

## **2007 LEGISLATION**

During the 2007 legislative session, several new laws were passed that will have an impact on pharmacists. The following brief summary is adapted from a report given to the Board at its June meeting. The actual text of the laws can be found after the summary.

### ◆ **Schedule II and III controlled substances electronic reporting system.**

The Board is required to apply for federal grants to establish a system by which all Schedule II and III prescriptions dispensed in the state will be electronically reported to the Board. Prescribers and dispensers who are actively treating a patient will be able to access a profile of any CII or CIII prescriptions dispensed to that patient for a period not exceeding the previous six months. The system itself is to be implemented by January 1, 2009. However, due to the timelines involved in obtaining the federal grants, it is unlikely that a system can be in place by that date.

Board staff will apply for federal grants as soon as possible. The Board is prohibited from implementing the program if it does not receive sufficient non-state funding. In that event, the Board will need to work with the Governor's Office and the Legislature to seek additional state funding. Staff has informed key legislative leaders that additional administrative employees will be required once the program is operational. Staff has also made the case to those legislators that, should state-funding be required, it should not come solely from Board of Pharmacy revenues. Instead, all Boards that license prescribers and dispensers should share in the cost.

### ◆ **Identification requirement for schedule II or III controlled substance.** The following language was passed as part of the controlled substances electronic reporting system bill mentioned above.

"Subd. 2d. Identification requirement for schedule II or III controlled substance.

(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".

Notice that this requirement applies only to cash prescriptions.

### ◆ **Dispensing of contraceptives by registered nurses,** will be allowed in certain situations. Specifically, RNs working in family planning agencies will be allowed to dispense contraceptives under protocol with a physician or nurse practitioner.

### ◆ **Long-Term Care Resident Access to Pharmaceuticals Act.** Pharmacies are permitted to repackage a resident's prescription drugs, which have been lawfully dispensed from bulk prescription containers by an original dispensing pharmacy, into a unit-dose system compatible with the system used by the long-term care facility. **However, the Board has**

**received communication from the U.S. Drug Enforcement Administration indicating that pharmacies are NOT allowed to repackage controlled substances in this manner.**

This bill was proposed by a legislator who was concerned that some patients in nursing homes could not receive their prescription drugs from mail-order pharmacies. Such patients are required by their insurer to use mail-order pharmacies that won't or can't provide drugs in the unit-dose packaging that nursing homes require. Consequently, the patients had to pay full cash price to a local pharmacy that could supply the drugs in unit-dose packaging.

Board staff worked with a coalition of organizations representing pharmacies and long-term care facilities to suggest changes in the language originally proposed. The original language would have required pharmacies to do such repackaging; the adopted law makes it optional. Language proposed by Board staff requires the mail order pharmacies to cooperate with the local pharmacy by providing the information necessary to do the repackaging.

- ◆ **Substitution.** The Governor and Legislature adopted language proposed by the Board that brings Minnesota Statutes §151.21 into compliance with certain provisions of the federal Medicare Modernization Act (MMA). The MMA preempts state laws that require anything to be handwritten on prescriptions. The new language still requires “DAW” or “dispensed as written” to be handwritten on any paper prescription handed to a patient. (Assuming the prescriber wants to prohibit substitution). However, prescribers can electronically indicate that the prescription is “DAW” if the prescription is electronically transmitted.
- ◆ **Technicians.** The statutory language concerning the Board’s powers in regards to technicians was amended as follows:

“(9) to register as pharmacy technicians all applicants who the board determines are qualified to carry out the duties of a pharmacy technician; and

The new language more clearly allows the Board to establish, in rule, additional requirements for registration. (e.g. – requirements for education or training, continuing education, etc.)

- ◆ **Central Service Pharmacy and Certification.** At least one pharmacy chain and the Minnesota Retail Merchant’s Association were concerned about a provision in the newly adopted rules that requires certification of prescriptions to be done at the pharmacy that ultimately dispenses, delivers, or mails the prescriptions to the patient. Consequently, they approached the Legislature with a proposal to change state law in such a way as to invalidate the Board’s rules.

Board staff testified during legislative hearings that the proposed language might endanger patients because it failed to distinguish between the different types of “central service pharmacy” models that exist. Board staff explained to the legislators that the Board was willing to work with the pharmacies that were concerned about the new rules to issue a variance. (Since the model employed by those pharmacies was such that certification at the central service pharmacy did make more sense).

The legislature did agree to changes in language that reduce the risk to the public. The language that passed adds the definition of “central service pharmacy” that the Board adopted in rule to the statutes. Essentially, any pharmacy that performs any part of the dispensing process for another pharmacy is defined as a central service pharmacy.

The new law reads: “A pharmacist must certify a prescription, in compliance with Minnesota Board of Pharmacy rules, before the prescription is dispensed, delivered, mailed, or shipped to a patient or a patient’s caregiver. However, if the prescription has been certified by a pharmacist at a licensed central service pharmacy, in compliance with Minnesota Board of Pharmacy rules, an additional certification is not required at the pharmacy that dispenses, mails, or ships the completed prescription to the patient”.

Thus, certification, which heretofore has been required only in rule, is now required by law. This will limit the ability of the Board to grant variances in this area, since variances to law aren’t allowed.

- ◆ **Online questionnaires.** A prescription or drug order for a legend drug is no longer 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 adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment. This means that pharmacies will not be able to operate as “fulfillment centers” for Internet operations that have prescribers write prescriptions based solely on an online questionnaire.
- ◆ **Return of drugs to pharmacies by county jails.** The Association of Minnesota Counties, was able to get the following language passed:

“Notwithstanding Minnesota Rules, part 6800.2700, pharmacies may accept returns of unused drugs 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 on hand twenty-four hours a day, seven days a week and the medication must be stored in a secured locked storage locker”.

In an effort to work cooperatively with the authors of the bill (in hopes of getting language passed that was more acceptable), Board staff pointed out that the language does not actually state that pharmacies can redispense drugs that are returned by jails. At one point, the words “and redispense” were in one version of the bill that was passed by committees in both the House and Senate. Staff contacted the Office of the Revisor of Statutes about this issue because there was a Revisor’s bill introduced that would have added back the words “and redispense”.

The Revisor’s bill did not pass. Therefore, the Board can’t assume that the intent of the Legislature, as a whole, was to allow pharmacies to redispense the returned drugs. That may or may not have been the intent of the authors, but other members of the Legislature may have voted differently on the bill if the language allowing pharmacies to redispense drugs returned from jails was in the version of the bill they voted on. Furthermore, the Board can’t assume that the intent of the Governor in signing the bill was to allow pharmacies to redispense such drugs.

The only clear intent is that the Legislature and Governor want the counties to save money. In theory, that could happen if pharmacies gave credit to the counties for returned drugs, but did not redispense those drugs. That might be unfair to pharmacies, but during the past decade, many pieces of legislation have been introduced or passed that require healthcare providers to in some way receive less money or pay more in taxes, etc.

Board staff will seek to have this issue clarified in statute during the 2008 session. Pharmacies should consult with the own legal counsel if they are considering redispensing drugs returned from county jails.

#### LANGUAGE FROM THE FROM OMNIBUS HEALTH AND HUMAN SERVICES BILL

**379.9** Section 1. Minnesota Statutes 2006, section 13.381, is amended by adding a **379.10**subdivision to read:

**379.11** Subd. 16a. **Prescription electronic reporting system.** Access to data in the  
**379.12**prescription electronic reporting system is governed by section 152.126.

**379.13** Sec. 2. Minnesota Statutes 2006, section 148.235, is amended by adding a subdivision **379.14**to read:

**379.15** Subd. 11. **Dispensing by protocol.** A registered nurse in a family planning agency  
**379.16**as defined in Minnesota Rules, part 9505.0280, subpart 3, may dispense oral contraceptives  
**379.17**prescribed by a licensed practitioner as defined in section 151.01, subdivision 23, pursuant  
**379.18**to a dispensing protocol established by the agency's medical director or under the direction  
**379.19**of a physician. The dispensing protocol must address the requirements of sections 151.01,  
**379.20**subdivision 30, and 151.212, subdivision 1.

**379.21** Sec. 3. Minnesota Statutes 2006, section 151.19, subdivision 2, is amended to read:

**379.22** Subd. 2. **Nonresident pharmacies.** The board shall require and provide for an  
**379.23**annual nonresident special pharmacy registration for all pharmacies located outside of this  
**379.24**state that regularly dispense medications for Minnesota residents and mail, ship, or deliver  
**379.25**prescription medications into this state. Nonresident special pharmacy registration shall  
**379.26**be granted by the board upon the disclosure and certification by a pharmacy:

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

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

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

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

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

**380.8** (6) that during its regular hours of operation, but not less than six days per week, for  
**380.9a** minimum of 40 hours per week, a toll-free telephone service is provided to facilitate  
**380.10**communication between patients in this state and a pharmacist at the pharmacy who has  
**380.11**access to the patients' records; the toll-free number must be disclosed on the label affixed  
**380.12**to each container of drugs dispensed to residents of this state; and

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

**380.18** Sec. 4. **[151.415] LONG-TERM CARE RESIDENT ACCESS TO**  
**380.19****PHARMACEUTICALS ACT.**

**380.20** Subdivision 1. **Title; citation.** This section may be cited as the "Long-Term Care  
**380.21**Resident Access to Pharmaceuticals Act."

**380.22** Subd. 2. **Definitions.** For the purposes of this section, the following terms have the

380.23 meanings given them unless otherwise provided by text:

380.24 (a) "Board" means the Board of Pharmacy.

380.25 (b) "Contract pharmacy" means a pharmacy, licensed under this chapter, which is

380.26 under contract to a long-term care facility.

380.27 (c) "Long-term care facility" means a nursing home licensed under sections 144A.02

380.28 to 144A.10, or a boarding care home licensed under sections 144.50 to 144.56. Facilities

380.29 not certified under title XIX of the federal Social Security Act are not included in this

380.30 definition.

380.31 (d) "Original dispensing pharmacy" shall mean a pharmacy, licensed in any state in

380.32 the United States, which dispenses drugs in bulk prescription containers to a person who

380.33 is a resident in a long-term care facility.

380.34 Subd. 3. **Authorization to administer and repackage drugs.** (a) A contract

380.35 pharmacist or pharmacy may repackage a resident's prescription drugs, which have been

381.1 lawfully dispensed from bulk prescription containers by an original dispensing pharmacy,

381.2 into a unit-dose system compatible with the system used by the long-term care facility.

381.3 (b) A long-term care facility may administer drugs to residents of the facility that

381.4 have been repackaged according to this subdivision. The contract pharmacy shall notify

381.5 the long-term care facility whenever medications have been dispensed according to

381.6 this subdivision and must certify that the repackaging and dispensing has been done in

381.7 accordance with this subdivision.

381.8 (c) Drugs may be dispensed for a resident of a long-term care facility according to

381.9 this subdivision, provided that:

381.10 (1) the drug is dispensed by the original dispensing pharmacy according to a current,

381.11 valid prescription;

381.12 (2) the original bulk prescription container for the resident is delivered by the

381.13 original dispensing pharmacy directly to the contract pharmacist or pharmacy;

381.14 (3) the contract pharmacist or pharmacy verifies the name and strength of the drug,

381.15 the name of the manufacturer of the drug, the manufacturer's lot or control number, the

381.16 manufacturer's expiration date for the drug, and the date the drug was dispensed by the

381.17 original dispensing pharmacy;

381.18 (4) the contract pharmacist or pharmacy verifies the validity and accuracy of the

381.19 current prescription order;

381.20 (5) the contract pharmacist or pharmacy repackages the drug in board-approved

381.21 unit-dose packaging, with labeling that complies with Minnesota Rules, part 6800.6300,

381.22 and that identifies that the drug has been repackaged according to this section;

381.23 (6) the resident for whom the medication is repackaged obtains medications from or

381.24 receives medications at a discounted rate from the original dispensing pharmacy under the

381.25 resident's state or federal health assistance program or a private health insurance plan; and

381.26 (7) the resident for whom the medication is to be repackaged, or the resident's

381.27 authorized representative, has signed an informed consent form provided by the facility

381.28 which includes an explanation of the repackaging process and which notifies the resident

381.29 of the immunities from liability provided in this section.

381.30 Subd. 4. **Maintenance of records.** For each drug repackaged by a contract

381.31 pharmacy under this section, the contract pharmacy shall maintain a record for at least

381.32 two years of the following information:

381.33 (1) the name, manufacturer, manufacturer's lot number, manufacturer's expiration

381.34 date, and quantity of the drug prescribed;

381.35 (2) the name and address of the resident for whom the drug was repackaged;

381.36 (3) the name and address or other identifier of the prescriber;

382.1 (4) the date the prescription was issued and the date the drug was repackaged;

382.2 (5) the date the repackaged drug was delivered to the long-term care facility;

382.3 (6) the directions for use;

382.4 (7) a copy of the label that was affixed to the repackaged drug;

382.5 (8) the initials of the packager;

382.6 (9) the initials of the supervising pharmacist; and

382.7 (10) the name and business address of the original dispensing pharmacy.

382.8 Subd. 5. **Duties of the original dispensing pharmacy.** Upon request of the

382.9 resident, the resident's authorized representative, or a contract pharmacy or licensed

382.10 health care facility acting on behalf of the resident, the original dispensing pharmacy  
382.11 is required to deliver medications dispensed for the resident directly to the contract  
382.12 pharmacist or pharmacy. The original dispensing pharmacy is further required to provide  
382.13 the contract pharmacist or pharmacy with the name and strength of the drug, the name of  
382.14 the manufacturer of the drug, the manufacturer's lot or control number, the manufacturer's  
382.15 expiration date for the drug, and the date the drug was dispensed.

382.16 Subd. 6. **Redispensing of returned drugs prohibited.** Unused drugs repackaged  
382.17 according to this section that are returned to any pharmacy shall not be redispensed.

382.18 Subd. 7. **Immunity from civil liability.** (a) A contract pharmacist or pharmacy  
382.19 and its employees or agents repackaging a drug acquired from an original dispensing  
382.20 pharmacy shall be immune from civil liability arising from harm caused by the drug due  
382.21 to acts or omissions of other persons outside of the contract pharmacist or pharmacy if the  
382.22 contract pharmacist or pharmacy properly repackages the drug according to this section.

382.23 (b) A long-term care facility and the facility's employees or agents who properly  
382.24 administer a drug repackaged by a contract pharmacist or pharmacy under this section  
382.25 shall be immune from civil liability arising from harm caused by the drug due to acts or  
382.26 omissions of other persons outside the long-term care facility.

382.27 Subd. 8. **Handling fee.** A contract pharmacist or pharmacy may charge a monthly  
382.28 fee of no more than 250 percent of the medical assistance program dispensing fee for  
382.29 each drug repackaged according to this section, but no more than \$100 per month for  
382.30 each individual resident.

### 383.4 Sec. 6. **[152.126] SCHEDULE II AND III CONTROLLED SUBSTANCES**

#### 383.5 **PRESCRIPTION ELECTRONIC REPORTING SYSTEM.**

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

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

383.10 (b) "Controlled substances" means those substances listed in section 152.02,  
383.11 subdivisions 3 and 4, and those substances defined by the board pursuant to section  
383.12 152.02, subdivisions 7, 8, and 12.

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

383.16 (d) "Dispenser" means a person authorized by law to dispense a controlled substance,  
383.17 pursuant to a valid prescription. A dispenser does not include a licensed hospital pharmacy  
383.18 that distributes controlled substances for inpatient hospital care.

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

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

383.22 Subd. 2. **Prescription electronic reporting system.** (a) The board shall establish  
383.23 by January 1, 2009, an electronic system for reporting the information required under  
383.24 subdivision 4 for all controlled substances dispensed within the state. Data for controlled  
383.25 substance prescriptions that are dispensed in a quantity small enough to provide treatment  
383.26 to a patient for a period of 48 hours or less need not be reported.

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

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

384.1 (1) the Department of Health;

384.2 (2) the Department of Human Services;

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

384.4 (4) a professional medical association, which may include an association of pain

384.5management and chemical dependency specialists;

384.6 (5) a professional pharmacy association;

384.7 (6) a consumer privacy or security advocate; and

384.8 (7) a consumer or patient rights organization.

384.9 (b) The advisory committee shall advise the board on the development and operation

384.10of the electronic reporting system, including, but not limited to:

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

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

384.13 (3) an evaluation process for the program.

384.14 (c) The Board of Pharmacy, after consultation with the advisory committee, shall

384.15present recommendations and draft legislation on the issues addressed by the advisory

384.16committee under paragraph (b), to the legislature by December 15, 2007.

384.17 Subd. 4. **Reporting requirements; notice.** (a) Each dispenser must submit the

384.18following data to the board or its designated vendor, subject to the notice required under

384.19paragraph (d):

384.20 (1) name of the prescriber;

384.21 (2) national provider identifier of the prescriber;

384.22 (3) name of the dispenser;

384.23 (4) national provider identifier of the dispenser;

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

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

384.26 (7) date the prescription was written;

384.27 (8) date the prescription was filled;

384.28 (9) name and strength of the controlled substance;

384.29 (10) quantity of controlled substance prescribed; and

384.30 (11) quantity of controlled substance dispensed.

384.31 (b) The dispenser must submit the required information by a procedure and in a

384.32format established by the board.

384.33 (c) A dispenser is not required to submit this data for those controlled substance

384.34prescriptions dispensed for:

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

385.1 (2) individuals receiving assisted living services under chapter 144G or through a

385.2medical assistance home and community-based waiver;

385.3 (3) individuals receiving medication intravenously;

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

385.5 (5) individuals receiving services from a home care provider regulated under chapter

385.6144A.

385.7 (d) A dispenser must not submit data under this subdivision unless a conspicuous

385.8notice of the reporting requirements of this section is given to the patient for whom the

385.9prescription was written.

385.10 Subd. 5. **Use of data by board.** (a) The board shall develop and maintain a database

385.11of the data reported under subdivision 4. The board shall maintain data that could identify

385.12an individual prescriber or dispenser in encrypted form. The database may be used by

385.13permissible users identified under subdivision 6 for the identification of:

385.14 (1) individuals receiving prescriptions for controlled substances from prescribers

385.15who subsequently obtain controlled substances from dispensers in quantities or with

385.16a frequency inconsistent with standards accepted by national and international pain

385.17management associations of dosage for those controlled substances; and

385.18 (2) individuals presenting forged or otherwise false or altered prescriptions for

385.19controlled substances to dispensers.

385.20 (b) No permissible user identified under subdivision 6 may access the database

385.21for the sole purpose of identifying prescribers of controlled substances for unusual or

385.22excessive prescribing patterns without a valid search warrant or court order.

385.23 (c) No personnel of a state or federal occupational licensing board or agency may

385.24access the database for the purpose of obtaining information to be used to initiate or

385.25substantiate a disciplinary action against a prescriber.

385.26 (d) Data reported under subdivision 4 shall be retained by the board in the database

385.27for a 12-month period, and shall be removed from the database 12 months from the date

385.28the data was received.

385.29 Subd. 6. **Access to reporting system data.** (a) Except as indicated in this

385.30subdivision, the data submitted to the board under subdivision 4 is private data on

385.31individuals as defined in section 13.02, subdivision 12, and not subject to public disclosure.

385.32 (b) Except as specified in subdivision 5, the following persons shall be considered

385.33permissible users and may access the data submitted under subdivision 4 in the same or

385.34similar manner, and for the same or similar purposes, as those persons who are authorized

385.35to access similar private data on individuals under federal and state law:

386.1 (1) a prescriber, to the extent the information relates specifically to a current patient

386.2of the prescriber, to whom the practitioner is prescribing or considering prescribing any

386.3controlled substance;

386.4 (2) a dispenser, to the extent the information relates specifically to a current patient

386.5to whom that dispenser is dispensing or considering dispensing any controlled substance;

386.6 (3) an individual who is the recipient of a controlled substance prescription for

386.7which data was submitted under subdivision 4, or a guardian of the individual, parent or

386.8guardian of a minor, or health care agent of the individual acting under a health care

386.9directive under chapter 145C;

386.10 (4) personnel of the board specifically assigned to conduct a bona fide investigation

386.11of a specific licensee;

386.12 (5) personnel of the board engaged in the collection of controlled substance

386.13prescription information as part of the assigned duties and responsibilities under this

386.14section;

386.15 (6) authorized personnel of a vendor under contract with the board who are engaged

386.16in the design, implementation, and maintenance of the electronic reporting system as part

386.17of the assigned duties and responsibilities of their employment, provided that access to data

386.18is limited to the minimum amount necessary to test and maintain the system databases;

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

386.20search warrant; and

386.21 (8) personnel of the medical assistance program assigned to use the data collected

386.22under this section to identify recipients whose usage of controlled substances may warrant

386.23restriction to a single primary care physician, a single outpatient pharmacy, or a single

386.24hospital.

386.25 For purposes of clause (3), access by an individual includes persons in the definition

386.26of an individual under section 13.02.

386.27 (c) Any permissible user identified in paragraph (b), who directly accesses

386.28the data electronically, shall implement and maintain a comprehensive information

386.29security program that contains administrative, technical, and physical safeguards that

386.30are appropriate to the user's size and complexity, and the sensitivity of the personal

386.31information obtained. The permissible user shall identify reasonably foreseeable internal

386.32and external risks to the security, confidentiality, and integrity of personal information

386.33that could result in the unauthorized disclosure, misuse, or other compromise of the

386.34information and assess the sufficiency of any safeguards in place to control the risks.

387.1 (d) The board shall not release data submitted under this section unless it is provided

387.2with evidence, satisfactory to the board, that the person requesting the information is

387.3entitled to receive the data.

387.4 (e) The board shall not release the name of a prescriber without the written consent

387.5of the prescriber or a valid search warrant or court order. The board shall provide a

387.6mechanism for a prescriber to submit to the board a signed consent authorizing the release

387.7of the prescriber's name when data containing the prescriber's name is requested.

387.8 (f) The board shall maintain a log of all persons who access the data and shall ensure

387.9that any permissible user complies with paragraph (c) prior to attaining direct access to

387.10the data.

387.11 Subd. 7. **Disciplinary action.** (a) A dispenser who knowingly fails to submit data to

387.12the board as required under this section is subject to disciplinary action by the appropriate

387.13health-related licensing board.

387.14 (b) A prescriber or dispenser authorized to access the data who knowingly discloses

387.15the data in violation of state or federal laws relating to the privacy of health care data

387.16shall be subject to disciplinary action by the appropriate health-related licensing board.

387.17and appropriate civil penalties.

387.18 Subd. 8. **Evaluation and reporting.** (a) The board shall evaluate the prescription 387.19electronic reporting system to determine if the system is cost-effective and whether it is 387.20negatively impacting appropriate prescribing practices of controlled substances. The 387.21board may contract with a vendor to design and conduct the evaluation.

387.22 (b) The board shall submit the evaluation of the system to the legislature by January 387.2315, 2010.

387.24 Subd. 9. **Immunity from liability; no requirement to obtain information.** (a) A 387.25pharmacist, prescriber, or other dispenser making a report to the program in good faith 387.26under this section is immune from any civil, criminal, or administrative liability, which 387.27might otherwise be incurred or imposed as a result of the report, or on the basis that the 387.28pharmacist or prescriber did or did not seek or obtain or use information from the program.

387.29 (b) Nothing in this section shall require a pharmacist, prescriber, or other dispenser 387.30to obtain information about a patient from the program, and the pharmacist, prescriber, 387.31or other dispenser, if acting in good faith, is immune from any civil, criminal, or 387.32administrative liability that might otherwise be incurred or imposed for requesting, 387.33receiving, or using information from the program.

387.34**EFFECTIVE DATE.**This section is effective July 1, 2007, or upon receiving 387.35sufficient nonstate funds to implement the prescription electronic reporting program, 387.36whichever is later. In the event that nonstate funds are not secured by the Board of 388.1Pharmacy to adequately fund the implementation of the prescription electronic reporting 388.2program, the board is not required to implement this section without a subsequent 388.3appropriation from the legislature.

402.30 Sec. 24. **FEDERAL GRANTS.**

402.31 The Board of Pharmacy shall apply for any applicable federal grants or other nonstate 402.32funds to establish and fully implement the prescription electronic reporting system.

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

403.2 Sec. 25. **BOARD OF PHARMACY.**

403.3 The Board of Pharmacy shall not increase the license fees of pharmacists or 403.4pharmacies in order to adequately fund the prescription electronic reporting system under 403.5Minnesota Statutes, section 152.126, without specific authority from the legislature.

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

403.7 Sec. 26. **BOARD OF MEDICAL PRACTICE.**

403.8 The Board of Medical Practice shall convene a work group to discuss the appropriate 403.9prescribing of controlled substances listed in Minnesota Statutes, section 152.02, 403.10subdivisions 3 and 4, and those substances defined by the Board of Pharmacy under 403.11Minnesota Statutes, section 152.02, subdivisions 7, 8, and 12, for pain management, and 403.12shall report to the legislature by December 15, 2007.

407.8 (c) A prescription or drug order for a legend drug is not valid if it is based solely 407.9on an online questionnaire, unless it can be established that the prescription or order was 407.10based on a documented patient evaluation adequate to establish a diagnosis and identify 407.11underlying conditions and contraindications to treatment.

407.12 Sec. 9. Minnesota Statutes 2006, section 152.11, is amended by adding a subdivision to 407.13read:

407.14 Subd. 2d. **Identification requirement for schedule II or III controlled substance.**

407.15 (a) No person may dispense a controlled substance included in schedule II or III without 407.16requiring the person purchasing the controlled substance, who need not be the person for 407.17whom the controlled substance prescription is written, to present valid photographic 407.18identification, unless the person purchasing the controlled substance, or if applicable the 407.19person for whom the controlled substance prescription is written, is known to the dispenser.

407.20 (b) This subdivision applies only to purchases of controlled substances that are not 407.21covered, in whole or in part, by a health plan company or other third-party payor. The 407.22Board of Pharmacy shall report to the legislature by July 1, 2009, on the effect of this

~~407.23~~subdivision. The board shall include in the report the incidence of complaints, if any,  
~~407.24~~generated by the requirements of this subdivision and whether this subdivision is creating  
~~407.25~~barriers to pharmaceutical access.

## FROM TECHNICAL CORRECTIONS BILL FOR HEALTH-LICENSING BOARDS

Sec. 122. Minnesota Statutes 2006, section 151.01, is amended by adding a subdivision to read:

Subd. 31. **Electronic signature.** "Electronic signature" means an electronic sound, symbol, or process attached to or associated with a record and executed or adopted by a person with the intent to sign the record.

Sec. 123. Minnesota Statutes 2006, section 151.01, is amended by adding a subdivision to read:

Subd. 32. **Electronic transmission.** "Electronic transmission" means transmission of information in electronic form.

Sec. 124. Minnesota Statutes 2006, section 151.06, subdivision 1, is amended to read:

Subdivision 1. **Generally; rules.** (a) Powers and duties. The Board of Pharmacy shall have the power and it shall be its duty:

- (1) to regulate the practice of pharmacy;
- (2) to regulate the manufacture, wholesale, and retail sale of drugs within this state;
- (3) to regulate the identity, labeling, purity, and quality of all drugs and medicines dispensed in this state, using the United States Pharmacopeia and the National Formulary, or any revisions thereof, or standards adopted under the federal act as the standard;
- (4) to enter and inspect by its authorized representative any and all places where drugs, medicines, medical gases, or veterinary drugs or devices are sold, vended, given away, compounded, dispensed, manufactured, wholesaled, or held; it may secure samples or specimens of any drugs, medicines, medical gases, or veterinary drugs or devices after paying or offering to pay for such sample; it shall be entitled to inspect and make copies of any and all records of shipment, purchase, manufacture, quality control, and sale of these items provided, however, that such inspection shall not extend to financial data, sales data, or pricing data;
- (5) to examine and license as pharmacists all applicants whom it shall deem qualified to be such;
- (6) to license wholesale drug distributors;
- (7) to deny, suspend, revoke, or refuse to renew any registration or license required under this chapter, to any applicant or registrant or licensee upon any of the following grounds:
  - (i) fraud or deception in connection with the securing of such license or registration;
  - (ii) in the case of a pharmacist, conviction in any court of a felony;
  - (iii) in the case of a pharmacist, conviction in any court of an offense involving moral turpitude;
  - (iv) habitual indulgence in the use of narcotics, stimulants, or depressant drugs; or habitual indulgence in intoxicating liquors in a manner which could cause conduct endangering public health;
  - (v) unprofessional conduct or conduct endangering public health;
  - (vi) gross immorality;
  - (vii) employing, assisting, or enabling in any manner an unlicensed person to practice pharmacy;
  - (viii) conviction of theft of drugs, or the unauthorized use, possession, or sale thereof;
  - (ix) violation of any of the provisions of this chapter or any of the rules of the State Board of Pharmacy;
  - (x) in the case of a pharmacy license, operation of such pharmacy without a pharmacist present and on duty;

(xi) in the case of a pharmacist, physical or mental disability which could cause incompetency in the practice of pharmacy;

(xii) in the case of a pharmacist, the suspension or revocation of a license to practice pharmacy in another state; or

(xiii) in the case of a pharmacist, aiding suicide or aiding attempted suicide in violation of section 609.215 as established by any of the following:

(A) a copy of the record of criminal conviction or plea of guilty for a felony in violation of section 609.215, subdivision 1 or 2;

(B) a copy of the record of a judgment of contempt of court for violating an injunction issued under section 609.215, subdivision 4;

(C) a copy of the record of a judgment assessing damages under section 609.215, subdivision 5 ; or

(D) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board shall investigate any complaint of a violation of section 609.215, subdivision 1 or 2;

(8) to employ necessary assistants and ~~make~~ adopt rules for the conduct of its business;

(9) to register as pharmacy technicians all applicants who the board determines are qualified to carry out the duties of a pharmacy technician; and

(10) to perform such other duties and exercise such other powers as the provisions of the act may require.

(b) Temporary suspension. In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend a license for not more than 60 days if the board finds that a pharmacist has violated a statute or rule that the board is empowered to enforce and continued practice by the pharmacist would create an imminent risk of harm to others. The suspension shall take effect upon written notice to the pharmacist, specifying the statute or rule violated. At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held under the Administrative Procedure Act. The pharmacist shall be provided with at least 20 days' notice of any hearing held under this subdivision.

(c) Rules. For the purposes aforesaid, it shall be the duty of the board to make and publish uniform rules not inconsistent herewith for carrying out and enforcing the provisions of this chapter. The board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists. A pharmacist in the exercise of the pharmacist's professional judgment, upon the presentation of a new prescription by a patient or the patient's caregiver or agent, shall perform the prospective drug utilization review required by rules issued under this subdivision.

Sec. 125. Minnesota Statutes 2006, section 151.21, subdivision 1, is amended to read:

Subdivision 1. **Generally.** Except as provided in this section, it shall be unlawful for any pharmacist, ~~assistant pharmacist~~, or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber.

Sec. 126. Minnesota Statutes 2006, section 151.21, subdivision 2, is amended to read:

Subd. 2. **Brand name specified.** When a pharmacist receives a written paper or hard copy prescription on which the prescriber has personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has expressly indicated that the prescription is to be dispensed as communicated, the pharmacist shall dispense the brand name legend drug as prescribed.

Sec. 127. Minnesota Statutes 2006, section 151.21, subdivision 3, is amended to read:

Subd. 3. **Brand name not specified.** When a pharmacist receives a written paper or

hard copy prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has not expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects. A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug product unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug other than the brand name drug prescribed.

Sec. 128. Minnesota Statutes 2006, section 151.21, is amended by adding a subdivision to read:

**Subd. 3a. Prescriptions by electronic transmission.** Nothing in this section permits a prescriber to maintain "dispense as written" or "D.A.W." as a default on all prescriptions. Prescribers must add the "dispense as written" or "D.A.W." designation to electronic prescriptions individually, as appropriate.

Sec. 129. Minnesota Statutes 2006, section 214.103, subdivision 8, is amended to read:

**Subd. 8. Dismissal of a complaint.** A complaint may not be dismissed without the concurrence of at least two board members and, upon the request of the complainant, a review by a representative of the attorney general's office. The designee of the attorney general must review before dismissal any complaints which allege any violation of chapter 609, any conduct which would be required to be reported under section 626.556 or 626.557, any sexual contact or sexual conduct with a client, any violation of a federal law, any actual or potential inability to practice the regulated profession or occupation by reason of illness, use of alcohol, drugs, chemicals, or any other materials, or as a result of any mental or physical condition, any violation of state medical assistance laws, or any disciplinary action related to credentialing in another jurisdiction or country which was based on the same or related conduct specified in this subdivision.

**EFFECTIVE DATE.** This section is effective August 1, 2009.

Sec. 130. Minnesota Statutes 2006, section 214.103, subdivision 9, is amended to read:

**Subd. 9. Information to complainant.** A board shall furnish to a person who made a complaint a written description of the board's complaint process, and actions of the board relating to the complaint. The written notice from the board must advise the complainant of the right to appeal the board's decision to the attorney general within 30 days of receipt of the notice.

**EFFECTIVE DATE.** This section is effective August 1, 2009.

## **FROM SENATE FILE 1759**

A bill for an act

relating to health professions; allowing the return of drugs dispensed by pharmacies in certain circumstances; assuring certification of prescriptions; 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 2006, section 151.01, is amended by adding a subdivision to read:

Subd. 31. **Central service pharmacy.** "Central service pharmacy" means a pharmacy that may provide dispensing functions, drug utilization review, packaging, labeling, or delivery of a prescription product to another pharmacy for the purpose of filling a prescription.

Sec. 2. **[151.215] CERTIFICATION.**

A pharmacist must certify a prescription, in compliance with Minnesota Board of Pharmacy rules, before the prescription is dispensed, delivered, mailed, or shipped to a patient or a patient's caregiver. However, if the prescription has been certified by a pharmacist at a licensed central service pharmacy, in compliance with Minnesota Board of Pharmacy rules, an additional certification is not required at the pharmacy that dispenses, mails, or ships the completed prescription to the patient."

"Section 3. Minnesota Statutes 2006, 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 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 adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment."

Section 4. **[151.56] COUNTY RETURN OF UNUSED DRUGS OR MEDICAL DEVICES.**

Notwithstanding Minnesota Rules, part 6800.2700, pharmacies may accept returns of unused drugs 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 on hand twenty-four hours a day, seven days a week and the medication must be stored in a secured locked storage locker.

