

SENATE/HOUSE FILE _____
BY (PROPOSED BOARD OF PHARMACY
BILL)

A BILL FOR

1 An Act relating to the Iowa prescription monitoring program,
2 including by establishing an advisory committee, authorizing
3 a registration surcharge, expanding information collection
4 and reporting requirements, and making penalties applicable.
5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. Section 124.550, Code 2018, is amended by adding
2 the following new subsection:

3 NEW SUBSECTION. 3. "*Proactive notification*" means
4 a notification by the board, generated based on factors
5 determined by the board and issued to a specific prescribing
6 practitioner or pharmacist, indicating that a patient may
7 be practitioner shopping or pharmacy shopping or at risk of
8 abusing or misusing a controlled substance.

9 Sec. 2. Section 124.551, subsection 1, Code 2018, is amended
10 to read as follows:

11 1. Contingent upon the receipt of funds pursuant to
12 section 124.557 sufficient to carry out the purposes of
13 this subchapter, the board, in conjunction with the advisory
14 ~~council~~ committee created in section 124.555, shall establish
15 and maintain an information program for drug prescribing and
16 dispensing.

17 Sec. 3. Section 124.552, Code 2018, is amended to read as
18 follows:

19 **124.552 Information reporting.**

20 1. ~~Each~~ Unless otherwise prohibited by federal or state law,
21 each licensed pharmacy that dispenses controlled substances
22 identified pursuant to section 124.554, subsection 1, paragraph
23 "g", to patients in the state, ~~and~~ each licensed pharmacy
24 located in the state that dispenses such controlled substances
25 identified pursuant to section 124.554, subsection 1,
26 paragraph "g", to patients inside or outside the state, unless
27 specifically excepted in this section or by rule, and each
28 prescribing practitioner furnishing, dispensing, or supplying
29 controlled substances to the prescribing practitioner's
30 patient, shall submit the following prescription information
31 to the program:

32 a. Pharmacy identification.

33 b. Patient identification.

34 c. Prescribing practitioner identification.

35 d. The date the prescription was issued by the prescribing

1 practitioner.

2 e. The date the prescription was dispensed.

3 f. An indication of whether the prescription dispensed is
4 new or a refill.

5 g. Identification of the drug dispensed.

6 h. Quantity of the drug dispensed.

7 i. The number of days' supply of the drug dispensed.

8 j. Serial or prescription number assigned by the pharmacy.

9 k. Type of payment for the prescription.

10 l. Other information identified by the board ~~and advisory~~
11 ~~council~~ by rule.

12 2. Information shall be submitted electronically in a
13 secure format specified by the board unless the board has
14 granted a waiver and approved an alternate secure format.

15 3. Information shall be timely transmitted as designated by
16 the board ~~and advisory council~~ by rule, unless the board grants
17 an extension. The board may grant an extension if either of
18 the following occurs:

19 a. The pharmacy or prescribing practitioner suffers
20 a mechanical or electronic failure, or cannot meet the
21 deadline established by the board for other reasons beyond the
22 pharmacy's or practitioner's control.

23 b. The board is unable to receive electronic submissions.

24 4. This section shall not apply to a ~~prescribing~~
25 ~~practitioner furnishing, dispensing, supplying, or~~
26 ~~administering drugs to the prescribing practitioner's patient,~~
27 ~~or to~~ dispensing by a licensed pharmacy for the purposes of
28 inpatient hospital care, inpatient hospice care, or long-term
29 residential facility patient care.

30 Sec. 4. Section 124.553, subsection 1, paragraph b, Code
31 2018, is amended to read as follows:

32 b. An individual who requests the individual's own program
33 information in accordance with the procedure established in
34 rules of the board ~~and advisory council~~ adopted under section
35 124.554.

1 Sec. 5. Section 124.553, subsection 1, Code 2018, is amended
2 by adding the following new paragraph:

3 NEW PARAGRAPH. *g.* A prescribing practitioner or pharmacist
4 through the use of a targeted distribution of proactive
5 notifications.

6 Sec. 6. Section 124.553, subsections 2, 3, and 7, Code 2018,
7 are amended to read as follows:

8 2. The board shall maintain a record of each person that
9 requests information from the program and of all proactive
10 notifications distributed to prescribing practitioners and
11 dispensing pharmacists as provided in subsection 1, paragraph
12 "g". Pursuant to rules adopted by the board ~~and advisory~~
13 ~~council~~ under section 124.554, the board may use the records
14 to document and report statistical information, and may
15 provide program information for statistical, public research,
16 public policy, or educational purposes, after removing
17 personal identifying information of a patient, prescribing
18 practitioner, dispenser, or other person who is identified in
19 the information.

20 3. Information contained in the program and any information
21 obtained from it, and information contained in the records
22 of requests for information from the program and information
23 distributed to prescribing practitioners and dispensing
24 pharmacists as provided in subsection 1, paragraph "g",
25 is privileged and strictly confidential information. Such
26 information is a confidential public record pursuant to section
27 22.7, and is not subject to discovery, subpoena, or other
28 means of legal compulsion for release except as provided in
29 this subchapter. Information from the program shall not be
30 released, shared with an agency or institution, or made public
31 except as provided in this subchapter.

32 7. ~~The~~ Except as allowed in section 124.557, the
33 board shall not charge a fee to a pharmacy, pharmacist, or
34 prescribing practitioner for the establishment, maintenance,
35 or administration of the program, including costs for forms

1 required to submit information to or access information from
2 the program, ~~except that the~~. The board may charge a fee
3 to an individual who requests the individual's own program
4 information. A fee charged to an individual pursuant to this
5 subsection shall not exceed the actual cost of providing the
6 requested information and shall be considered a repayment
7 receipt as defined in section 8.2.

8 Sec. 7. Section 124.554, Code 2018, is amended to read as
9 follows:

10 **124.554 Rules and reporting.**

11 1. The board ~~and advisory council~~, in consultation with the
12 advisory committee, shall ~~jointly~~ adopt rules in accordance
13 with chapter 17A to carry out the purposes of, and to enforce
14 the provisions of, this subchapter. The rules shall include
15 but not be limited to the development of procedures relating
16 to:

17 *a.* Identifying each patient about whom information is
18 entered into the program.

19 *b.* An electronic format for the submission of information
20 from pharmacies and prescribing practitioners.

21 *c.* A waiver to submit information in another format for
22 a pharmacy or prescribing practitioner unable to submit
23 information electronically.

24 *d.* An application by a pharmacy or prescribing practitioner
25 for an extension of time for transmitting information to the
26 program.

27 *e.* The submission by an authorized requestor of a request
28 for information and a procedure for the verification of the
29 identity of the requestor.

30 *f.* Use by the board or advisory ~~council~~ committee of the
31 program request records required by section 124.553, subsection
32 2, to document and report statistical information.

33 *g.* Including all schedule II, schedule III, schedule IV,
34 ~~controlled substances and those substances in schedules III~~
35 ~~and IV that the advisory council and board determine can be~~

1 ~~addictive or fatal if not taken under the proper care and~~
2 ~~direction of a prescribing practitioner~~ schedule V controlled
3 substances except when dispensed by a pharmacist without a
4 prescription.

5 *h.* Access by a pharmacist or prescribing practitioner to
6 information in the program ~~pursuant to a written agreement with~~
7 ~~the board and advisory council.~~

8 *i.* The correction or deletion of erroneous information in
9 the program.

10 *j.* The establishment of thresholds or other criteria or
11 measures to be used in identifying an at-risk patient as
12 provided in section 124.553, subsection 1, paragraph "g", and
13 the targeted distribution of proactive notifications suggesting
14 review of the patient's prescription history.

15 *k.* User registration processes and requirements.

16 2. Beginning January ~~1, 2007~~ 15, 2019, and annually by
17 January ~~1~~ 15 thereafter, the board and advisory ~~council~~
18 committee shall present to the general assembly and the
19 governor a report prepared consistent with section 124.555,
20 subsection 3, paragraph "d", which shall include but not be
21 limited to the following:

22 *a.* The cost to the state of implementing and maintaining the
23 program.

24 *b.* Information from pharmacies, prescribing practitioners,
25 the board, the advisory ~~council~~ committee, and others regarding
26 the benefits or detriments of the program.

27 *c.* Information from pharmacies, prescribing practitioners,
28 the board, the advisory ~~council~~ committee, and others regarding
29 the board's effectiveness in providing information from the
30 program.

31 Sec. 8. Section 124.555, Code 2018, is amended to read as
32 follows:

33 **124.555 Advisory ~~council~~ committee established.**

34 An advisory ~~council~~ committee shall be established to
35 provide oversight to the board and the program and to comanage

1 program activities. The board ~~and~~, in consultation with
2 the advisory ~~council~~ committee, shall ~~jointly~~ adopt rules
3 specifying the duties and activities of the advisory ~~council~~
4 committee and related matters.

5 1. The ~~council~~ committee shall consist of ~~eight~~ a minimum
6 of four members appointed by the ~~governor~~ board. The members
7 shall include but not be limited to at least one member from
8 each of the following categories: ~~three~~ licensed pharmacists,
9 ~~four~~ physicians licensed under chapter 148, ~~and one~~ licensed
10 prescribing ~~practitioner~~ practitioners who ~~is~~ are not a
11 ~~physician~~ physicians, and public members who are not health
12 care professionals. The ~~governor shall~~ board may solicit
13 recommendations for ~~council~~ committee members from Iowa health
14 professional licensing boards, associations, ~~and~~ societies,
15 and other interested groups. The license of each health care
16 professional member appointed to and serving on the advisory
17 ~~council~~ committee shall be current and in good standing with
18 the professional's licensing board.

19 2. The ~~council~~ committee shall advance the goals of the
20 program, which include identification of misuse and diversion
21 of controlled substances identified pursuant to section
22 124.554, subsection 1, paragraph "g", reduction of overdoses
23 and deaths as a result of prescription controlled substance
24 use and abuse, and enhancement of the quality of health care
25 delivery in this state.

26 3. Duties of the ~~council~~ committee shall include but not be
27 limited to the following:

28 a. Ensuring the confidentiality of the patient, prescribing
29 practitioner, and dispensing pharmacist and pharmacy.

30 b. Respecting and preserving the integrity of the patient's
31 treatment relationship with the patient's health care
32 providers.

33 c. Encouraging and facilitating cooperative efforts
34 among health care practitioners and other interested and
35 knowledgeable persons in developing best practices for

1 prescribing and dispensing controlled substances and in
2 educating health care practitioners and patients regarding
3 controlled substance use and abuse.

4 *d.* Making recommendations regarding the continued benefits
5 of maintaining the program in relationship to cost and other
6 burdens to the patient, prescribing practitioner, pharmacist,
7 and the board. The ~~council's~~ committee's recommendations shall
8 be included in reports required by section 124.554, subsection
9 2.

10 ~~*e.* One physician and one pharmacist member of the council~~
11 ~~shall include in their duties the responsibility for monitoring~~
12 ~~and ensuring that patient confidentiality, best interests, and~~
13 ~~civil liberties are at all times protected and preserved during~~
14 ~~the existence of the program.~~

15 4. Members of the advisory ~~council~~ committee shall
16 be eligible to request and receive actual expenses for
17 their duties as members of the advisory ~~council~~ committee,
18 subject to reimbursement limits imposed by the department of
19 administrative services, and shall also be eligible to receive
20 a per diem compensation as provided in section 7E.6, subsection
21 1.

22 Sec. 9. Section 124.556, Code 2018, is amended to read as
23 follows:

24 **124.556 Education and treatment.**

25 The program for drug prescribing and dispensing shall
26 include education initiatives and outreach to consumers,
27 prescribing practitioners, and pharmacists, and shall also
28 include assistance for identifying substance abuse treatment
29 programs and providers. The board and advisory ~~council~~
30 committee shall adopt rules, as provided under section 124.554,
31 to implement this section.

32 Sec. 10. Section 124.557, Code 2018, is amended to read as
33 follows:

34 **124.557 Drug information program fund.**

35 The drug information program fund is established to be used

1 by the board to fund or assist in funding the program. The
2 board may make deposits into the fund from any source, public
3 or private, including grants or contributions of money or other
4 items of value, which it determines necessary to carry out the
5 purposes of this subchapter. The board may add a surcharge
6 of not more than twenty-five percent to the applicable fee
7 for a registration issued pursuant to section 124.302 and the
8 surcharge shall be deposited into the fund. Moneys received
9 by the board to establish and maintain the program must
10 be used for the expenses of administering this subchapter.
11 Notwithstanding section 8.33, amounts contained in the fund
12 that remain unencumbered or unobligated at the close of the
13 fiscal year shall not revert but shall remain available for
14 expenditure for the purposes designated in future years.

15 Sec. 11. Section 124.558, subsection 1, Code 2018, is
16 amended to read as follows:

17 1. *Failure to comply with requirements.* A pharmacist,
18 pharmacy, prescribing practitioner, or agent of a pharmacist
19 or prescribing practitioner who knowingly fails to comply
20 with the confidentiality requirements of this subchapter
21 or who delegates program information access to another
22 individual except as provided in section 124.553, is subject to
23 disciplinary action by the appropriate professional licensing
24 board. A pharmacist, ~~or~~ pharmacy, or prescribing practitioner
25 that knowingly fails to comply with other requirements of this
26 subchapter is subject to disciplinary action by the board.
27 Each licensing board may adopt rules in accordance with chapter
28 17A to implement the provisions of this section.

29 Sec. 12. TRANSITION — APPOINTMENT AND TERMS OF ADVISORY
30 COMMITTEE MEMBERS. This Act's amendments changing the name of
31 the "advisory council" to the "advisory committee" shall not
32 affect the appointment of a member who served on the advisory
33 council immediately prior to the effective date of this Act.
34 That member shall continue to serve on the advisory committee
35 at the pleasure of the governor.

1 Sec. 13. TRANSITION — ADMINISTRATIVE RULES AND OTHER
2 ACTIONS AND DOCUMENTS. Any rule, form, order, or directive
3 promulgated by the advisory council created in section 124.550,
4 in force and effect immediately prior to the effective date of
5 this Act, shall continue in full force and effect until the
6 earlier of the following:

- 7 1. It is amended, rescinded, or supplemented by the
8 affirmative actions of the board of pharmacy.
9 2. It expires by its own terms.

10 EXPLANATION

11 The inclusion of this explanation does not constitute agreement with
12 the explanation's substance by the members of the general assembly.

13 This bill alters the Iowa prescription monitoring program
14 (PMP) by establishing an advisory committee, authorizing a
15 registration surcharge, expanding information collection and
16 reporting requirements, and making penalties applicable to
17 dispensing practitioners.

18 The bill adds dispensing prescribers to the list of persons
19 required to report to the PMP the dispensation of reportable
20 controlled substances to patients in Iowa, subject to the
21 same exceptions provided to pharmacies, unless otherwise
22 prohibited by state or federal law. The bill also eliminates
23 the PMP advisory council and creates an advisory committee to
24 assume the duties of the advisory council, with members to be
25 appointed from among health care professionals and the general
26 public by the board in numbers to be determined by the board,
27 provided the committee consists of at least four members.
28 The bill provides that members of the advisory council shall
29 continue to serve on the advisory committee and that any
30 rule, form, order, or directive promulgated by the advisory
31 council shall continue to be in force and effect until they are
32 amended, rescinded, or supplemented by the board of pharmacy
33 or expire by their own terms.

34 The bill also allows the board, in consultation with
35 the PMP advisory committee, to establish criteria for the

1 identification of patients who are potentially misusing or
2 abusing prescription controlled substances and authorizes the
3 board to proactively notify the pharmacists and prescribing
4 practitioner involved in the patient's care of its concerns.

5 The bill authorizes the collection of dispensing records for
6 all schedule II, III, IV, and V controlled substances except
7 when the schedule V controlled substance is dispensed by a
8 pharmacist without a prescription. The bill also authorizes,
9 but does not require, the board to impose a surcharge to
10 be deposited into the drug information program fund on
11 controlled substances Act registrations, which any person who
12 manufactures, distributes, or dispenses a controlled substance
13 must obtain and maintain, to be used for the expenses of
14 administering the PMP.

15 The bill adds to the goals of the program the reduction of
16 overdoses and deaths as a result of prescription controlled
17 substance use and abuse. The bill also changes the due
18 date for annual reports to the governor and the legislature
19 regarding the program from January 1 to January 15.

20 The bill makes prescribing practitioners subject to
21 disciplinary action by the board under Code section 124.558 for
22 failure to comply with the reporting requirement.