CHAPTER 321–S.F.No. 2941

An act relating to health; regulating free or discounted chiropractic examinations or treatments; changing provisions for prescribing and filing drugs; amending Minnesota Statutes 2006, sections 148.10, by adding a subdivision; 151.01, subdivision 23; 151.37, subdivision 7; Minnesota Statutes 2007 Supplement, sections 148.235, subdivision 11; 151.37, subdivision 2; 151.56; 152.126; repealing Minnesota Statutes 2007 Supplement, section 148.235, subdivision 12.

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

Section 1. Minnesota Statutes 2006, section 148.10, is amended by adding a subdivision to read:

Subd. 1a. **Free or discounted examination or treatment.** (a) Free or discounted examinations must provide sufficient information to allow for a diagnosis and initiation of treatment, with the exception of examinations clearly identified as for the purpose of screening. Free or discounted chiropractic treatments shall be comparable to similar nondiscounted chiropractic treatments.

(b) When using the word "free," or any other term with essentially the same meaning in reference to delivering any service, examination, or treatment, the following statement must be presented to the patient or guardian for signature and kept on file: "I understand that one or more services provided have been or will be free of charge. Any subsequent services provided will be provided at the fees that have been or will be explained to me."

Sec. 2. Minnesota Statutes 2007 Supplement, section 148.235, subdivision 11, is amended to read:

Subd. 11. **Dispensing by protocol.** Subject to the requirements of this subdivision, a registered nurse in a family planning agency as defined in Minnesota Rules, part 9505.0280, subpart 3, may dispense ~~oral~~ contraceptives prescribed by a licensed practitioner as defined in section 151.01, subdivision 23, pursuant to a dispensing protocol established by the agency's medical director or under the direction of a physician. The dispensing protocol must address the requirements of sections 151.01, subdivision 30, and 151.212, subdivision 1. In addition, the registered nurse may not dispense ~~oral~~ contraceptives if the patient is under 12 years of age.

Sec. 3. Minnesota Statutes 2006, section 151.01, subdivision 23, is amended to read:

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathy duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, or licensed veterinarian. For purposes of sections 151.15, subdivision 4, 151.37, subdivision 2, ~~paragraph~~ paragraphs (b), (e), and (f), and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A, or an advanced practice nurse authorized to prescribe, dispense, and administer under section 148.235.

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

Sec. 4. Minnesota Statutes 2007 Supplement, section 151.37, subdivision 2, is amended to read:

Subd. 2. **Prescribing and filing.** (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner's direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9, physician assistant, or medical student or resident to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18.

(b) A licensed practitioner that dispenses for profit a legend drug that is to be administered orally, is ordinarily dispensed by a pharmacist, and is not a vaccine, must file with the practitioner's licensing board a statement indicating that the practitioner dispenses legend drugs for profit, the general circumstances under which the practitioner dispenses for profit, and the types of legend drugs generally dispensed. It is unlawful to dispense legend drugs for profit after July 31, 1990, unless the statement has been filed with the appropriate licensing board. For purposes of this paragraph, "profit" means (1) any amount received by the practitioner in excess of the acquisition cost of a legend drug for legend drugs that are purchased in prepackaged form, or (2) any amount received by the practitioner in excess of the acquisition cost of a legend drug plus the cost of making the drug available if the legend drug requires compounding, packaging, or other treatment. The statement filed under this paragraph is public data under section 13.03. This paragraph does not apply to a licensed doctor of veterinary medicine or a registered pharmacist. Any person other than a licensed practitioner with the authority to prescribe, dispense, and administer a legend drug under paragraph (a) shall not dispense for profit. To dispense for profit does not include dispensing by a community health clinic when the profit from dispensing is used to meet operating expenses.

(c) A prescription or drug order for ~~a legend drug~~ the following drugs is not valid ~~if it is based solely on an online questionnaire~~, unless it can be established that the prescription or order was based on a documented patient evaluation, including an examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment:

(1) controlled substance drugs listed in section 152.02, subdivisions 3 to 5;

(2) drugs defined by the Board of Pharmacy as controlled substances under section 152.02, subdivisions 7, 8, and 12;

(3) muscle relaxants;

(4) centrally acting analgesics with opioid activity;

(5) drugs containing butalbital; or

(6) phoshodiesterase type 5 inhibitors when used to treat erectile dysfunction.

(d) For the purposes of paragraph (c), the requirement for an examination shall be met if an in-person examination has been completed in any of the following circumstances:

(1) the prescribing practitioner examines the patient at the time the prescription or drug order is issued;

(2) the prescribing practitioner has performed a prior examination of the patient;

(3) another prescribing practitioner practicing within the same group or clinic as the prescribing practitioner has examined the patient;

(4) a consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient; or

(5) the referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.

(e) Nothing in paragraph (c) or (d) prohibits a licensed practitioner from prescribing a drug through the use of a guideline or protocol pursuant to paragraph (a) of this subdivision.

(f) Nothing in this chapter prohibits a licensed practitioner from issuing a prescription or dispensing a legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases guidance document issued by the United States Centers for Disease Control.

(g) Nothing in paragraph (c) or (d) limits prescription, administration, or dispensing of legend drugs through a public health clinic or other distribution mechanism approved by the commissioner of health or a board of health in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, intentional, or accidental release of a biological, chemical, or radiological agent.

(h) No pharmacist employed by, under contract to, or working for a pharmacy licensed under section 151.19, subdivision 1, may dispense a legend drug based on a prescription that the pharmacist knows, or would reasonably be expected to know, is not valid under paragraph (c) of this subdivision.

(i) No pharmacist employed by, under contract to, or working for a pharmacy licensed under section 151.19, subdivision 2, may dispense a legend drug, to a resident of this state, based on a prescription that the pharmacist knows, or would reasonably be expected to know, is not valid under paragraph (c) of this subdivision.

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

Sec. 5. Minnesota Statutes 2006, section 151.37, subdivision 7, is amended to read:

Subd. 7. **Exclusion for prescriptions.** Nothing in this chapter shall prohibit the possession of a legend drug by a person for that person's use when it has been dispensed to the person in accordance with a written or oral prescription by a practitioner. Nothing in this chapter shall prohibit a person, for whom a legend drug has been dispensed in

accordance with a written or oral prescription by a practitioner, from designating a family member, caregiver, or other individual to handle the legend drug for the purpose of assisting the person in obtaining or administering the drug.

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

Sec. 6. Minnesota Statutes 2007 Supplement, section 151.56, is amended to read:

151.56 COUNTY RETURN OF UNUSED DRUGS OR MEDICAL DEVICES.

Notwithstanding Minnesota Rules, part 6800.2700, pharmacies may accept returns of ~~unused drugs~~ and redispense unopened, unused drugs in board-approved unit dose packaging and medical devices from county jails and juvenile correctional facilities. In order to return unused drugs and medical devices, the county jail or juvenile correctional facility must have a ~~trained medication technician~~ correctional employee trained in the delivery and storage of medications on hand 24 hours a day, seven days a week, and the medication must be stored in a secured locked storage locker.

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

Sec. 7. Minnesota Statutes 2007 Supplement, section 152.126, is amended to read:

152.126 SCHEDULE II AND III CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM.

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

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

(b) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 and 4, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12.

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

(f) "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, ~~2009~~ 2010, an electronic system for reporting the information required under

subdivision 4 for all controlled substances dispensed within the state. ~~Data for controlled substance prescriptions that are dispensed in a quantity small enough to provide treatment to a patient for a period of 48 hours or less need not be reported.~~

(b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, and maintenance of the electronic reporting system. The vendor's role shall be limited to providing technical support to the board concerning the software, databases, and computer systems required to interface with the existing systems currently used by pharmacies to dispense prescriptions and transmit prescription data to other third parties.

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

~~(7)~~ (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 Board of Pharmacy, after consultation with the advisory committee, shall present recommendations and draft legislation on the issues addressed by the advisory committee under paragraph (b), to the legislature by December 15, 2007.

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;

~~(6)~~ (8) date of birth of the patient for whom the prescription was written;

~~(7)~~ (9) date the prescription was written;

~~(8)~~ (10) date the prescription was filled;

~~(9)~~ (11) name and strength of the controlled substance;

~~(10)~~ (12) quantity of controlled substance prescribed; ~~and~~

~~(11)~~ (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.

(d) A dispenser must not submit data under this subdivision unless 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 ~~of dosage for those controlled substances~~; 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 database for a 12-month period, and shall be removed from the database 12 months from the date the data was received.

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, to the extent the information relates specifically to a current patient ~~of the prescriber~~, to whom the ~~practitioner~~ prescriber is prescribing or considering prescribing any controlled substance;

(2) a dispenser, to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance;

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

(5) 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) authorized personnel of a vendor under contract with the board who are engaged in the design, implementation, and maintenance of the electronic reporting system as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to test and maintain the system databases;

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

(8) personnel of the medical assistance program assigned to use the data collected under this section to identify recipients whose usage of controlled substances may warrant restriction to a single primary care physician, a single outpatient pharmacy, or a single hospital.

For purposes of clause (3), 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 and shall ensure that any permissible user complies with paragraph (c) prior to attaining direct access to the data.

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 cost-effective and whether it~~ 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 January 15, ~~2010~~ 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.

Sec. 8. **REPEALER.**

Minnesota Statutes 2007 Supplement, section 148.235, subdivision 12, is repealed.

Presented to the governor May 12, 2008

Signed by the governor May 15, 2008, 1:10 p.m.