SENATE
STATE OF MINNESOTA
EIGHTY-EIGHTH LEGISLATURE

S.F. No. 1081

(SENATE AUTHORS: ROSEN)

DATE	D-PG	OFFICIAL STATUS
03/05/2013	574	Introduction and first reading Referred to Health, Human Services and Housing
03/21/2013	1398a	Comm report: To pass as amended and re-refer to Judiciary Joint rule 2.03, referred to Rules and Administration
04/10/2013	1736	Rules suspended Joint rule 2.03 Comm report: Adopt previous comm report
04/15/2013		Comm report: To pass as amended Second reading

A bill for an act

relating to health; changing licensing requirements for businesses regulated by the Board of Pharmacy; making changes to the prescription monitoring program; amending Minnesota Statutes 2012, sections 151.01, subdivision 27; 151.19, subdivisions 1, 3; 151.37, subdivision 4; 151.47, subdivision 1, by adding a subdivision; 151.49; 152.126; proposing coding for new law in Minnesota Statutes, chapter 151; repealing Minnesota Statutes 2012, sections 151.19, subdivision 2; 151.25; 151.45; 151.47, subdivision 2; 151.48.

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

Section 1. Minnesota Statutes 2012, section 151.01, subdivision 27, is amended to read:

Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:

(1) interpretation and evaluation of prescription drug orders;

(2) compounding, labeling, and dispensing drugs and devices (except labeling by a manufacturer or packager of nonprescription drugs or commercially packaged legend drugs and devices);

(3) participation in clinical interpretations and monitoring of drug therapy for assurance of safe and effective use of drugs;

(4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; drug regimen reviews; and drug or drug-related research;

(5) participation in administration of influenza vaccines to all eligible individuals ten years of age and older and all other vaccines to patients 18 years of age and older under standing orders from a physician licensed under chapter 147 or by written protocol with a physician licensed under chapter 147 provided that:

(i) the standing orders or protocol include, at a minimum, the name, dosage, and route of each vaccine that may be given, the patient population to whom the vaccine may be given, contraindications and precautions to the vaccine, the procedure for handling an

adverse reaction, the name and signature of the physician, the address of the physician, a phone number at which the physician can be contacted, and the date and time period for which the standing orders or protocol are valid;

~~(i)~~ (ii) the pharmacist ~~is trained in~~ has successfully completed a program approved by the ~~American~~ Accreditation Council ~~of Pharmaceutical~~ for Pharmacy Education, specifically for the administration of immunizations, or ~~graduated from a college of pharmacy in 2001 or thereafter; and~~ a program approved according to rules adopted by the board;

(iii) the pharmacist completes continuing education concerning the administration of immunizations, as required by Minnesota Rules;

(iv) the pharmacist has a current cardiopulmonary resuscitation certificate;

~~(ii)~~ (v) the pharmacist reports the administration of the immunization to the patient's primary physician or clinic or to the Minnesota Immunization Information Connection;

(vi) the pharmacist complies with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices (ACIP), except that a pharmacist does not need to comply with those guidelines if administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147 when the order is consistent with United States Food and Drug Administration approved labeling of the vaccine; and

(vii) the pharmacist complies with Centers for Disease Control and Prevention guidelines relating to immunization schedules, vaccine storage and handling, and vaccine administration and documentation;

(6) participation in the practice of managing drug therapy and modifying drug therapy~~, according to section 151.21, subdivision 1,~~ according to a written protocol between the specific pharmacist and the individual dentist, optometrist, physician, podiatrist, or veterinarian who is responsible for the patient's care and authorized to independently prescribe drugs. Any significant changes in drug therapy must be reported by the pharmacist to the patient's medical record;

(7) participation in the storage of drugs and the maintenance of records;

(8) ~~responsibility for participation in~~ patient counseling on therapeutic values, content, hazards, and uses of drugs and devices; and

(9) offering or performing those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a pharmacy.

Sec. 2. Minnesota Statutes 2012, section 151.19, subdivision 1, is amended to read:

Subdivision 1. **Pharmacy ~~registration~~ licensure requirements.** ~~The board shall require and provide for the annual registration of every pharmacy now or hereafter doing business within this state. Upon the payment of any applicable fee specified in section 151.065, the board shall issue a registration certificate in such form as it may prescribe to such persons as may be qualified by law to conduct a pharmacy. Such certificate shall be displayed in a conspicuous place in the pharmacy for which it is issued and expire on the 30th day of June following the date of issue. It shall be unlawful for any person to conduct a pharmacy unless such certificate has been issued to the person by the board.~~ (a) No person shall operate a pharmacy without first obtaining a license from the board and paying any applicable fee specified in section 151.065. The license shall be displayed in a conspicuous place in the pharmacy for which it is issued and expires on June 30 following the date of issue. It is unlawful for any person to operate a pharmacy unless the license has been issued to the person by the board.

(b) Application for a pharmacy license under this section shall be made in a manner specified by the board.

(c) No license shall be issued or renewed for a pharmacy located within the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal and state law and according to rules adopted by the board. No license shall be issued for a pharmacy located outside of the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal law and, when dispensing medications for residents of this state, the laws of this state and Minnesota Rules.

(d) No license shall be issued or renewed for a pharmacy that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of such licensure or registration.

(e) The board shall require a separate license for each pharmacy located within the state and for each pharmacy located outside of the state at which any portion of the dispensing process occurs for drugs dispensed to residents of this state.

(f) The board shall not issue an initial or renewed license for a pharmacy unless the pharmacy passes an inspection conducted by an authorized representative of the board. In the case of a pharmacy located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

(g) The board shall not issue an initial or renewed license for a pharmacy located outside of the state unless the applicant discloses and certifies:

(1) the location, names, and titles of all principal corporate officers and all pharmacists who are involved in dispensing drugs to residents of this state;

(2) that it maintains its records of drugs dispensed to residents of this state so that the records are readily retrievable from the records of other drugs dispensed;

(3) that it agrees to cooperate with, and provide information to, the board concerning matters related to dispensing drugs to residents of this state;

(4) that, during its regular hours of operation, but no less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records; the toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state; and

(5) that, upon request of a resident of a long-term care facility located in this state, the resident's authorized representative, or a contract pharmacy or licensed health care facility acting on behalf of the resident, the pharmacy will dispense medications prescribed for the resident in unit-dose packaging or, alternatively, comply with section 151.415, subdivision 5.

Sec. 3. Minnesota Statutes 2012, section 151.19, subdivision 3, is amended to read:

Subd. 3. **Sale of federally restricted medical gases.** ~~The board shall require and provide for the annual registration of every person or establishment not licensed as a pharmacy or a practitioner engaged in the retail sale or distribution of federally restricted medical gases. Upon the payment of any applicable fee specified in section 151.065, the board shall issue a registration certificate in such form as it may prescribe to those persons or places that may be qualified to sell or distribute federally restricted medical gases. The certificate shall be displayed in a conspicuous place in the business for which it is issued and expire on the date set by the board. It is unlawful for a person to sell or distribute federally restricted medical gases unless a certificate has been issued to that person by the board.~~ (a) A person or establishment not licensed as a pharmacy or a practitioner shall not engage in the retail sale or distribution of federally restricted medical gases without first obtaining a registration from the board and paying the applicable fee specified in section 151.065. The registration shall be displayed in a conspicuous place in the business for which it is issued and expires on the date set by the board. It is unlawful for a person to sell or distribute federally restricted medical gases unless a certificate has been issued to that person by the board.

(b) Application for a medical gas distributor registration under this section shall be made in a manner specified by the board.

(c) No registration shall be issued or renewed for a medical gas distributor located within the state unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board. No license shall be issued for a medical gas distributor located outside of the state unless the applicant agrees to operate in a manner prescribed by federal law and, when distributing medical gases for residents of this state, the laws of this state and Minnesota Rules.

(d) No registration shall be issued or renewed for a medical gas distributor that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of the licensure or registration. The board may, by rule, establish standards for the registration of a medical gas distributor that is not required to be licensed or registered by the state in which it is physically located.

(e) The board shall require a separate registration for each medical gas distributor located within the state and for each facility located outside of the state from which medical gases are distributed to residents of this state.

(f) The board shall not issue an initial or renewed registration for a medical gas distributor unless the medical gas distributor passes an inspection conducted by an authorized representative of the board. In the case of a medical gas distributor located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Sec. 4. **[151.252] LICENSING OF DRUG MANUFACTURERS; FEES; PROHIBITIONS.**

Subdivision 1. **Requirements.** (a) No person shall act as a manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) Application for a manufacturer license under this section shall be made in a manner specified by the board.

(c) No license shall be issued or renewed for a manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) No license shall be issued or renewed for a manufacturer that is required to be registered pursuant to United State Code, title 21, section 360, unless the applicant supplies the board with proof of registration. The board may establish by rule the standards for licensure of manufacturers that are not required to be registered under United States Code, title 21, section 360.

(e) No license shall be issued or renewed for a manufacturer that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a manufacturer that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each facility located within the state at which manufacturing occurs and for each facility located outside of the state at which drugs that are shipped into the state are manufactured.

(g) The board shall not issue an initial or renewed license for a manufacturing facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a manufacturing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Subd. 2. **Prohibition.** It is unlawful for any person engaged in manufacturing to sell legend drugs to anyone located in this state except as provided in this chapter.

Sec. 5. Minnesota Statutes 2012, section 151.37, subdivision 4, is amended to read:

Subd. 4. **Research.** (a) Any qualified person may use legend drugs in the course of a bona fide research project, but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so.

(b) Drugs may be dispensed or distributed by a pharmacy licensed by the board for use by, or administration to, patients enrolled in a bona fide research study that is being

conducted pursuant to either an investigational new drug application approved by the United States Food and Drug Administration or that has been approved by an institutional review board. For the purposes of this subdivision only:

(1) a prescription drug order is not required for a pharmacy to dispense a research drug, unless the study protocol requires the pharmacy to receive such an order;

(2) notwithstanding the prescription labeling requirements found in this chapter or the rules promulgated by the board, a research drug may be labeled as required by the study protocol; and

(3) dispensing and distribution of research drugs by pharmacies shall not be considered compounding, manufacturing, or wholesaling under this chapter.

(c) An entity that is under contract to a federal agency for the purpose of distributing drugs for bona fide research studies is exempt from the drug wholesaler licensing requirements of this chapter. Any other entity is exempt from the drug wholesaler licensing requirements of this chapter if the board finds that the entity is licensed or registered according to the laws of the state in which it is physically located and it is distributing drugs for use by, or administration to, patients enrolled in a bona fide research study that is being conducted pursuant to either an investigational new drug application approved by the United States Food and Drug Administration or that has been approved by an institutional review board.

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

Sec. 6. Minnesota Statutes 2012, section 151.47, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** (a) All wholesale drug distributors are subject to the requirements ~~in paragraphs (a) to (f)~~ of this subdivision.

~~(a)~~ (b) No person or distribution outlet shall act as a wholesale drug distributor without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(c) Application for a wholesale drug distributor license under this section shall be made in a manner specified by the board.

~~(b)~~ (d) No license shall be issued or renewed for a wholesale drug distributor to operate unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board.

~~(c) The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within the state, or for a parent entity with divisions, subsidiaries, or affiliate companies within the state, when operations~~

~~are conducted at more than one location and joint ownership and control exists among all the entities.~~

(e) No license may be issued or renewed for a drug wholesale distributor that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a drug wholesale distributor that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each drug wholesale distributor facility located within the state and for each drug wholesale distributor facility located outside of the state from which drugs are shipped into the state or to which drugs are reverse distributed.

(g) The board shall not issue an initial or renewed license for a drug wholesale distributor facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a drug wholesale distributor facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

~~(d)~~ (h) As a condition for receiving and retaining a wholesale drug distributor license issued under sections 151.42 to 151.51, an applicant shall satisfy the board that it has and will continuously maintain:

(1) adequate storage conditions and facilities;

(2) minimum liability and other insurance as may be required under any applicable federal or state law;

(3) a viable security system that includes an after hours central alarm, or comparable entry detection capability; restricted access to the premises; comprehensive employment applicant screening; and safeguards against all forms of employee theft;

(4) a system of records describing all wholesale drug distributor activities set forth in section 151.44 for at least the most recent two-year period, which shall be reasonably accessible as defined by board regulations in any inspection authorized by the board;

(5) principals and persons, including officers, directors, primary shareholders, and key management executives, who must at all times demonstrate and maintain their

capability of conducting business in conformity with sound financial practices as well as state and federal law;

(6) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed, including all pertinent corporate licensee information, if applicable, or other ownership, principal, key personnel, and facilities information found to be necessary by the board;

(7) written policies and procedures that assure reasonable wholesale drug distributor preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods, and product recalls;

(8) sufficient inspection procedures for all incoming and outgoing product shipments; and

(9) operations in compliance with all federal requirements applicable to wholesale drug distribution.

~~(e)~~ (i) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section.

~~(f) A wholesale drug distributor shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement or other compensation authorized under section 151.461, clauses (3) to (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling $100 or more, to a particular practitioner during the year, and shall identify the practitioner. Reports filed under this provision are public data.~~

Sec. 7. Minnesota Statutes 2012, section 151.47, is amended by adding a subdivision to read:

Subd. 3. **Prohibition.** It is unlawful for any person engaged in wholesale drug distribution to sell drugs to anyone located within the state or to receive drugs in reverse distribution from anyone located within the state except as provided in this chapter.

Sec. 8. Minnesota Statutes 2012, section 151.49, is amended to read:

151.49 LICENSE RENEWAL APPLICATION PROCEDURES.

Application blanks or notices for renewal of a license required by sections 151.42 to 151.51 shall be mailed or otherwise provided to each licensee on or before the first

day of the month prior to the month in which the license expires and, if application for renewal of the license with the required fee and supporting documents is not made before the expiration date, the existing license or renewal shall lapse and become null and void upon the date of expiration.

Sec. 9. Minnesota Statutes 2012, section 152.126, is amended to read:

152.126 ~~CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM~~ PRESCRIPTION MONITORING PROGRAM.

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

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

~~(b)~~ (c) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to ~~5~~ 6, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12. For the purpose of this section only, "controlled substances" includes tramadol and butalbital.

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

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

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

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

Subd. 1a. **Treatment of intractable pain.** This section is not intended to limit or interfere with the legitimate prescribing of controlled substances for pain. No prescriber shall be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance according to the provisions of section 152.125.

Subd. 2. **Prescription electronic reporting system.** (a) The board shall establish by January 1, 2010, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state.

(b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, operation, and maintenance of the electronic reporting system.

Subd. 3. **Prescription ~~Electronic Reporting~~ Monitoring Program 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; and

(10) an association of medical examiners and coroners.

(b) The advisory committee shall advise the board on the development and operation of the ~~electronic reporting system~~ prescription monitoring program, 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.

Subd. 4. **Reporting requirements; notice.** (a) Each dispenser must submit the following data to the board or its designated vendor~~, subject to the notice required under paragraph (d)~~:

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) prescription number;

(6) name of the patient for whom the prescription was written;

(7) address of the patient for whom the prescription was written;

(8) date of birth of the patient for whom the prescription was written;

(9) date the prescription was written;

(10) date the prescription was filled;

(11) name and strength of the controlled substance;

(12) quantity of controlled substance prescribed;

(13) quantity of controlled substance dispensed; and

(14) number of days supply.

(b) The dispenser must submit the required information by a procedure and in a format established by the board. The board may allow dispensers to omit data listed in this subdivision or may require the submission of data not listed in this subdivision provided the omission or submission is necessary for the purpose of complying with the electronic reporting or data transmission standards of the American Society for Automation in Pharmacy, the National Council on Prescription Drug Programs, or other relevant national standard-setting body.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for~~:~~

~~(1) individuals residing in licensed skilled nursing or intermediate care facilities;~~

~~(2) individuals receiving assisted living services under chapter 144G or through a medical assistance home and community-based waiver;~~

~~(3) individuals receiving medication intravenously;~~

~~(4) individuals receiving hospice and other palliative or end-of-life care; and~~

~~(5) individuals receiving services from a home care provider regulated under chapter 144A.~~ individuals residing in a health care facility as defined in section 151.58, subdivision 2, paragraph (b), when a drug is distributed through the use of an automated drug distribution system according to section 151.58.

(d) A dispenser must ~~not submit data under this subdivision unless~~ provide a conspicuous notice of the reporting requirements of this section ~~is given~~ to the patient for whom the prescription was written.

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

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

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

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

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

(d) Data reported under subdivision 4 shall be retained by the board in ~~the~~ an active database for a 12-month period, and shall be removed from the active database no later than 12 months from the last day of the month during which the data was received. The board may transfer data into an inactive database provided that the data thus transferred may only be used by the authorized staff of the board for the purposes of administering, operating, and maintaining the prescription monitoring program and conducting trend analyses and other studies as necessary to evaluate the effectiveness of the program. Data in the inactive database shall not be accessible to any other persons for any reason. No data that can be used to identify an individual may be transferred to the inactive database.

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

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

(1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is prescribing or considering prescribing any controlled substance or to whom the prescriber is providing other medical treatment for which access to the data may be necessary and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(2) a dispenser or an agent or employee of the dispenser to whom the dispenser has delegated the task of accessing the data, to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance or to whom the dispenser is providing other pharmaceutical care for which access to the data may be necessary and with the provision that the dispenser remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(3) a licensed pharmacist who is providing pharmaceutical care for which access to the data may be necessary or when consulted by a prescriber who is requesting data in accordance with clause (1);

~~(3)~~ (4) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4, or a guardian of the individual, parent or

guardian of a minor, or health care agent of the individual acting under a health care directive under chapter 145C;

~~(4)~~ (5) personnel of the board specifically assigned to conduct a bona fide investigation of a specific licensee;

~~(5)~~ (6) personnel of the board engaged in the collection of controlled substance prescription information as part of the assigned duties and responsibilities under this section;

~~(6)~~ (7) authorized personnel of a vendor under contract with the board who are engaged in the design, implementation, operation, and maintenance of the ~~electronic reporting system~~ prescription monitoring program as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities;

~~(7)~~ (8) federal, state, and local law enforcement authorities acting pursuant to a valid search warrant; ~~and~~

~~(8)~~ (9) personnel of the ~~medical assistance program~~ Minnesota health care programs assigned to use the data collected under this section to identify and manage recipients whose usage of controlled substances may warrant restriction to a single primary care ~~physician~~ provider, a single outpatient pharmacy, ~~or~~ and a single hospital;

(10) a coroner or medical examiner, or an agent or employee of the coroner or medical examiner to whom the coroner or medical examiner has delegated the task of accessing the data, conducting an investigation pursuant to section 390.11, and with the provision that the coroner or medical examiner remains responsible for the use or misuse of data accessed by a delegated agent or employee; and

(11) personnel of the health professionals services program established pursuant to section 214.31, to the extent that the information relates specifically to an individual who is currently enrolled in and being monitored by the program and provided that the information cannot be given to a health-related licensing board except as provided by section 214.33, subdivision 3.

For purposes of clause ~~(3)~~ (4), access by an individual includes persons in the definition of an individual under section 13.02.

(c) Any permissible user identified in paragraph (b), who directly accesses the data electronically, shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information

that could result in the unauthorized disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(d) The board shall not release data submitted under this section unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

(e) ~~The board shall not release the name of a prescriber without the written consent of the prescriber or a valid search warrant or court order. The board shall provide a mechanism for a prescriber to submit to the board a signed consent authorizing the release of the prescriber's name when data containing the prescriber's name is requested.~~

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

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

(g) The board may participate in an interstate prescription monitoring program data exchange system provided that permissible users in other states may have access to the data only as allowed under this section and that section 13.05, subdivision 6, shall apply to any contract or memorandum of understanding that the board enters into under this paragraph.

Subd. 7. **Disciplinary action.** (a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.

(b) A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of health care data shall be subject to disciplinary action by the appropriate health-related licensing board, and appropriate civil penalties.

~~Subd. 8. **Evaluation and reporting.** (a) The board shall evaluate the prescription electronic reporting system to determine if the system is negatively impacting appropriate prescribing practices of controlled substances. The board may contract with a vendor to design and conduct the evaluation.~~

~~(b) The board shall submit the evaluation of the system to the legislature by July 15, 2011.~~

Subd. 9. **Immunity from liability; no requirement to obtain information.** (a) A pharmacist, prescriber, or other dispenser making a report to the program in good faith under this section is immune from any civil, criminal, or administrative liability, which

might otherwise be incurred or imposed as a result of the report, or on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program.

(b) Nothing in this section shall require a pharmacist, prescriber, or other dispenser to obtain information about a patient from the program, and the pharmacist, prescriber, or other dispenser, if acting in good faith, is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting, receiving, or using information from the program.

Subd. 10. **Funding.** (a) The board may seek grants and private funds from nonprofit charitable foundations, the federal government, and other sources to fund the enhancement and ongoing operations of the prescription ~~electronic reporting system~~ monitoring program established under this section. Any funds received shall be appropriated to the board for this purpose. The board may not expend funds to enhance the program in a way that conflicts with this section without seeking approval from the legislature.

(b) Notwithstanding any other section, the administrative services unit for the health-related licensing boards shall apportion between the Board of Medical Practice, the Board of Nursing, the Board of Dentistry, the Board of Podiatric Medicine, the Board of Optometry, the Board of Veterinary Medicine, and the Board of Pharmacy an amount to be paid through fees by each respective board. The amount apportioned to each board shall equal each board's share of the annual appropriation to the Board of Pharmacy from the state government special revenue fund for operating the prescription ~~electronic reporting system~~ monitoring program under this section. Each board's apportioned share shall be based on the number of prescribers or dispensers that each board identified in this paragraph licenses as a percentage of the total number of prescribers and dispensers licensed collectively by these boards. Each respective board may adjust the fees that the boards are required to collect to compensate for the amount apportioned to each board by the administrative services unit.

Sec. 10. **REPEALER.**

Minnesota Statutes 2012, sections 151.19, subdivision 2; 151.25; 151.45; 151.47, subdivision 2; and 151.48, are repealed.

151.19 REGISTRATION; FEES.

Subd. 2. **Nonresident pharmacies.** The board shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of this state that regularly dispense medications for Minnesota residents and mail, ship, or deliver prescription medications into this state. Nonresident special pharmacy registration shall be granted by the board upon payment of any applicable fee specified in section 151.065 and the disclosure and certification by a pharmacy:

(1) that it is licensed in the state in which the dispensing facility is located and from which the drugs are dispensed;

(2) the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing drugs to residents of this state;

(3) that it complies with all lawful directions and requests for information from the Board of Pharmacy of all states in which it is licensed or registered, except that it shall respond directly to all communications from the board concerning emergency circumstances arising from the dispensing of drugs to residents of this state;

(4) that it maintains its records of drugs dispensed to residents of this state so that the records are readily retrievable from the records of other drugs dispensed;

(5) that it cooperates with the board in providing information to the Board of Pharmacy of the state in which it is licensed concerning matters related to the dispensing of drugs to residents of this state;

(6) that during its regular hours of operation, but not less than six days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records; the toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state; and

(7) that, upon request of a resident of a long-term care facility located within the state of Minnesota, the resident's authorized representative, or a contract pharmacy or licensed health care facility acting on behalf of the resident, the pharmacy will dispense medications prescribed for the resident in unit-dose packaging or, alternatively, comply with the provisions of section 151.415, subdivision 5.

151.25 REGISTRATION OF MANUFACTURERS; FEE; PROHIBITIONS.

The board shall require and provide for the annual registration of every person engaged in manufacturing drugs, medicines, chemicals, or poisons for medicinal purposes, now or hereafter doing business with accounts in this state. Upon a payment of any applicable fee specified in section 151.065, the board shall issue a registration certificate in such form as it may prescribe to such manufacturer. Such registration certificate shall be displayed in a conspicuous place in such manufacturer's or wholesaler's place of business for which it is issued and expire on the date set by the board. It shall be unlawful for any person to manufacture drugs, medicines, chemicals, or poisons for medicinal purposes unless such a certificate has been issued to the person by the board. It shall be unlawful for any person engaged in the manufacture of drugs, medicines, chemicals, or poisons for medicinal purposes, or the person's agent, to sell legend drugs to other than a pharmacy, except as provided in this chapter.

151.45 WHOLESALE DRUG DISTRIBUTOR ADVISORY TASK FORCE.

The board shall appoint a Wholesale Drug Distributor Advisory Task Force composed of five members, to be selected and to perform duties and responsibilities as follows:

(a) One member shall be a pharmacist who is neither a member of the board nor a board employee.

(b) Two members shall be representatives of wholesale drug distributors as defined in section 151.44, paragraph (b).

(c) One member shall be a representative of drug manufacturers.

(d) One member shall be a public member as defined by section 214.02.

(e) The advisory task force shall review and make recommendations to the board on the merit of all rules dealing with wholesale drug distributors and drug manufacturers that are proposed by the board; and no rule affecting wholesale drug distributors proposed by the board shall be adopted without first being submitted to the task force for review and comment.

(f) In making advisory task force appointments, the board shall consider recommendations received from each of the wholesale drug distributor, pharmacist, and drug manufacturer

classes cited in paragraphs (a) to (c), and shall adopt rules that provide for solicitation of the recommendations.

151.47 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS.

Subd. 2. **Requirements must conform with federal law.** All requirements set forth in this section shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration; and in case of conflict between a wholesale drug distributor licensing requirement imposed by the board and a Food and Drug Administration wholesale drug distributor guideline, the latter shall control.

151.48 OUT-OF-STATE WHOLESALE DRUG DISTRIBUTOR LICENSING.

(a) It is unlawful for an out-of-state wholesale drug distributor to conduct business in the state without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) Application for an out-of-state wholesale drug distributor license under this section shall be made on a form furnished by the board.

(c) No person acting as principal or agent for any out-of-state wholesale drug distributor may sell or distribute drugs in the state unless the distributor has obtained a license.

(d) The board may adopt regulations that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity to the extent that an out-of-state wholesale drug distributor:

(1) possesses a valid license granted by another state under legal standards comparable to those that must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(2) can show that the other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.