

SENATE BILL NO. 393

INTRODUCED BY KENNEDY

IN THE SENATE

FEBRUARY 14, 1991 INTRODUCED AND REFERRED TO COMMITTEE
ON PUBLIC HEALTH, WELFARE, & SAFETY.

FIRST READING.

FEBRUARY 23, 1991 COMMITTEE RECOMMEND BILL
DO PASS AS AMENDED. REPORT ADOPTED.

FEBRUARY 25, 1991 PRINTING REPORT.

SECOND READING, DO PASS.

FEBRUARY 26, 1991 ENGROSSING REPORT.

THIRD READING, PASSED.
AYES, 49; NOES, 0.

TRANSMITTED TO HOUSE.

IN THE HOUSE

MARCH 4, 1991 INTRODUCED AND REFERRED TO COMMITTEE
ON HUMAN SERVICES & AGING.

FIRST READING.

MARCH 23, 1991 COMMITTEE RECOMMEND BILL BE
CONCURRED IN AS AMENDED. REPORT
ADOPTED.

APRIL 6, 1991 SECOND READING, CONCURRED IN AS
AMENDED.

ON MOTION, RULES SUSPENDED. BILL
PLACED ON THIRD READING THIS DAY.

THIRD READING, CONCURRED IN.
AYES, 96; NOES, 1.

RETURNED TO SENATE WITH AMENDMENTS.

IN THE SENATE

APRIL 17, 1991 RECEIVED FROM HOUSE.

SECOND READING, AMENDMENTS
CONCURRED IN.

APRIL 18, 1991

THIRD READING, AMENDMENTS
CONCURRED IN.

APRIL 19, 1991

SENT TO ENROLLING.

REPORTED CORRECTLY ENROLLED.

1 *Senate* BILL NO. *393*
 2 INTRODUCED BY *Kennedy*
 3

4 A BILL FOR AN ACT ENTITLED: "AN ACT AUTHORIZING THE BOARD
 5 OF PHARMACY TO ESTABLISH STANDARDS FOR DRUG UTILIZATION
 6 REVIEW AND PATIENT COUNSELING BY PHARMACISTS; REQUIRING
 7 OUT-OF-STATE MAIL SERVICE PHARMACIES TO BE LICENSED BY THE
 8 BOARD AND TO COMPLY WITH PATIENT COUNSELING REQUIREMENTS
 9 THROUGH TOLL-FREE TELEPHONE NUMBERS; PROVIDING ADDITIONAL
 10 STANDARDS FOR OUT-OF-STATE MAIL SERVICE PHARMACIES; AND
 11 PROVIDING A PENALTY."

12
 13 WHEREAS, the United States Congress has enacted a
 14 requirement in 42 U.S.C. 1396r-8 of the Social Security Act
 15 that states participating in Medicaid institute programs of
 16 drug utilization review and patient counseling by
 17 pharmacists; and

18 WHEREAS, similar changes in pharmacy practice could
 19 benefit the health and welfare of all Montanans and not just
 20 Medicaid recipients, and to that end the Board of Pharmacy
 21 should have the authority to set standards for pharmacists
 22 concerning drug utilization review and patient counseling,
 23 including standards for pharmacists who fill prescriptions
 24 by mail order from outside this state.

25 STATEMENT OF INTENT

1 A statement of intent is needed for this bill because it
 2 grants the board of pharmacy additional regulatory and
 3 rulemaking authority. In order to benefit all
 4 patient-consumers, the board may adopt rules similar to
 5 medicaid regulations governing drug utilization review and
 6 patient counseling. The board is also required to adopt
 7 rules to regulate the activities of out-of-state mail
 8 service pharmacies, including their licensing, reporting
 9 requirements, drug utilization review and patient
 10 counseling, and site inspections.

11
12 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

13 NEW SECTION. **Section 1.** Standards for prospective drug
 14 utilization review and patient counseling. (1) The board may
 15 by rule set standards for the provision of prospective drug
 16 utilization review information from a pharmacist to a
 17 patient before a prescription is dispensed to the patient or
 18 his representative. The review may include, when applicable,
 19 an appropriate level of screening for potential drug therapy
 20 problems due to therapeutic duplication, drug disease
 21 contraindications, drug interactions, incorrect drug dosage
 22 or duration of drug treatment, drug-allergy interactions,
 23 and clinical abuse or misuse. The sources for the standards
 24 must be nationally recognized compendia as the board may
 25 designate.

INTRODUCED BILL
SB 393



1 (2) Under the standards provided for in this section,
 2 the pharmacist should offer to discuss those matters that,
 3 in his professional judgment, he considers significant to
 4 the patient's safe and proper use of the prescribed drug.
 5 The counseling should encompass the topics set forth in
 6 section 42 U.S.C. 1396r-8 of the Social Security Act.

7 (3) Communications between a pharmacist and a patient
 8 pursuant to the standards provided for in this section
 9 constitute health care information for the purposes of Title
 10 50, chapter 16, part 5.

11 (4) Standards established by the board under this
 12 section apply to all patients seen by a pharmacist or to
 13 categories of patients as the board may designate.

14 NEW SECTION. Section 2. Legislative declaration. The
 15 legislature recognizes that with the proliferation of
 16 alternate methods of health care delivery, there has arisen
 17 among third-party payers and insurance companies the desire
 18 to control the cost and utilization of pharmacy services
 19 through a variety of mechanisms, including the use of mail
 20 service pharmacies located outside this state. As a result,
 21 the legislature finds and declares that to continue to
 22 protect the consumer-patients of this state, all
 23 out-of-state mail service pharmacies that provide services
 24 to this state's residents must be licensed with the board,
 25 disclose specific information about their services, and

1 provide pharmacy services at a high level of competence.

2 NEW SECTION. Section 3. Out-of-state mail service
 3 pharmacy defined. "Out-of-state mail service pharmacy" means
 4 a pharmacy located outside this state that:

5 (1) ships, mails, or delivers by any lawful means a
 6 dispensed legend drug to a resident in this state pursuant
 7 to a legally issued prescription;

8 (2) provides to a resident of this state information on
 9 drugs or devices that may include but is not limited to
 10 advice relating to therapeutic values, potential hazards,
 11 and uses; or

12 (3) counsels pharmacy patients residing in this state
 13 concerning adverse and therapeutic effects of drugs.

14 NEW SECTION. Section 4. License requirements. (1)
 15 Every out-of-state mail service pharmacy must be licensed by
 16 the board. In order to be licensed by the board to do
 17 business in this state and for annual renewal of its
 18 license, an out-of-state mail service pharmacy:

19 (a) (i) must be licensed and in good standing in the
 20 state in which its dispensing facilities are located; and

21 (ii) shall comply with all applicable laws, regulations,
 22 and standards of that state and the United States and, if
 23 requested by the board, provide evidence that it has so
 24 complied;

25 (b) shall submit an application in form and content as

1 determined by the board, including information on ownership
2 and location and the identity of a licensed pharmacist in
3 charge of the out-of-state mail service pharmacy;

4 (c) shall pay an initial license fee and annual renewal
5 fee in an amount to be determined by the board; and

6 (d) shall submit to the board, at the beginning of each
7 calendar quarter, the following information concerning each
8 prescription for a scheduled controlled substance shipped,
9 mailed, or delivered to a resident of this state:

10 (i) the name of the patient;

11 (ii) the name of the practitioner;

12 (iii) the number of the prescription;

13 (iv) the date of the prescription;

14 (v) the name of the drug; and

15 (vi) the strength and quantity of the dosage.

16 (2) In lieu of providing the information required in
17 subsection (1)(d), an out-of-state mail service pharmacy may
18 submit to an onsite inspection by the board.

19 NEW SECTION. Section 5. Inspections. If the licensing
20 or regulatory agency of the state in which an out-of-state
21 mail service pharmacy is domiciled fails or refuses to
22 inspect the out-of-state mail service pharmacy after
23 receiving a request for an inspection from the board of this
24 state, the board may cancel the out-of-state pharmacy's
25 right to do business in this state unless the out-of-state

1 pharmacy agrees to an onsite inspection by the board of this
2 state.

3 NEW SECTION. Section 6. Product selection of
4 prescribed drugs -- notification. (1) An out-of-state mail
5 service pharmacy may not substitute a prescription drug
6 unless the substitution is made in compliance with the laws
7 of this state and the rules and regulations of the board.

8 (2) An out-of-state mail service pharmacy may not
9 dispense a substitute drug product to a resident of this
10 state without notifying the patient of the substitution
11 either by telephone or in writing.

12 NEW SECTION. Section 7. Patient communication --
13 telephone service. Every out-of-state mail service pharmacy
14 shall provide a toll-free telephone service, available at
15 least 6 days a week and for 40 hours a week, to facilitate
16 communication as may be required under [sections 1 through
17 8], between patients in this state and a pharmacist who has
18 access to the patient's records at the out-of-state mail
19 service pharmacy. The toll-free telephone number must be
20 affixed to all drug product containers dispensed to patients
21 in this state.

22 NEW SECTION. Section 8. Penalty. In addition to all
23 other penalties provided by law, a person violating [section
24 1 and sections 4 through 7] shall be fined not more than
25 \$250 for each violation.

1 NEW SECTION. Section 9. Codification instruction.
2 [Sections 1 through 8] are intended to be codified as an
3 integral part of Title 37, chapter 7, and the provisions of
4 Title 37, chapter 7, apply to [sections 1 through 8].

5 NEW SECTION. Section 10. Severability. If a part of
6 [this act] is invalid, all valid parts that are severable
7 from the invalid part remain in effect. If a part of [this
8 act] is invalid in one or more of its applications, the part
9 remains in effect in all valid applications that are
10 severable from the invalid applications.

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18 WHEREAS, similar changes in pharmacy practice could
19 benefit the health and welfare of all Montanans and not just
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 2 the pharmacist should offer to discuss those matters that,
 3 in his professional judgment, he considers significant to
 4 the patient's safe and proper use of the prescribed drug.
 5 The counseling should encompass the topics set forth in
 6 section 42 U.S.C. 1396r-8 of the Social Security Act.

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 9 constitute health care information for the purposes of Title
 10 50, chapter 16, part 5.

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 13 categories of patients as the board may designate. HOWEVER,
 14 STANDARDS PROVIDED FOR IN THIS SECTION MAY NOT APPLY TO
 15 INPATIENTS OF A HEALTH CARE FACILITY IN WHICH A NURSE OR
 16 OTHER LICENSED HEALTH CARE PROFESSIONAL IS AUTHORIZED TO
 17 ADMINISTER THE PRESCRIBED DRUG.

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 23 through a variety of mechanisms, including the use of mail
 24 service pharmacies located outside this state. As a result,
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16 (3) counsels pharmacy patients residing in this state
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18 NEW SECTION. Section 4. License requirements. (1)
 19 Every out-of-state mail service pharmacy must be licensed by
 20 the board. In order to be licensed by the board to do
 21 business in this state and for annual renewal of its
 22 license, an out-of-state mail service pharmacy:

23 (a) (i) must be licensed and in good standing in the
 24 state in which its dispensing facilities are located; and

25 (ii) shall comply with all applicable laws, regulations,

1 and standards of that state and the United States and, if
2 requested by the board, provide evidence that it has so
3 complied;

4 (b) shall submit an application in form and content as
5 determined by the board, including information on ownership
6 and location and the identity of a licensed pharmacist in
7 charge of the out-of-state mail service pharmacy;

8 (c) shall pay an initial license fee and annual renewal
9 fee in an amount to be determined by the board; and

10 (d) shall submit to the board, at the beginning of each
11 calendar quarter, the following information concerning each
12 prescription for a scheduled controlled substance shipped,
13 mailed, or delivered to a resident of this state:

- 14 (i) the name of the patient;
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20 (2) In lieu of providing the information required in
21 subsection (1)(d), an out-of-state mail service pharmacy may
22 submit to an onsite inspection by the board.

23 NEW SECTION. **Section 5. Inspections.** If the licensing
24 or regulatory agency of the state in which an out-of-state
25 mail service pharmacy is domiciled fails or refuses to

1 inspect the out-of-state mail service pharmacy after
2 receiving a request for an inspection from the board of this
3 state, the board may cancel the out-of-state pharmacy's
4 right to do business in this state unless the out-of-state
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6 state.

7 NEW SECTION. **Section 6. Product selection of**
8 **prescribed drugs -- notification.** (1) An out-of-state mail
9 service pharmacy may not substitute a prescription drug
10 unless the substitution is made in compliance with the laws
11 of this state and the rules and regulations of the board.

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13 dispense a substitute drug product to a resident of this
14 state without notifying the patient of the substitution
15 either by telephone or in writing.

16 NEW SECTION. **Section 7. Patient communication --**
17 **telephone service.** Every out-of-state mail service pharmacy
18 shall provide a toll-free telephone service, available at
19 least 6 days a week and for 40 hours a week, to facilitate
20 communication as may be required under [sections 1 through
21 8], between patients in this state and a pharmacist who has
22 access to the patient's records at the out-of-state mail
23 service pharmacy. The toll-free telephone number must be
24 affixed to all drug product containers dispensed to patients
25 in this state.

1 NEW SECTION. Section 8. Penalty. In addition to all
2 other penalties provided by law, a person violating [section
3 1 and sections 4 through 7] shall be fined not more than
4 \$250 for each violation.

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6 [Sections 1 through 8] are intended to be codified as an
7 integral part of Title 37, chapter 7, and the provisions of
8 Title 37, chapter 7, apply to [sections 1 through 8].

9 NEW SECTION. Section 10. Severability. If a part of
10 [this act] is invalid, all valid parts that are severable
11 from the invalid part remain in effect. If a part of [this
12 act] is invalid in one or more of its applications, the part
13 remains in effect in all valid applications that are
14 severable from the invalid applications.

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25 STATEMENT OF INTENT

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



HOUSE STANDING COMMITTEE REPORT

March 23, 1991

Page 1 of 1

Mr. Speaker: We, the committee on Human Services and Aging report that Senate Bill 393 (third reading copy -- blue) be concurred in as amended .

Signed: Angela Russell
Angela Russell, Chairman

CARRIED BY: REP HESSMORF

And, that such amendments read:

1. Page 5, line 7.

Following: ";"

Insert: "and"

2. Page 5, line 9.

Strike: "; and"

Insert: "."

3. Page 5, lines 10 through 22.

Following: line 9

Strike: subdivision (d) in its entirety

HOUSE
SB 393

HOUSE COMMITTEE OF THE WHOLE AMENDMENT
Senate Bill 393
Representative Messmore

April 6, 1991 10:26 am
Page 1 of 1

Mr. Chairman: I move to amend Senate Bill 393 (third reading copy -- blue).

Signed: Rep. Dick Messmore
Representative Messmore

And, that such amendments to Senate Bill 393 read as follows:

1. Amend the House committee on Human Services and Aging amendments, dated March 23, 1991, as follows:

Strike: amendment #3 and replace with:

3. Page 5, lines 10 through 22.

Following: line 9

Strike: lines 10 through 22 in their entirety

ADOPT

REJECT

HOUSE
SB 393

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