MINNESOTA BOARD OF PHARMACY

2012 LEGISLATIVE CHANGES RELEVANT TO PHARMACY

Use of Automated Drug Distribution Systems (ADDS) in Certain Healthcare Facilities and Physician Dispensing in Health Professional Shortage Areas

Legislation concerning the use of ADDS in certain healthcare facilities was introduced at the request of a long term care pharmacy. (HF2626/SF2173). Since this legislation had the support of the Chair of the House Health and Human Services Finance Committee (who co-authored the bill), Board staff worked with the proponents to craft compromise language.

Legislation concerning physician dispensing in health professional shortage areas (HPSA) was introduced at the request of a clinic located in a HPSA. (HF2510 /SF2195). The Senate's chief author requested technical assistance from Board staff. Executive branch agencies are required to provide such technical assistance when requested. Staff worked with Senate counsel to draft the current version of the legislation.

These bills were combined on the Senate floor, with the language of HF 2626 being amended into SF 2173. The House agreed to this merging of bills and SF 2173 was passed by both bodies unanimously. Staff expressed to the Governor's Office the Board's neutrality concerning the ADDS language and opposition to the physician dispensing language. However staff also expressed understanding that the Governor would most likely sign the legislation, given unanimous passage by both the House and Senate. The Governor did sign this legislation on April 9th and it became Chapter 166 of the 2012 Session laws. (See Appendix A).

Electronic Prescribing on Controlled Substances

Staff drafted legislation in this area at the direction of the Board. (HF2532/SF2128). The legislation will allow controlled substances to be electronically prescribed in accordance with applicable federal rules. It was passed unanimously by both the House and the Senate and was signed into law by the Governor on April 28, 2012. (Chapter 246 of 2012 Session law - see Appendix B).

Controlled Substances Legislation

Staff drafted legislation in this area at the request of Rep. Bob Barrett. (HF2508/SF2319). The legislation enjoyed broad, bipartisan support in the House and Senate. (Although it

did not pass unanimously in the House) The Governor signed this legislation into law on April 27th as Chapter 240 of 2012 Session Law. (The legislation is quite lengthy and can be viewed at:

https://www.revisor.mn.gov/laws/?id=240&doctype=Chapter&year=2012&type=0).

The Board was granted expedited rule-making authority for the purpose of placing substances into Schedule I. However, any rules adopted in this area using the expedited rule-making process will remain in effect only if ratified by the Legislature during the legislative session that occurs immediately after the rules are promulgated. In addition, the expedited rule-making authority sunsets in 2014.

Appendix A

CHAPTER 166--S.F.No. 2173
An act relating to health; allowing a licensed physician to dispense drugs in a health care facility located in a designated health professional shortage area under certain conditions; authorizing automated drug distribution systems; amending Minnesota Statutes 2010, section 151.01, by adding subdivisions; Minnesota Statutes 2011 Supplement, section 151.19, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapter 151.

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

Section 1. Minnesota Statutes 2010, section 151.01, is amended by adding a subdivision to read:

Subd. 2a. **Limited service pharmacy.** "Limited service pharmacy" means a pharmacy that has been issued a restricted license by the board to perform a limited range of the activities that constitute the practice of pharmacy.

Sec. 2. Minnesota Statutes 2010, section 151.01, is amended by adding a subdivision to read:

Subd. 34. **Health professional shortage area.** "Health professional shortage area" means an area designated as such by the federal Secretary of Health and Human Services, as provided under Code of Federal Regulations, title 42, part 5, and United States Code, title 42, section 254E.

Sec. 3. Minnesota Statutes 2011 Supplement, section 151.19, is amended by adding a subdivision to read:

Subd. 4. **Licensing of physicians to dispense drugs; renewals.** (a) The board may grant a license to any physician licensed under chapter 147 who provides services in a health care facility located in a designated health professional shortage area authorizing the physician to dispense drugs to individuals for whom pharmaceutical care is not reasonably available. The license may be renewed annually. Any physician licensed under this subdivision shall be limited to dispensing drugs in a limited service pharmacy and shall be governed by the rules adopted by the board when dispensing drugs.

(b) For the purposes of this subdivision, pharmaceutical care is not reasonably available if the limited service pharmacy in which the physician is dispensing drugs is located in a health professional shortage area, and no other licensed pharmacy is located within 15 miles of the limited service pharmacy.

(c) For the purposes of this subdivision, section 151.15, subdivision 2, shall not apply, and section 151.215 shall not apply provided that a physician granted a license under this subdivision certifies each filled prescription in accordance with Minnesota Rules, part 6800.3100, subpart 3.

(d) Notwithstanding section 151.102, a physician granted a license under this subdivision may be assisted by a pharmacy technician if the technician holds a valid certification from the Pharmacy Technician Certification Board or from another national certification body for pharmacy technicians that requires passage of a nationally

recognized psychometrically valid certification examination for certification as determined by the board. The physician may supervise the pharmacy technician as long as the physician assumes responsibility for all functions performed by the technician. For purposes of this subdivision, supervision does not require the physician to be physically present if the physician or a licensed pharmacist is available, either electronically or by telephone.

(e) Nothing in this subdivision shall be construed to prohibit a physician from dispensing drugs pursuant to section 151.37 and Minnesota Rules, parts 6800.9950 to 6800.9954.

Sec. 4. **[151.58] AUTOMATED DRUG DISTRIBUTION SYSTEMS.**

Subdivision 1. **Scope.** This section applies only to the use of automated drug distribution systems located within the facilities specified in subdivision 2. Except as provided in this section, all applicable provisions of this chapter, chapter 152, and Minnesota Rules, chapter 6800, must be followed.

Subd. 2. **Definitions.** For purposes of this section only, the terms defined in this subdivision have the meanings given.

(a) "Automated drug distribution system" or "system" means a mechanical system approved by the board that performs operations or activities, other than compounding or administration, related to the storage, packaging, or dispensing of drugs, and collects, controls, and maintains all required transaction information and records.

(b) "Health care facility" means a nursing home licensed under section 144A.02; a housing with services establishment registered under section 144D.01, subdivision 4, in which a home provider licensed under chapter 144A is providing centralized storage of medications; or a community behavioral health hospital or Minnesota sex offender program facility operated by the Department of Human Services.

(c) "Managing pharmacy" means a pharmacy licensed by the board that controls and is responsible for the operation of an automated drug distribution system.

Subd. 3. **Authorization.** A pharmacy may use an automated drug distribution system to fill prescription drug orders for patients of a health care facility. The automated drug distribution system may be located in a health care facility that is not at the same location as the managing pharmacy. When located within a health care facility, the system is considered to be an extension of the managing pharmacy.

Subd. 4. **Notification.** (a) At least 60 days prior to the initial use of an automated drug distribution system, the managing pharmacy must provide the board with written notification of the address at which the automated drug distribution system will be located, the manufacturer and model of the automated drug distribution system, and written policies and procedures that govern the operation of the system. The policies and procedures must address the requirements of subdivision 5 and the rules of the board. If the managing pharmacy will be using a system identical to the one for which it has previously provided notification to the board, and will be using identical policies and procedures, it must notify the board of the address at which the automated drug distribution system will be located and the manufacturer and model of the automated drug distribution system at least seven days in advance of using the system.

(b) The managing pharmacy must notify the board whenever an automated drug distribution system is taken permanently out of service.

(c) The managing pharmacy must notify the board whenever an automated drug distribution system is replaced. It must also provide the board with new written policies and procedures, unless an identical system is used as the replacement, 60 days prior to the replacement of the system.

Subd. 5. **Operation of automated drug distribution systems.** (a) The managing pharmacy and the pharmacist in charge are responsible for the operation of an automated drug distribution system.

(b) Access to an automated drug distribution system must be limited to pharmacy and nonpharmacy personnel authorized to procure drugs from the system, except that field service technicians may access a system located in a health care facility for the purposes of servicing and maintaining it while being monitored either by the managing pharmacy, or a licensed nurse within the health care facility. In the case of an automated drug distribution system that is not physically located within a licensed pharmacy, access for the purpose of procuring drugs shall be limited to licensed nurses. Each person authorized to access the system must be assigned an individual specific access code. Alternatively, access to the system may be controlled through the use of biometric identification procedures. A policy specifying time access parameters, including time-outs, logoffs, and lockouts, must be in place.

(c) For the purposes of this section only, the requirements of section 151.215 are met if the following clauses are met:

(1) a pharmacist employed by and working at the managing pharmacy must review, interpret, and approve all prescription drug orders before any drug is distributed from the system to be administered to a patient. A pharmacy technician may perform data entry of prescription drug orders provided that a pharmacist certifies the accuracy of the data entry before the drug can be released from the automated drug distribution system. A pharmacist must certify the accuracy of the filling of any cassettes, canisters, or other containers that contain drugs that will be loaded into the automated drug distribution system; and

(2) when the automated drug dispensing system is located and used within the managing pharmacy, a pharmacist must personally supervise and take responsibility for all packaging and labeling associated with the use of an automated drug distribution system.

(d) Access to drugs when a pharmacist has not reviewed and approved the prescription drug order is permitted only when a formal and written decision to allow such access is issued by the pharmacy and the therapeutics committee or its equivalent. The committee must specify the patient care circumstances in which such access is allowed, the drugs that can be accessed, and the staff that are allowed to access the drugs.

(e) In the case of an automated drug distribution system that does not utilize bar coding in the loading process, the loading of a system located in a health care facility may be performed by a pharmacy technician, so long as the activity is continuously supervised, through a two-way audiovisual system by a pharmacist on duty within the managing pharmacy. In the case of an automated drug distribution system that utilizes bar coding in the loading process, the loading of a system located in a health care facility may be performed by a pharmacy technician or a licensed nurse, provided that the managing pharmacy retains an electronic record of loading activities.

(f) The automated drug distribution system must be under the supervision of a

pharmacist. The pharmacist is not required to be physically present at the site of the automated drug distribution system if the system is continuously monitored electronically by the managing pharmacy. A pharmacist on duty within a pharmacy licensed by the board must be continuously available to address any problems detected by the monitoring or to answer questions from the staff of the health care facility. The licensed pharmacy may be the managing pharmacy or a pharmacy which is acting as a central services pharmacy, pursuant to Minnesota Rules, part 6800.4075, for the managing pharmacy.

Presented to the governor April 5, 2012
Signed by the governor April 9, 2012, 01:04 p.m.

Appendix B

CHAPTER 246--H.F.No. 2532

An act

relating to health; allowing the electronic prescribing of controlled substances; amending Minnesota Statutes 2010, section 152.11.

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

Section 1. Minnesota Statutes 2010, section 152.11, is amended to read:

152.11 ~~WRITTEN OR ORAL~~ PRESCRIPTIONS~~, REQUISITES~~.

Subdivision 1. **~~Written~~ General prescription ~~requirement~~ requirements for ~~Schedule II~~ controlled substances.** (a) A written prescription or an oral prescription reduced to writing, when issued for a controlled substance in Schedule II, III, IV, or V, is void unless (1) it is written in ink and contains the name and address of the person for whose use it is intended; (2) it states the amount of the controlled substance to be compounded or dispensed, with directions for its use; (3) if a written prescription, it contains the handwritten signature, address, and federal registry number of the prescriber and a designation of the branch of the healing art pursued by the prescriber; and if an oral prescription, the name and address of the prescriber and a designation of the prescriber's branch of the healing art; and (4) it shows the date when signed by the prescriber, or the date of acceptance in the pharmacy if an oral prescription.

(b) An electronic prescription for a controlled substance in Schedule II, III, IV, or V is void unless it complies with the standards established pursuant to section 62J.497 and with those portions of Code of Federal Regulations, title 21, parts 1300, 1304, 1306 and 1311 that pertain to electronic prescriptions.

(c) A prescription for a controlled substance in Schedule II, III, IV, or V that is transmitted by facsimile, either computer to facsimile machine or facsimile machine to facsimile machine, is void unless it complies with the applicable requirements of Code of Federal Regulations, title 21, part 1306.

(d) Every licensed pharmacy that dispenses a controlled substance prescription shall retain the original prescription in a file for a period of not less than two years, open to inspection by any officer of the state, county, or municipal government whose duty it is to aid and assist with the enforcement of this chapter. An original electronic or facsimile prescription may be stored in an electronic database, provided that the database provides a means by which original prescriptions can be retrieved, as transmitted to the pharmacy, for a period of not less than two years.

(e) Every licensed pharmacy shall distinctly label the container in which a controlled substance is dispensed with the directions contained in the prescription for the use of that controlled substance.

Subd. 1a. **Prescription requirements for Schedule II controlled substances.** No person may dispense a controlled substance included in Schedule II of section 152.02 without a prescription ~~written~~ issued by a doctor of medicine, a doctor of osteopathy licensed to practice medicine, a doctor of dental surgery, a doctor of dental medicine,

a doctor of podiatry, or a doctor of veterinary medicine, lawfully licensed to prescribe in this state or by a practitioner licensed to prescribe controlled substances by the state in which the prescription is issued, and having a current federal Drug Enforcement Administration registration number. The prescription must either be printed or written in ink and contain the handwritten signature of the prescriber or be transmitted electronically or by facsimile as permitted under subdivision 1. Provided that in emergency situations, as authorized by federal law, such drug may be dispensed upon oral prescription reduced promptly to writing and filed by the pharmacist. Such prescriptions shall be retained in conformity with section 152.101. No prescription for a Schedule II substance may be refilled.

~~For the purposes of this chapter, a written prescription or oral prescription, which shall be reduced to writing, for a controlled substance in Schedule II, III, IV or V is void unless (1) it is written in ink and contains the name and address of the person for whose use it is intended; (2) it states the amount of the controlled substance to be compounded or dispensed, with directions for its use; (3) if a written prescription, it contains the signature, address and federal registry number of the prescriber and a designation of the branch of the healing art pursued by the prescriber; and if an oral prescription, the name and address of the prescriber and a designation of the prescriber's branch of the healing art; and (4) it shows the date when signed by the prescriber, or the date of acceptance in the pharmacy if an oral prescription. Every licensed pharmacist who compounds any such prescription shall retain such prescription in a file for a period of not less than two years, open to inspection by any officer of the state, county, or municipal government, whose duty it is to aid and assist with the enforcement of this chapter. Every such pharmacist shall distinctly label the container with the directions contained in the prescription for the use thereof.~~

Subd. 2. **~~Written or oral~~ Prescription ~~requirement~~ requirements for Schedule III or IV controlled substances.** No person may dispense a controlled substance included in Schedule III or IV of section 152.02 without a ~~written or oral~~ prescription ~~from~~ issued, as permitted under subdivision 1, by a doctor of medicine, a doctor of osteopathy licensed to practice medicine, a doctor of dental surgery, a doctor of dental medicine, a doctor of podiatry, a doctor of optometry limited to Schedule IV, or a doctor of veterinary medicine, lawfully licensed to prescribe in this state or from a practitioner licensed to prescribe controlled substances by the state in which the prescription is issued, and having a current federal drug enforcement administration registration number. Such prescription may not be dispensed or refilled except with the ~~written or verbal~~ documented consent of the prescriber, and in no event more than six months after the date on which such prescription was issued and no such prescription may be refilled more than five times.

Subd. 2a. **Federal registration number exemption.** A prescription need not bear a federal drug enforcement administration registration number that authorizes the prescriber to prescribe controlled substances if the drug prescribed is not a controlled substance in Schedule II, III, IV, or V. No person shall impose a requirement inconsistent with this subdivision.

Subd. 2b. **Restriction on release of federal registration number.** No person or entity may offer for sale, sell, lease, or otherwise release a federal drug enforcement administration registration number for any reason, except for drug enforcement purposes authorized by this chapter and the federal controlled substances registration system. For purposes of this section, an entity includes a state governmental agency or regulatory board, a health plan company as defined under section 62Q.01, subdivision 4, a managed care organization as defined under section 62Q.01, subdivision 5, or any other entity that maintains prescription data.

Subd. 2c. **Restriction on use of federal registration number.** No entity may use a federal drug enforcement administration registration number to identify or monitor the prescribing practices of a prescriber to whom that number has been assigned, except for drug enforcement purposes authorized by this chapter and the federal controlled substances registration system. For purposes of this section, an entity includes a health plan company as defined under section 62Q.01, subdivision 4, a managed care organization as defined under section 62Q.01, subdivision 5, or any other entity that maintains prescription data.

Subd. 2d. **Identification requirement for Schedule II or III controlled substance prescriptions.** (a) No person may dispense a controlled substance included in Schedule II or III without requiring the person purchasing the controlled substance, who need not be the person for whom the controlled substance prescription is written, to present valid photographic identification, unless the person purchasing the controlled substance, or if applicable the person for whom the controlled substance prescription is written, is known to the dispenser.

(b) This subdivision applies only to purchases of controlled substances that are not covered, in whole or in part, by a health plan company or other third-party payor. ~~The Board of Pharmacy shall report to the legislature by July 1, 2009, on the effect of this subdivision. The board shall include in the report the incidence of complaints, if any, generated by the requirements of this subdivision and whether this subdivision is creating barriers to pharmaceutical access.~~

Subd. 3. **Dispensing orphan drugs.** For the purpose of ~~subdivisions 1 and 2~~ this section, nothing shall prohibit the dispensing of orphan drugs prescribed by a person practicing in and licensed by another state as a physician, dentist, veterinarian, or podiatrist; who has a current federal drug enforcement administration registration number; and who may legally prescribe Schedule II, III, IV, or V controlled substances in that state.