebourne in Bibbliote
5	PHARMACIST TO USE THE SERVICES OF A PHARMACY TECHNICIAN
6	UNDER THE TERMS OF AN APPROVED UTILIZATION PLAN; PROVIDING
7	FOR TRAINING OF PHARMACY TECHNICIANS; PROVIDING FOR FEES AND
8	PENALTIES; AMENDING SECTIONS 37-7-101, 37-7-301, AND
9	37-7-323, MCA; AND PROVIDING EFFECTIVE DATES."
LO	
11	STATEMENT OF INTENT
L 2	It is the intent of the legislature that the board of
L 3	pharmacy, to implement [sections 3 through 7], adopt rules
14	that, among other issues, describe the functions that a
15	pharmacy technician is permitted to perform, including but
16	not limited to:
17	(1) removing a stock bottle from the shelf and counting
18	and pouring the contents into a suitable container under
19	direct supervision of a pharmacist;
20	(2) typing a prescription label and affixing it to a
21	prescription bottle, with a final check and any patient
22	counseling performed by the pharmacist;
23	(3) entering prescription information into a data
24	processing system under supervision of a pharmacist who must
25	be able to check all entries;

HOUSE BILL NO. 118

INTRODUCED BY J. BROWN

A RILL FOR AN ACT ENTITIED. "AN ACT ALLOWING A LICENSED

1	(4) main	taining	preser	iption	1	ecord	s,	includ	ing
2	prescription	numbers,	refill	data,	and	other	infor	mation	or
3	the patient p	rofile sy	stem;						

- 4 (5) prepackaging unit dose drugs for internal
  5 distribution. These prepackage unit dose drugs must be
  6 quarantined together with bulk containers until a pharmacist
  7 performs a final check and maintains appropriate records.
- 8 (6) selling nonprescription drugs in their original9 containers without engaging in patient counseling;
- 10 (7) receiving and checking in pharmaceuticals,
  11 including controlled substances, if the pharmacy technician
  12 initials and dates all invoices with the actual date the
  13 drugs were received;
- 14 (8) participating in the biennial inventory of
  15 controlled substances, provided a pharmacist supervises the
  16 process. The supervising pharmacist must cosign the
  17 inventory list with the participating pharmacist and
  18 pharmacy technician.
- 19 (9) compounding intravenous solutions if a mechanism 20 for verification exists that includes checking of the 21 original order, solutions, additives, dosages, and clarity.
- The legislature also intends that the board adopt rules establishing standards for the training required by [section
- 24 5], which must include instruction in:
- 25 (1) orientation to the practice of pharmacy;

industrial

HB 0118/02

1	(2) pharmacy terminology and basic pharmaceutics;
2	(3) state and federal laws relating to the practice of
3	pharmacy;
4	(4) pharmaceutical calculations;
5	(5) processing prescription drug orders;
6	(6) telephone procedure and communication;
7	(7) pharmaceutical compounding, including intravenous
8	admixture; and
9	(8) use of pharmacy computer systems, if applicable.
10	The legislature further intends that the board's rules
11	allow a supervising pharmacist to use the services of only
12	one technician at a time, except that the pharmacist may use
13	two technicians at a time if both pharmacy technicians are
14	performing any of the following procedures:
15	(1) intravenous admixture and other sterile product
16	preparation;
17	(2) filling of unit dose cassettes;
18	(3) prepackaging; and
19	(4) bulk compounding.
20	
21	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
22	Section 1. Section 37-7-101, MCA, is amended to read:
23	*37-7-101. Definitions. Unless the context requires
24	otherwise, in parts 1 through 3 of this chapter, the
25	following definitions apply:

4	substances, whether simple, compound, or obtained through
5	the process of the science and art of chemistry, whether of
6	organic or inorganic origin.
7	(3) "Commercial purposes" means the ordinary purposes
8	of trade, agriculture, industry, and commerce, exclusive of
9	the practices of medicine and pharmacy.
.0	(4) "Continuing education" means professional
.1	pharmaceutical postgraduate education in the following
. 2	areas:
. 3	<ul><li>(a) the socioeconomic and legal aspects of health care;</li></ul>
. 4	(b) the properties and actions of drugs and dosage
5	forms; and
L6	(c) the etiology, characteristics, and therapeutics of

provided for in Title 2, chapter 15, part 18.

(6) (a) "Drug" means:

(5) "Department" means the department of commerce

(i) articles recognized in the official United States

(ii) articles intended for use in diagnosis, cure,

mitigation, treatment, or prevention of disease in man or

Pharmacopoeia/National Formulary or a supplement to them;

2-15-1843.

16 17

18

19

20

21

22

23

(2) "Chemical"

the disease state.

other animals;

(1) "Board" means the board of pharmacy provided for in

medicinal

-3-

- 1 (iii) articles (other than food) intended to affect the 2 structure or function of the body of man or other animals; 3 and
- 4 (iv) articles intended for use as a component of an article specified in subsection (i), (ii), or (iii).
- 6 (b) "Drug" does not include devices or their components, parts, or accessories.

9

10

11

- (7) "Intern" means a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons under the supervision of a registered and licensed pharmacist.
- 12 (8) "Medicine" means a remedial agent which has the 13 property of curing, preventing, treating, or mitigating 14 diseases or which is used for this purpose.
- 15 (9) "Person" includes an individual, partnership,16 corporation, or association.
- 17 (10) "Pharmacist" means a natural person licensed by the
  18 department to prepare, compound, dispense, and sell drugs,
  19 medicines, chemicals, and poisons and who may affix to his
  20 name the term "R.Ph.".
- 21 (11) "Pharmacy" means an established place registered by 22 the department of commerce in which prescriptions, drugs 23 requiring a prescription, medicines, chemicals, and poisons 24 are compounded, dispensed, vended, or sold.
- 25 (12) "Pharmacy technician" means an individual who

- assists a pharmacist in the practice of pharmacy pursuant to
- 2 an approved utilization plan.

which destroys living tissue with which it comes in contact.

- 7 (13)(14) "Prescription" means an order given 8 individually for the person for whom prescribed, directly
- 9 from the prescriber to the furnisher or indirectly to the
- 10 furnisher, by means of an order signed by the prescriber and
- 11 bearing the name and address of the prescriber, his license
- 12 classification, the name of the patient, the name and the 13 quantity of the drug or drugs prescribed, the directions for
- 14 use and the date of its issue. These stipulations apply to
- 15 both written and telephoned prescriptions.
- 16 (15) "Utilization plan" means a plan under which a
- 17 pharmacist may use the services of a pharmacy technician in
- 18 the practice of pharmacy to perform tasks that:
- 19 (a) do not require the exercise of the pharmacist's
- 20 independent professional judgment; and
- 21 (b) are verifiable VERIFIED by the pharmacist.
- (14)(16) "Wholesale" means a sale for the purpose of
- 23 resale."
- Section 2. Section 37-7-301, MCA, is amended to read:
- 25 "37-7-301. Sale of drugs or medicines unlawful except

and the second and th

- 1 as provided. Except as provided in [sections 3 through 7],
  2 it is unlawful for a:
- 3 (1) It--is--unlawful--for--any person to compound,
  4 dispense, vend, or sell at retail drugs, medicines,
  5 chemicals, or poisons in any place other than a pharmacy,
  6 except as hereinafter provided;
- 7 (2) #t--is--unlawful--for--any proprietor, owner, or 8 manager of a pharmacy or any other person to permit the 9 compounding or dispensing of prescriptions or the vending or 10 selling at retail of drugs, medicines, chemicals, or poisons in any pharmacy except by a registered and licensed 11 12 pharmacist or by an intern registered and licensed by the department, and under the supervision of a registered and 13 14 licensed pharmacist;
- 15 (3) It--is-unlawful-for-any person to assume or pretend 16 to the title of pharmacist or intern unless such the person 17 has a license as such, issued and in force pursuant to parts 18 1 through 3 of this chapter;
- 19 (4) it-is-unlawful-for-any person other than a licensed
  20 and registered pharmacist or a licensed and registered
  21 intern under the supervision of a licensed and registered
  22 pharmacist to compound, dispense, vend, or sell at retail
  23 drugs, medicines, chemicals, or poisons except as provided
  24 in parts 1 through 3."
- 25 NEW SECTION. Section 3. Use of services of pharmacy

- 1 technician -- utilization plan required -- contents --
- 2 responsibility of pharmacist. (1) In the practice of
- 3 pharmacy, a pharmacist may use the services of a pharmacy
- technician who is:
- (a) at least 18 years old;
- 6 (b) a high school graduate or has attained an 7 equivalent degree;
  - (c) supervised by the pharmacist; and
- 9 (d) acting pursuant to the provisions of a utilization10 plan approved by the board or its designee.
- 11 (2) A pharmacy technician utilization plan must set 12 forth:
- 13 (a) the name and qualifications of the supervising
  14 pharmacist or pharmacists;
- 15 (b) the nature and location of the supervising
  16 pharmacist's pharmacy practice;
- 17 (c) the name and qualifications of the pharmacy
  18 technician OR TECHNICIANS;
- 19 (d) a summary of the tasks performed by the pharmacy
  20 technician and the methods by which a supervising pharmacist
  21 may verify and document the tasks. "Verify" means the
  22 personal confirmation by a supervising pharmacist of the
- 23 correctness of the tasks undertaken by the pharmacy
- 24 technician.
- 25 (e) a description of the training provided by the

supervising	pharmacist	to th	e pharmacy	technician	that	is
required by	[section 5	]; and				

2

3

15

16

- f) any other information the board considers relevant.
- 3) The board OR ITS DESIGNEE shall approve a utilization plan if it determines that the duties to be 5 6 deletated to a pharmacy technician are:
- .a) assigned, VERIFIED, and supervised DOCUMENTED by 7 8 the supervising pharmacist; and
- 9 .b) within the scope of the training and competence of 10 the pharmacy technician.
- 11 (4) A supervising pharmacist is responsible for the actions of a pharmacy technician who performs services for 12 13 the pharmacist under the terms of a utilization plan.
- NEW SECTION. Section 4. Preparation and approval of 14 utilization plan -- revocation of or refusal to renew plan -- contested case hearing. (1) A supervising pharmacist shall:
- 18 (a) prepare the utilization plan under which the 19 services of a pharmacy technician are used by the pharmacist 20 and submit a summary of the plan to the board or its 21 designee for approval;
- 22 (b) keep on file in the pharmacy a copy of the 23 utilization plan for inspection by the board or its 24 designee; and
- 25 (c) annually review the utilization plan and provide

- documentation to the board or its designee that the plan accurately reflects the current use of the services of a 2 pharmacy technician.
  - (2) The board or its designee shall refuse to approve or shall revoke or fail to renew approval of a utilization plan if it does not conform to the provisions of [sections 3 through 7] and rules adopted under those sections.
- 8 (3) One year after the board or its designee revokes 9 approval of a utilization plan, the supervising pharmacist may reapply for approval by complying with the requirements 10 of [sections 3 through 7] and with rules adopted under those 11 12 sections.
- 13 (4) Before refusing to approve or before revoking or 14 failing to renew approval of a utilization plan, the board 15 or its designee shall provide the supervising pharmacist a 16 reasonable time in which to supply additional information 17 demonstrating compliance with the requirements of {sections 18 3 through 7) and with rules adopted under those sections and 19 the opportunity to request a hearing.
- 20 (5) If a supervising pharmacist requests a hearing, the 21 board shall conduct the hearing in accordance with the contested case procedures in Title 2, chapter 4, part 6. 22
- 23 NEW SECTION. Section 5. Training pharmacy 24 technician. (1) A supervising pharmacist shall:
- 25 (a) provide initial training to a pharmacy technician

and the control of the standing of the standin

7

9

10

16

- that relates to the tasks the pharmacy technician may perform pursuant to a utilization plan;
- 3 (b) assure the continuing competence of a pharmacy 4 technician through inservice education and training to 5 supplement the initial training; and
- 6 (c) prepare and maintain a written record of initial7 and inservice training.

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

- (2) An initial training program must include on-the-job practical training and didactic education through a program approved by the board or its designee that is commensurate with the tasks a pharmacy technician may perform, prior to the regular performance of those tasks.
- NEW SECTION. Section 6. Utilization plan approval fee

  -- renewal of approval -- renewal fee. (1) A pharmacist who
  uses the services of a pharmacy technician under an approved
  utilization plan shall pay to the board OR ITS DESIGNEE a
  utilization plan approval fee in an amount set by the board
  OR ITS DESIGNEE as provided in 37-1-134. Payment must be
  made when the utilization plan is submitted to-the-board and
  is not refundable.
- (2) Approval of a pharmacy technician utilization plan expires 1 year from the date of approval. The board <u>OR ITS DESIGNEE</u> shall grant renewal of approval upon payment of a renewal fee in an amount set by the board <u>OR ITS DESIGNEE</u> and documentation as required by {section 4(1)(c)}.

- provided in 37-1-134, for other costs associated with implementation of [sections 3 through 7], including the costs of onsite inspection of the utilization plan and of the record of training required by [section 5] at the participating pharmacy.
  - (4) The IF THE BOARD SETS THE FEES, THE board shall deposit fees received in the state special revenue fund for use by the board in administration of [sections 3 through 7], subject to 37-1-101(6).
- NEW SECTION. Section 7. Auxiliary personnel. To
  perform clerical tasks, a pharmacist may use the services of
  auxiliary or support personnel who are not considered to be
  acting as pharmacy technicians if they do not perform the
  tasks of pharmacy technicians.
  - Section 8. Section 37-7-323, MCA, is amended to read:
- 17 "37-7-323. Penalty enforcement. (1) Any A person,
  18 firm, partnership, or corporation violating any of the
  19 provisions of parts 1 through 3 of this chapter shall—be is
  20 guilty of a misdemeanor and upon conviction for each
  21 violation shall be punished accordingly, and any-thereof
  22 convicted shall automatically lose any license issued by the
  23 board.
- 24 (2) In addition to the penalty provided in subsection
  25 (1), the board may withdraw its approval of a utilization

1	plan	previously	approved	for	a	supervising	pharmacist	who:

- 2 (a) violates any provision of [sections 3 through 7] or
- 3 rules adopted under those sections;
- 4 (b) obtained the approval of the utilization plan
- 5 through fraud; or
- 6 (c) acts in a manner contrary to the terms of the
- 7 <u>utilization plan.</u>
- 8 (3) The board may seek an injunction to enforce the
- 9 provisions of subsection (2)."
- 10 NEW SECTION. Section 9. Codification instruction.
- [Sections 3 through 7] are intended to be codified as an
- 12 integral part of Title 37, chapter 7, part 3, and the
- 13 provisions of Title 37, chapter 7, part 3, apply to
- 14 [sections 3 through 7].
- 15 NEW SECTION. Section 10. Effective dates. (1) [Section
- 16 9 and this section) are effective on passage and approval.
- [2] [Sections 1 through 8] are effective January 1,
- LB 1992.

-End-

52nd Legislature

23

24

25

HB 0118/03

1 2 3

4

5

7

10

11

12

13

18

HB 0118/03

T	HOUSE BILL NO. 118
2	INTRODUCED BY J. BROWN
3	
4	A BILL FOR AN ACT ENTITLED: "AN ACT ALLOWING A LICENSED
5	PHARMACIST TO USE THE SERVICES OF A PHARMACY TECHNICIAN
6	UNDER THE TERMS OF AN APPROVED UTILIZATION PLAN; PROVIDING
7	FOR TRAINING OF PHARMACY TECHNICIANS; PROVIDING FOR FEES AND
8	PENALTIES; AMENDING SECTIONS 37-7-101, 37-7-301, AND
9	37-7-323, MCA; AND PROVIDING EFFECTIVE DATES."
10	
11	STATEMENT OF INTENT
12	It is the intent of the legislature that the board of
13	pharmacy, to implement (sections 3 through 7), adopt rules
14	that, among other issues, describe the functions that a
15	pharmacy technician is permitted to perform, including but
16	not limited to:
17	(1) removing a stock bottle from the shelf and counting
18	and pouring the contents into a suitable container under
19	direct supervision of a pharmacist;
20	(2) typing a prescription label and affixing it to a
21	prescription bottle, with a final check and any patient
22	counseling performed by the pharmacist;

(3) entering prescription information into a data

processing system under supervision of a pharmacist who must

be able to check all entries;

(4) main	taining	prescr	iption	1	records	s, includ	in
prescription	numbers,	refil1	data,	and	other	information	0
the patient p	rofile sy	stem;					

- (5) prepackaging unit dose drugs for internal distribution. These prepackage unit dose drugs must be quarantined together with bulk containers until a pharmacist performs a final check and maintains appropriate records.
- (6) selling nonprescription drugs in their original 8 containers without engaging in patient counseling; 9
  - pharmaceuticals, (7) receiving and checking in including controlled substances, if the pharmacy technician initials and dates all invoices with the actual date the drugs were received;
- (8) participating in the biennial inventory of 14 controlled substances, provided a pharmacist supervises the 15 16 process. The supervising pharmacist must cosign the inventory list with the participating pharmacist 17 pharmacy technician.
- (9) compounding intravenous solutions if a mechanism 19 for verification exists that includes checking of the 20 original order, solutions, additives, dosages, and clarity. 21
- The legislature also intends that the board adopt rules 22 23 establishing standards for the training required by [section 5], which must include instruction in: 24
- (1) orientation to the practice of pharmacy; 25

THIRD READING

12

13

areas:

1 .	<ul><li>(2) pharmacy terminology and basic pharmaceutics;</li></ul>
2	(3) state and federal laws relating to the practice of
3	pharmacy;
4	(4) pharmaceutical calculations;
5	(5) processing prescription drug orders;
6	(6) telephone procedure and communication;
7	(7) pharmaceutical compounding, including intravenous
8	admixture; and
9	(8) use of pharmacy computer systems, if applicable.
10	The legislature further intends that the board's rules
11	allow a supervising pharmacist to use the services of only
12	one technician at a time, except that the pharmacist may use
13	two technicians at a time if both pharmacy technicians are
14	performing any of the following procedures:
15	(1) intravenous admixture and other sterile product
16	preparation;
17	(2) filling of unit dose cassettes;
18	(3) prepackaging; and
19	(4) bulk compounding.
20	
21	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
22	Section 1. Section 37-7-101, MCA, is amended to read:
23	"37-7-101. Definitions. Unless the context requires
24	otherwise, in parts 1 through 3 of this chapter, the

-3-

2	2-15-1843.
3	(2) "Chemical" means medicinal or industrial
4	substances, whether simple, compound, or obtained through
5	the process of the science and art of chemistry, whether of
6	organic or inorganic origin.
7	(3) "Commercial purposes" means the ordinary purposes
8	of trade, agriculture, industry, and commerce, exclusive of
9	the practices of medicine and pharmacy.
10	(4) "Continuing education" means professional
11	pharmaceutical postgraduate education in the following

(1) "Board" means the board of pharmacy provided for in

- (a) the socioeconomic and legal aspects of health care;
- (b) the properties and actions of drugs and dosage
  forms; and
- 16 (c) the etiology, characteristics, and therapeutics of 17 the disease state.
- 18 (5) "Department" means the department of commerce
  19 provided for in Title 2, chapter 15, part 18.
- 20 (6) (a) "Drug" means:
- 21 (i) articles recognized in the official United States
  22 Pharmacopoeia/National Formulary or a supplement to them;
- 23 (ii) articles intended for use in diagnosis, cure, 24 mitigation, treatment, or prevention of disease in man or 25 other animals;

25

following definitions apply:

HB 0118/03 HB 0118/03

- 1 (iii) articles (other than food) intended to affect the
  2 structure or function of the body of man or other animals;
  3 and
- 4 (iv) articles intended for use as a component of an 5 article specified in subsection (i), (ii), or (iii).

6

7

8

10

11

12

13

14

- (b) "Drug" does not include devices or their components, parts, or accessories.
- (7) "Intern" means a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons under the supervision of a registered and licensed pharmacist.
- (8) "Medicine" means a remedial agent which has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.
- (9) "Person" includes an individual, partnership,corporation, or association.
- 17 (10) "Pharmacist" means a natural person licensed by the
  18 department to prepare, compound, dispense, and sell drugs,
  19 medicines, chemicals, and poisons and who may affix to his
  20 name the term "R.Ph.".
- 21 (11) "Pharmacy" means an established place registered by
  22 the department of commerce in which prescriptions, drugs
  23 requiring a prescription, medicines, chemicals, and poisons
  24 are compounded, dispensed, vended, or sold.
- 25 (12) "Pharmacy technician" means an individual who

-5-

- assists a pharmacist in the practice of pharmacy pursuant to
  an approved utilization plan.
- 3 <u>+±2+(13)</u> "Poison" means a substance which, when 4 introduced into the system, either directly or by 5 absorption, produces violent, morbid, or fatal changes or 6 which destroys living tissue with which it comes in contact.
- 7 +13+(14) "Prescription" means order given individually for the person for whom prescribed, directly 8 9 from the prescriber to the furnisher or indirectly to the furnisher, by means of an order signed by the prescriber and 10 11 bearing the name and address of the prescriber, his license classification, the name of the patient, the name and the 12 13 quantity of the drug or drugs prescribed, the directions for use and the date of its issue. These stipulations apply to 14
- 16 (15) "Utilization plan" means a plan under which a

  17 pharmacist may use the services of a pharmacy technician in
- 18 the practice of pharmacy to perform tasks that:

both written and telephoned prescriptions.

15

- 19 (a) do not require the exercise of the pharmacist's
  20 independent professional judgment; and
- 21 (b) are verifiable VERIFIED by the pharmacist.
- 22 (14)(16) "Wholesale" means a sale for the purpose of resale."
- Section 2. Section 37-7-301, MCA, is amended to read:
- 25 \*37-7-301. 3ale of drugs or medicines unlawful except

HB 118

-6- HB 118

as provided. Except as provided in [sections 3 through 7],
it is unlawful for a:

1

2

3

7

8

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

- (1) ft--is--unlawful--for--any person to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons in any place other than a pharmacy, except as hereinafter provided;
- (2) #t--is--unlawful--for--any proprietor, owner, or manager of a pharmacy or any other person to permit the compounding or dispensing of prescriptions or the vending or selling at retail of drugs, medicines, chemicals, or poisons in any pharmacy except by a registered and licensed pharmacist or by an intern registered and licensed by the department; and under the supervision of a registered and licensed pharmacist;
- (3) It--is-unlawful-for-any person to assume or pretend to the title of pharmacist or intern unless such the person has a license as such, issued and in force pursuant to parts 1 through 3 of this chapter:
- (4) ft-is-unlawful-for-any person other than a licensed and registered pharmacist or a licensed and registered intern under the supervision of a licensed and registered pharmacist to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons except as provided in parts 1 through 3."

-7-

25 NEW SECTION. Section 3. Use of services of pharmacy

- technician -- utilization plan required -- contents --
- 2 responsibility of pharmacist. (1) In the practice of
- 3 pharmacy, a pharmacist may use the services of a pharmacy
- 4 technician who is:

R

19

20

21

22

- (a) at least 18 years old;
- 6 (b) a high school graduate or has attained an
  7 eguivalent degree;
  - (c) supervised by the pharmacist; and
- 9 (d) acting pursuant to the provisions of a utilization
  10 plan approved by the board or its designee.
- 11 (2) A pharmacy technician utilization plan must set 12 forth:
- (a) the name and qualifications of the supervisingpharmacist or pharmacists;
- 15 (b) the nature and location of the supervising
  16 pharmacist's pharmacy practice;
- 17 (c) the name and qualifications of the pharmacy
  18 technician OR TECHNICIANS;
  - (d) a summary of the tasks performed by the pharmacy technician and the methods by which a supervising pharmacist may verify and document the tasks. "Verify" means the personal confirmation by a supervising pharmacist of the
- 23 correctness of the tasks undertaken by the pharmacy
- 24 technician.
- 25 (e) a description of the training provided by the

HB 118

- supervising pharmacist to the pharmacy technician that is
  required by [section 5]; and
  - (f) any other information the board considers relevant.

18

19

20

21

- 4 (3) The board OR ITS DESIGNEE shall approve a 5 utilization plan if it determines that the duties to be 6 delegated to a pharmacy technician are:
- 7 (a) assigned, VERIFIED, and supervised DOCUMENTED by 8 the supervising pharmacist; and
- 9 (b) within the scope of the training and competence of 10 the pharmacy technician.
- 11 (4) A supervising pharmacist is responsible for the 12 actions of a pharmacy technician who performs services for 13 the pharmacist under the terms of a utilization plan.
- NEW SECTION. Section 4. Preparation and approval of utilization plan -- revocation of or refusal to renew plan -- contested case hearing. (1) A supervising pharmacist shall:
  - (a) prepare the utilization plan under which the services of a pharmacy technician are used by the pharmacist and submit a summary of the plan to the board or its designee for approval;
- 22 (b) keep on file in the pharmacy a copy of the 23 utilization plan for inspection by the board or its 24 designee; and
- 25 (c) annually review the utilization plan and provide

-9-

- l documentation to the board or its designee that the plan
- 2 accurately reflects the current use of the services of a
- 3 pharmacy technician.
- 4 (2) The board or its designee shall refuse to approve 5 or shall revoke or fail to renew approval of a utilization

plan if it does not conform to the provisions of [sections 3

- 7 through 7] and rules adopted under those sections.
- 8 (3) One year after the board or its designee revokes
  9 approval of a utilization plan, the supervising pharmacist
  10 may reapply for approval by complying with the requirements
- of [sections 3 through 7] and with rules adopted under those
- 12 sections.

- 13 (4) Before refusing to approve or before revoking or
- 14 failing to renew approval of a utilization plan, the board
- or its designee shall provide the supervising pharmacist a
- 16 reasonable time in which to supply additional information
- demonstrating compliance with the requirements of [sections
- 18 3 through 7] and with rules adopted under those sections and
- 19 the opportunity to request a hearing.
- (5) If a supervising pharmacist requests a hearing, the
   board shall conduct the hearing in accordance with the
- contested case procedures in Title 2, chapter 4, part 6.
- NEW SECTION. Section 5. Training of pharmacy
- 24 technician. (1) A supervising pharmacist shall:
- 25 (a) provide initial training to a pharmacy technician

that relates to the tasks the pharmacy technician may perform pursuant to a utilization plan;

- (b) assure the continuing competence of a pharmacy technician through inservice education and training to supplement the initial training; and
- 6 (c) prepare and maintain a written record of initial7 and inservice training.
  - (2) An initial training program must include on-the-job practical training and didactic education through a program approved by the board or its designee that is commensurate with the tasks a pharmacy technician may perform, prior to the regular performance of those tasks.
  - NEW SECTION. Section 6. Utilization plan approval fee

    -- renewal of approval -- renewal fee. (1) A PHARMACY IN

    WHICH A pharmacist who uses the services of a pharmacy
    technician under an approved utilization plan shall pay to
    the board OR ITS DESIGNEE a utilization plan approval fee in
    an amount set by the board OR-ITS-DESIGNEE as provided in
    37-1-134. Payment must be made when the utilization plan is
    submitted to-the-board and is not refundable.
  - (2) Approval of a pharmacy technician utilization plan expires 1 year from the date of approval. The board OR ITS

    DESIGNEE shall grant renewal of approval upon payment of a renewal fee in an amount set by the board OR-ITS--DESIGNEE and documentation as required by [section 4(1)(c)].

- 1 (3) The board OR-ITS--DESIGNEE may adopt fees, as
  2 provided in 37-1-134, for other costs associated with
  3 implementation of [sections 3 through 7], including the
  4 costs of onsite inspection of the utilization plan and of
  5 the record of training required by [section 5] at the
  6 participating pharmacy. THE BOARD MAY DESIGNATE A PRIVATE
  7 ENTITY TO COLLECT THE FEES ADOPTED BY THE BOARD.
  - (4) The <u>IP-THE-BOARD-SETS-THE-FEES,-THE</u> THE board shall deposit fees received in the state special revenue fund for use by the board in administration of [sections 3 through 7], subject to 37-1-101(6).
- NEW SECTION. Section 7. Auxiliary personnel. To
  perform clerical tasks, a pharmacist may use the services of
  auxiliary or support personnel who are not considered to be
  acting as pharmacy technicians if they do not perform the
  tasks of pharmacy technicians.
- Section 8. Section 37-7-323, MCA, is amended to read:
- 18 "37-7-323. Penalty enforcement. (1) Any A person,
  19 firm, partnership, or corporation violating any of the
  20 provisions of parts 1 through 3 of this chapter shall-be is
  21 guilty of a misdemeanor and upon conviction for each
  22 violation shall be punished accordingly, and any—thereof
  23 convicted shall automatically lose any license issued by the
  24 board.
  - (2) In addition to the penalty provided in subsection

-12-

HB 0118/03

- 1 (1), the board may withdraw its approval of a utilization
- 2 plan previously approved for a supervising pharmacist who:
- 3 (a) violates any provision of (sections 3 through 7) or
- 4 rules adopted under those sections;
- 5 (b) obtained the approval of the utilization plan
- 6 through fraud; or
- 7 (c) acts in a manner contrary to the terms of the
- 8 utilization plan.
- 9 (3) The board may seek an injunction to enforce the
- 10 provisions of subsection (2)."
- 11 NEW SECTION. Section 9. Codification instruction.
- 12 [Sections 3 through 7] are intended to be codified as an
- 13 integral part of Title 37, chapter 7, part 3, and the
- 14 provisions of Title 37, chapter 7, part 3, apply to
- 15 [sections 3 through 7].
- 16 NEW SECTION. Section 10. Effective dates. (1) [Section
- 17 9 and this section) are effective on passage and approval.
- 18 (2) [Sections 1 through 8] are effective January 1,
- 19 1992.

-End-

25

1	HOUSE BILL NO. 118
2	INTRODUCED BY J. BROWN
3	
4	A BILL FOR AN ACT ENTITLED: "AN ACT ALLOWING A LICENSED
5	PHARMACIST TO USE THE SERVICES OF A PHARMACY TECHNICIAN $\overline{\text{OR}}$
6	AUXILIARY UNDER THE TERMS OF AN APPROVED UTILIZATION PLAN;
7	PROVIDINGPORTRAININGOF-PHARMACY-TECHNICIANS? PROVIDING
8	FOR FEES AND PENALTIES; AMENDING SECTIONS 37-7-101,
9	37-7-301, AND 37-7-323, MCA; AND PROVIDING EFFECTIVE DATES."
10	
11	STATEMENT OF INTENT
12	It is the intent of the legislature that the board of
13	pharmacy, to implement [sections 3 through $7 \ \underline{5}$ ], adopt rules
14	that, among other issues, describe the functions that a
15	pharmacytechnicianispermitted-to-perform PHARMACIST IS
16	PERMITTED TO DELEGATE TO A PHARMACY TECHNICIAN OR AUXILIARY,
17	including but not limited to:
18	(1) removing a stock bottle from the shelf and counting
19	and pouring the contents into a suitable container under
20	direct supervision of a pharmacist;
21	(2) typing a prescription label and affixing it to a
22	prescription bottle, with a final check and any patient
23	counseling performed by the pharmacist;

(3) entering prescription information into a data

processing system under supervision of a pharmacist who must

2	<ul><li>(4) maintaining prescription records, including</li></ul>
3	prescription numbers, refill data, and other information on
4	the patient profile system;
5	(5) prepackaging unit dose drugs for internal
6	distribution. These prepackage unit dose drugs must be
7	quarantined together with bulk containers until a pharmacist
8	performs a final check and maintains appropriate records.
9	(6) selling nonprescription drugs in their original
10	containers without engaging in patient counseling;
11	(7) receiving and checking in pharmaceuticals,
12	including controlled substances, if the pharmacy technician
13	OR AUXILIARY initials and dates all invoices with the actual
14	date the drugs were received;
15	(8) participating in the biennial inventory of
16	controlled substances, provided a pharmacist supervises the
17	process. The supervising pharmacist must cosign the
18	inventory list with the participating pharmacist and
19	pharmacy technician OR AUXILIARY.
20	(9) compounding intravenous solutions if a mechanism
21	for verification exists that includes checking of the
22	original order, solutions, additives, dosages, and clarity.
23	Thelegislature-also-intends-that-the-board-adopt-rules
24	establishing-standards-for-the-training-required-by-fsection
25	5+7-which-must-include-instruction-in-

be able to check all entries;

transfer that the first th

2	(2)pharmacy-terminology-and-basic-pharmaceutics;
3	(3)state-and-federal-laws-relating-to-the-practiceof
4	pharmacy;
5	(4)pharmaceutical-calculations;
6	<pre>f5)processing-prescription-drug-orders;</pre>
7	(6)telephone-procedure-and-communication;
8	(7)pharmaceuticalcompounding,including-intravenous
9	admixture;-and
10	<pre>+8)use-of-pharmacy-computer-systems;-if-applicable;</pre>
11	The legislature further intends that the board's rules
12	allow a supervising pharmacist to use the services of only
13	one technician OR AUXILIARY at a time, except that the
14	pharmacist may use two technicians at a time if both
15	pharmacy-technicians are performing any of the following
16	procedures:
17	(1) intravenous admixture and other sterile product
18	preparation;
19	(2) filling of unit dose cassettes;
20	(3) prepackaging; and
21	(4) bulk compounding.
22	
23	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:
24	Section 1. Section 37-7-101, MCA, is amended to read:
25	*37-7-101. Definitions. Unless the context requires

fil--orientation-to-the-practice-of-pharmacy-

1

- otherwise, in parts 1 through 3 of this chapter, the following definitions apply:

  (1) "Board" means the board of pharmacy provided for in 2-15-1843.
- 5 (2) "Chemical" means medicinal or industrial 6 substances, whether simple, compound, or obtained through 7 the process of the science and art of chemistry, whether of 8 organic or inorganic origin.
- 9 (3) "Commercial purposes" means the ordinary purposes
  10 of trade, agriculture, industry, and commerce, exclusive of
  11 the practices of medicine and pharmacy.
- 12 (4) "Continuing education" means professional
  13 pharmaceutical postgraduate education in the following
  14 areas:
  - (a) the socioeconomic and legal aspects of health care;
- 16 (b) the properties and actions of drugs and dosage 17 forms; and
- 18 (c) the etiology, characteristics, and therapeutics of 19 the disease state.
- 20 (5) "Department" means the department of commerce
  21 provided for in Title 2, chapter 15, part 18.
- 22 (6) (a) "Drug" means:

15

- 23 (i) articles recognized in the official United States
  24 Pharmacopoeia/National Formulary or a supplement to them;
- 25 (ii) articles intended for use in diagnosis, cure,

-4-

10

11

12

13

14

15

16

17

- mitigation, treatment, or prevention of disease in man or
  other animals;
- 3 (iii) articles (other than food) intended to affect the 4 structure or function of the body of man or other animals; 5 and
- 6 (iv) articles intended for use as a component of an 7 article specified in subsection (i), (ii), or (iii).
- 8 (b) "Drug" does not include devices or their
  9 components, parts, or accessories.

10

11

12

13

14

15

16

19

20

21

22

- (7) "Intern" means a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons under the supervision of a registered and licensed pharmacist.
- (8) "Medicine" means a remedial agent which has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.
- 17 (9) "Person" includes an individual, partnership,
  18 corporation, or association.
  - (10) "Pharmacist" means a natural person licensed by the department to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons and who may affix to his name the term "R.Ph.".
- 23 (11) "Pharmacy" means an established place registered by 24 the department of commerce in which prescriptions, drugs 25 requiring a prescription, medicines, chemicals, and poisons

are compounded, dispensed, vended, or sold.

2 (12) "Pharmacy technician OR AUXILIARY" means an
3 individual who assists a pharmacist in the practice of
4 pharmacy pursuant to an approved utilization plan.

5 (12)(13) "Poison" means a substance which, when 6 introduced into the system, either directly or by 7 absorption, produces violent, morbid, or fatal changes or 8 which destroys living tissue with which it comes in contact.

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

- 18 (15) "Utilization plan" means a plan under which a

  19 pharmacist may use the services of a pharmacy technician OR

  20 AUXILIARY in the practice of pharmacy to perform tasks that:
- 21 (a) do not require the exercise of the pharmacist's
  22 independent professional judgment; and
- 23 (b) are verifiable VERIFIED by the pharmacist.
- 24  $(t^{\frac{1}{4}})(16)$  "Wholesale" means a sale for the purpose of 25 resale."

HB 118

Section 2. Section 37-7-301, MCA, is amended to read:

2

3

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

- \*37-7-301. Sale of drugs or medicines unlawful except as provided. Except as provided in [sections 3 through 7 5], it is unlawful for a:
- (1) It---is---unlawful--for--any person to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons in any place other than a pharmacy, except as hereinafter provided;
- (2) #t--is--unlawful--for--any proprietor, owner, or manager of a pharmacy or any other person to permit the compounding or dispensing of prescriptions or the vending or selling at retail of drugs, medicines, chemicals, or poisons in any pharmacy except by a registered and licensed pharmacist or by an intern registered and licensed by the department; and under the supervision of a registered and licensed pharmacist;
- (3) ft-is-unlawful-for-any person to assume or pretend to the title of pharmacist or intern unless such the person has a license as such, issued and in force pursuant to parts 1 through 3 of this chapter:
- (4) It-is-unlawful-for-any person other than a licensed and registered pharmacist or a licensed and registered intern under the supervision of a licensed and registered pharmacist to compound, dispense, vend, or sell at retail drugs, medicines, chemicals, or poisons except as provided

- in parts 1 through 3."
- 2 <u>NEW SECTION.</u> Section 3. Tuse of services of pharmacy 3 technician----utilization-plan-required UTILIZATION PLAN --
- 4 contents -- responsibility of pharmacist. (1)--In---the
- 5 practice-of-pharmacyy-a-pharmacist-may-use-the-services-of-a
- 6 pharmacy-technician-who-is:

- 9 equivalent-degree;
- 10 (c)--supervised-by-the-pharmacist;-and
- 11 (d)--acting-pursuant-to-the-provisions-of-a--utilization
- 12 plan-approved-by-the-board-or-its-designee:
- 13 (2)(1) A pharmacy-technician utilization plan must set
- 14 forth:

22

destructions and the contract of the contract

- 15 (a) the name and qualifications of the supervising
- 16 pharmacist or pharmacists;
- 17 (b) the nature and location of the supervising
- 18 pharmacist's pharmacy practice;
- 19 te)--the--name--and--qualifications--of---the---pharmacy
- 20 technician OR-TECHNICIANS;
- 21 (d)(C) a summary of the tasks performed-by-the-pharmacy
  - technician DELEGATED BY THE PHARMACIST and the methods by
- 23 which a supervising pharmacist may verify and document the
- 24 tasks. "Verify" means the personal confirmation by a
- 25 supervising pharmacist of the correctness of the tasks

HB 118

1 undertaken by the pharmacy technician.

15

16

17

18

- 2 te}--a--description--of--the--training--provided--by-the supervising-pharmacist-to-the-pharmacy--technician--that--is required-by-{section-5};-and 4
- tf)(D) any other information the board considers 5 relevant. 6
- +3+(2) The board OR--FTS--DESFGNEE shall approve a 7 utilization plan if it determines that the duties to be 8 9 delegated to-s-pharmacy-technician are:
- (a) assigned, VERIFIED, and supervised DOCUMENTED by 10 the supervising pharmacist; and 11
- (b) within the scope of the training and competence of 12 the pharmacy--technician PERSON TO WHOM THE AUTHORITY IS 13 DELEGATED. 14
  - (4)(3) A supervising pharmacist is responsible for the actions of a pharmacy technician OR AUXILIARY who performs services for the pharmacist under the terms of a utilization plan.
- 19 NEW SECTION. Section 4. Preparation and approval of utilization plan -- revocation of or refusal to renew plan 20 -- contested case hearing. (1) A supervising pharmacist 21 22 shall:
- 23 (a) prepare the utilization plan under--which---the services-of-a-pharmacy-technician-are-used-by-the-pharmacist 24 and submit a summary of the plan to the board or-its 25

designee for approval;

9

10

11

12

13

14

15

16

18

19

20

21

22

23

24

25

- 2 (b) keep on file in the pharmacy a copy of the utilization plan for inspection by the board er--its 3 designee; and
- (c) annually review the utilization plan and provide 5 documentation to the board or-its-designee that the plan accurately reflects the current use of the services of a pharmacy technician OR AUXILIARY.
  - (2) The board or-its-designee shall refuse to approve or shall revoke or fail to renew approval of a utilization plan if it does not conform to the provisions of {sections 3 through 7 5] and rules adopted under those sections.
- (3) One year after the board or-its-designee revokes approval of a utilization plan, the supervising pharmacist may reapply for approval by complying with the requirements of [sections 3 through 7 5] and with rules adopted under 17 those sections.
  - (4) Before refusing to approve or before revoking or failing to renew approval of a utilization plan, the board or--its--designee shall provide the supervising pharmacist a reasonable time in which to supply additional information demonstrating compliance with the requirements of (sections 3 through 7 5] and with rules adopted under those sections
  - (5) If a supervising pharmacist requests a hearing, the

and the opportunity to request a hearing.

-9-

board shall conduct the hearing in accordance with the contested case procedures in Title 2, chapter 4, part 6.

3 <u>NEW-SECTION:</u>--Section-5:--Training-----of-----pharmacy 4 technician:-(1)-A-supervising-pharmacist-shall:

{a}--provide-initial-training-to-a--pharmacy--technician
that--relates--to--the--tasks--the--pharmacy--technician-may
perform-pursuant-to-a-utilization-plan;

(b)--assure-the--continuing--competence--of--a--pharmacy
technician--through--inservice--education--and--training--to
supplement-the-initial-training--and

{c}--prepare--and--maintain--a-written-record-of-initial
and-inservice-training-

(2)--An-initial-training-program-must-include-on-the-job practical-training-and-didactic-education-through-a--program approved--by--the-board-or-its-designee-that-is-commensurate with-the-tasks-a-pharmacy-technician-may-perform,--prior--to the-regular-performance-of-those-tasks-

NEW SECTION. Section 5. Utilization plan approval fee

-- renewal of approval -- renewal fee. (1) A PHARMACY IN

WHICH A pharmacist who uses the services of a pharmacy
technician OR AUXILIARY under an approved utilization plan
shall pay to the board OR-ITS-DESIGNEE a utilization plan
approval fee in an amount set by the board OR-ITS-DESIGNEE
as provided in 37-1-134. Payment must be made when the
utilization plan is submitted to--the--board and is not

l refundable.

- 2 (2) Approval of a pharmacy-technician utilization plan
  3 expires 1 year from the date of approval. The board <u>OR-ITS</u>
  4 <u>BESIGNEE</u> shall grant renewal of approval upon payment of a
  5 renewal fee in an amount set by the board <u>OR-ITS-BESIGNEE</u>
  6 and documentation as required by (section 4(1)(c)).
  - (3) The board OR--ITS--DESIGNEE may adopt fees, as provided in 37-1-134, for other costs associated with implementation of [sections 3 through 7 5], including the costs of onsite inspection of the utilization plan and-of the-record-of--training--required--by--fsection--5} at the participating pharmacy. THE--BOARD-MAY-DESIGNATE-A-PRIVATE ENTITY-TO-COLLECT-THE-FEES-ADOPTED-BY-THE-BOARD-
  - (4) The IF-THE-BOARD-SETS-THE-PRES<sub>7</sub>-THE THE board shall deposit fees received in the state special revenue fund for use by the board in administration of [sections 3 through 7 5], subject to 37-1-101(6).

NEW-SECTION: --Section-7:--Auxiliary---personnel:-----To perform-clerical-tasks;-a-pharmacist-may-use-the-services-of auxiliary--or-support-personnel-who-are-not-considered-to-be acting-as-pharmacy-technicians-if-they-do--not--perform--the tasks-of-pharmacy-technicians-

Section 6. Section 37-7-323, MCA, is amended to read:

"37-7-323. Penalty -- enforcement. (1) Any A person, firm, partnership, or corporation violating any of the

HB 118

-12-

- 1 provisions of parts 1 through 3 of this chapter shall-be is
- guilty of a misdemeanor and upon conviction for each
- 3 violation shall be punished accordingly, and any-thereof
- 4 convicted shall automatically lose any license issued by the
- 5 board.
- 6 (2) In addition to the penalty provided in subsection
- 7 (1), the board may withdraw its approval of a utilization
- 8 plan previously approved for a supervising pharmacist who:
- 9 (a) violates any provision of [sections 3 through 7 5]
- 10 or rules adopted under those sections;
- 11 (b) obtained the approval of the utilization plan
- 12 through fraud; or
- 13 (c) acts in a manner contrary to the terms of the
- 14 utilization plan.
- 15 (3) The board may seek an injunction to enforce the
- provisions of subsection (2)."
- 17 NEW SECTION. Section 7. Codification instruction.
- 18 [Sections 3 through 7 5] are intended to be codified as an
- 19 integral part of Title 37, chapter 7, part 3, and the
- 20 provisions of Title 37, chapter 7, part 3, apply to
- 21 [sections 3 through 7 5].
- 22 NEW SECTION. Section 8. Effective dates. (1) [Section
- 9 7 and this section] are effective on passage and approval.
- 24 (2) [Sections 1 through 8 6] are effective January 1,
- 25 1992.