

State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-NINTH SESSION

H. F. No. 1652

03/09/2015 Authored by Baker and Clark
The bill was read for the first time and referred to the Committee on Health and Human Services Reform

03/18/2015 Adoption of Report: Amended and re-referred to the Committee on Civil Law and Data Practices

03/23/2015 Adoption of Report: Amended and re-referred to the Committee on Health and Human Services Reform

04/01/2016 Adoption of Report: Amended and re-referred to the Committee on Civil Law and Data Practices

04/11/2016 Adoption of Report: Placed on the General Register as Amended
Read Second Time

1.1 A bill for an act
1.2 relating to health; making changes to the Minnesota prescription monitoring
1.3 program; amending Minnesota Statutes 2014, section 152.126, subdivisions 1, 3,
1.4 5, 6; repealing Laws 2014, chapter 286, article 7, section 4.

1.5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.6 Section 1. Minnesota Statutes 2014, section 152.126, subdivision 1, is amended to read:

1.7 Subdivision 1. **Definitions.** (a) For purposes of this section, the terms defined in
1.8 this subdivision have the meanings given.

1.9 (b) "Board" means the Minnesota State Board of Pharmacy established under
1.10 chapter 151.

1.11 (c) "Controlled substances" means those substances listed in section 152.02,
1.12 subdivisions 3 to 6, and those substances defined by the board pursuant to section 152.02,
1.13 subdivisions 7, 8, and 12. For the purposes of this section, controlled substances includes
1.14 ~~tramadol~~ and butalbital and gabapentin.

1.15 (d) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision
1.16 30. Dispensing does not include the direct administering of a controlled substance to a
1.17 patient by a licensed health care professional.

1.18 (e) "Dispenser" means a person authorized by law to dispense a controlled substance,
1.19 pursuant to a valid prescription. For the purposes of this section, a dispenser does not
1.20 include a licensed hospital pharmacy that distributes controlled substances for inpatient
1.21 hospital care or a veterinarian who is dispensing prescriptions under section 156.18.

1.22 (f) "Prescriber" means a licensed health care professional who is authorized to
1.23 prescribe a controlled substance under section 152.12, subdivision 1 or 2.

1.24 (g) "Prescription" has the meaning given in section 151.01, subdivision ~~46~~ 16a.

2.1 Sec. 2. Minnesota Statutes 2014, section 152.126, subdivision 3, is amended to read:

2.2 Subd. 3. **Prescription Monitoring Program Advisory Task Force.** (a) The board
2.3 shall appoint an advisory task force consisting of at least one representative of:

2.4 (1) the Department of Health;

2.5 (2) the Department of Human Services;

2.6 (3) each health-related licensing board that licenses prescribers;

2.7 (4) a professional medical association, which may include an association of pain
2.8 management and chemical dependency specialists;

2.9 (5) a professional pharmacy association;

2.10 (6) a professional nursing association;

2.11 (7) a professional dental association;

2.12 (8) a consumer privacy or security advocate;

2.13 (9) a consumer or patient rights organization; and

2.14 (10) an association of medical examiners and coroners.

2.15 (b) The advisory task force shall advise the board on the development and operation
2.16 of the prescription monitoring program, including, but not limited to:

2.17 (1) technical standards for electronic prescription drug reporting;

2.18 (2) proper analysis and interpretation of prescription monitoring data;

2.19 (3) an evaluation process for the program; and

2.20 (4) criteria for the unsolicited provision of prescription monitoring data by the
2.21 board to prescribers and dispensers.

2.22 (c) The task force is governed by section 15.059. Notwithstanding any other
2.23 provisions of law to the contrary, the task force shall not expire.

2.24 Sec. 3. Minnesota Statutes 2014, section 152.126, subdivision 5, is amended to read:

2.25 Subd. 5. **Use of data by board.** (a) The board shall develop and maintain a database
2.26 of the data reported under subdivision 4. The board shall maintain data that could identify
2.27 an individual prescriber or dispenser in encrypted form. Except as otherwise allowed
2.28 under subdivision 6, the database may be used by permissible users identified under
2.29 subdivision 6 for the identification of:

2.30 (1) individuals receiving prescriptions for controlled substances from prescribers
2.31 who subsequently obtain controlled substances from dispensers in quantities or with a
2.32 frequency inconsistent with generally recognized standards of use for those controlled
2.33 substances, including standards accepted by national and international pain management
2.34 associations; and

3.1 (2) individuals presenting forged or otherwise false or altered prescriptions for
3.2 controlled substances to dispensers.

3.3 (b) No permissible user identified under subdivision 6 may access the database
3.4 for the sole purpose of identifying prescribers of controlled substances for unusual or
3.5 excessive prescribing patterns without a valid search warrant or court order.

3.6 (c) No personnel of a state or federal occupational licensing board or agency may
3.7 access the database for the purpose of obtaining information to be used to initiate or
3.8 substantiate a disciplinary action against a prescriber.

3.9 (d) Data reported under subdivision 4 shall be made available to permissible users for
3.10 a 12-month period beginning the day the data was received and ending 12 months from the
3.11 last day of the month in which the data was received, except that permissible users defined
3.12 in subdivision 6, paragraph (b), clauses (6) and (7), may use all data collected under this
3.13 section for the purposes of administering, operating, and maintaining the prescription
3.14 monitoring program and conducting trend analyses and other studies necessary to evaluate
3.15 the effectiveness of the program. Data retained beyond 24 months must be de-identified.

3.16 (e) The board shall not retain data reported under subdivision 4 for a period longer
3.17 than four years from the date the data was received.

3.18 Sec. 4. Minnesota Statutes 2014, section 152.126, subdivision 6, is amended to read:

3.19 Subd. 6. **Access to reporting system data.** (a) Except as indicated in this
3.20 subdivision, the data submitted to the board under subdivision 4 is private data on
3.21 individuals as defined in section 13.02, subdivision 12, and not subject to public disclosure.

3.22 (b) Except as specified in subdivision 5, the following persons shall be considered
3.23 permissible users and may access the data submitted under subdivision 4 in the same or
3.24 similar manner, and for the same or similar purposes, as those persons who are authorized
3.25 to access similar private data on individuals under federal and state law:

3.26 (1) a prescriber or an agent or employee of the prescriber to whom the prescriber has
3.27 delegated the task of accessing the data, to the extent the information relates specifically to
3.28 a current patient, to whom the prescriber is:

3.29 (i) prescribing or considering prescribing any controlled substance;

3.30 (ii) providing emergency medical treatment for which access to the data may be
3.31 necessary; or

3.32 (iii) providing other medical treatment for which access to the data may be necessary
3.33 and the patient has consented to access to the submitted data, and with the provision that
3.34 the prescriber remains responsible for the use or misuse of data accessed by a delegated
3.35 agent or employee;

4.1 (2) a dispenser or an agent or employee of the dispenser to whom the dispenser has
4.2 delegated the task of accessing the data, to the extent the information relates specifically
4.3 to a current patient to whom that dispenser is dispensing or considering dispensing any
4.4 controlled substance and with the provision that the dispenser remains responsible for the
4.5 use or misuse of data accessed by a delegated agent or employee;

4.6 (3) a licensed pharmacist who is providing pharmaceutical care for which access
4.7 to the data may be necessary to the extent that the information relates specifically to a
4.8 current patient for whom the pharmacist is providing pharmaceutical care if the patient
4.9 has consented to access to the submitted data or when consulted by a prescriber who is
4.10 requesting data in accordance with clause (1);

4.11 (4) an individual who is the recipient of a controlled substance prescription for
4.12 which data was submitted under subdivision 4, or a guardian of the individual, parent or
4.13 guardian of a minor, or health care agent of the individual acting under a health care
4.14 directive under chapter 145C;

4.15 (5) personnel or designees of the a health-related licensing board specifically listed
4.16 in section 214.01, subdivision 2, or of the Emergency Medical Services Regulatory Board,
4.17 assigned to conduct a bona fide investigation of a complaint received by that board that
4.18 alleges that a specific licensee is impaired by use of a drug for which data is collected
4.19 under subdivision 4, has engaged in activity that would constitute a crime as defined in
4.20 section 152.025, or has engaged in the behavior specified in subdivision 5, paragraph (a);

4.21 (6) personnel of the board engaged in the collection, review, and analysis
4.22 of controlled substance prescription information as part of the assigned duties and
4.23 responsibilities under this section;

4.24 (7) authorized personnel of a vendor under contract with the state of Minnesota who
4.25 are engaged in the design, implementation, operation, and maintenance of the prescription
4.26 monitoring program as part of the assigned duties and responsibilities of their employment,
4.27 provided that access to data is limited to the minimum amount necessary to carry out such
4.28 duties and responsibilities, and subject to the requirement of de-identification and time
4.29 limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

4.30 (8) federal, state, and local law enforcement authorities acting pursuant to a valid
4.31 search warrant;

4.32 (9) personnel of the Minnesota health care programs assigned to use the data
4.33 collected under this section to identify and manage recipients whose usage of controlled
4.34 substances may warrant restriction to a single primary care provider, a single outpatient
4.35 pharmacy, and a single hospital;

5.1 (10) personnel of the Department of Human Services assigned to access the data
5.2 pursuant to paragraph ~~(h)~~ (i); and

5.3 (11) personnel of the health professionals services program established under section
5.4 214.31, to the extent that the information relates specifically to an individual who is
5.5 currently enrolled in and being monitored by the program, and the individual consents to
5.6 access to that information. The health professionals services program personnel shall not
5.7 provide this data to a health-related licensing board or the Emergency Medical Services
5.8 Regulatory Board, except as permitted under section 214.33, subdivision 3.

5.9 For purposes of clause (4), access by an individual includes persons in the definition
5.10 of an individual under section 13.02; and

5.11 (12) personnel or designees of a health-related licensing board listed in section
5.12 214.01, subdivision 2, assigned to conduct a bona fide investigation of a complaint
5.13 received by that board that alleges that a specific licensee is inappropriately prescribing
5.14 controlled substances as defined in this section.

5.15 (c) By July 1, 2017, every prescriber licensed by a health-related licensing board
5.16 listed in section 214.01, subdivision 2, practicing within this state who is authorized to
5.17 prescribe controlled substances for humans and who holds a current registration issued
5.18 by the federal Drug Enforcement Administration, and every pharmacist licensed by the
5.19 board and practicing within the state, shall register and maintain a user account with the
5.20 prescription monitoring program. Data submitted by a prescriber, pharmacist, or their
5.21 delegate during the registration application process, other than their name, license number,
5.22 and license type, is classified as private pursuant to section 13.02, subdivision 12.

5.23 ~~(e) A permissible user~~ (d) Only permissible users identified in paragraph (b), clauses
5.24 (1), (2), (3), (6), (7), (9), and (10), may directly access the data electronically. No other
5.25 permissible user may directly access the data electronically. If the data is directly accessed
5.26 electronically, the permissible user shall implement and maintain a comprehensive
5.27 information security program that contains administrative, technical, and physical
5.28 safeguards that are appropriate to the user's size and complexity, and the sensitivity of the
5.29 personal information obtained. The permissible user shall identify reasonably foreseeable
5.30 internal and external risks to the security, confidentiality, and integrity of personal
5.31 information that could result in the unauthorized disclosure, misuse, or other compromise
5.32 of the information and assess the sufficiency of any safeguards in place to control the risks.

5.33 ~~(d)~~ (e) The board shall not release data submitted under subdivision 4 unless it
5.34 is provided with evidence, satisfactory to the board, that the person requesting the
5.35 information is entitled to receive the data.

6.1 ~~(e)~~ (f) The board shall maintain a log of all persons who access the data for a period
6.2 of at least three years and shall ensure that any permissible user complies with paragraph
6.3 ~~(e)~~ (d) prior to attaining direct access to the data.

6.4 ~~(f)~~ (g) Section 13.05, subdivision 6, shall apply to any contract the board enters into
6.5 pursuant to subdivision 2. A vendor shall not use data collected under this section for
6.6 any purpose not specified in this section.

6.7 ~~(g)~~ (h) The board may participate in an interstate prescription monitoring program
6.8 data exchange system provided that permissible users in other states have access to the
6.9 data only as allowed under this section, and that section 13.05, subdivision 6, applies
6.10 to any contract or memorandum of understanding that the board enters into under this
6.11 paragraph. ~~The board shall report to the chairs and ranking minority members of the senate
6.12 and house of representatives committees with jurisdiction over health and human services
6.13 policy and finance on the interstate prescription monitoring program by January 5, 2016.~~

6.14 ~~(h)~~ (i) With available appropriations, the commissioner of human services shall
6.15 establish and implement a system through which the Department of Human Services shall
6.16 routinely access the data for the purpose of determining whether any client enrolled in
6.17 an opioid treatment program licensed according to chapter 245A has been prescribed or
6.18 dispensed a controlled substance in addition to that administered or dispensed by the
6.19 opioid treatment program. When the commissioner determines there have been multiple
6.20 prescribers or multiple prescriptions of controlled substances, the commissioner shall:

6.21 (1) inform the medical director of the opioid treatment program only that the
6.22 commissioner determined the existence of multiple prescribers or multiple prescriptions of
6.23 controlled substances; and

6.24 (2) direct the medical director of the opioid treatment program to access the data
6.25 directly, review the effect of the multiple prescribers or multiple prescriptions, and
6.26 document the review.

6.27 If determined necessary, the commissioner of human services shall seek a federal waiver
6.28 of, or exception to, any applicable provision of Code of Federal Regulations, title 42,
6.29 section 2.34, paragraph (c), prior to implementing this paragraph.

6.30 ~~(i)~~ (j) The board shall review the data submitted under subdivision 4 on at least a
6.31 quarterly basis and shall establish criteria, in consultation with the advisory task force,
6.32 for referring information about a patient to prescribers and dispensers who prescribed or
6.33 dispensed the prescriptions in question if the criteria are met. ~~The board shall report
6.34 to the chairs and ranking minority members of the senate and house of representatives
6.35 committees with jurisdiction over health and human services policy and finance on the~~

7.1 ~~criteria established under this paragraph and the review process by January 5, 2016. This~~
7.2 ~~paragraph expires August 1, 2016.~~

7.3 Sec. 5. **REPEALER.**

7.4 Laws 2014, chapter 286, article 7, section 4, is repealed.

APPENDIX
Repealed Minnesota Session Laws: H1652-4

Laws 2014, chapter 286, article 7, section 4

Sec. 4. Minnesota Statutes 2012, section 152.126, subdivision 3, is amended to read:

Subd. 3. **Prescription Electronic Reporting Advisory Committee.** (a) The board shall convene an advisory committee. The committee must include at least one representative of:

- (1) the Department of Health;
- (2) the Department of Human Services;
- (3) each health-related licensing board that licenses prescribers;
- (4) a professional medical association, which may include an association of pain management and chemical dependency specialists;
- (5) a professional pharmacy association;
- (6) a professional nursing association;
- (7) a professional dental association;
- (8) a consumer privacy or security advocate; and
- (9) a consumer or patient rights organization.

(b) The advisory committee shall advise the board on the development and operation of the electronic reporting system, including, but not limited to:

- (1) technical standards for electronic prescription drug reporting;
- (2) proper analysis and interpretation of prescription monitoring data; and
- (3) an evaluation process for the program.

(c) The advisory committee expires June 30, 2018.

EFFECTIVE DATE. This section is effective the day following final enactment.