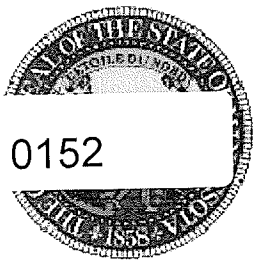


Minnesota Board of Pharmacy

Report to the Legislature on the Controlled Substances Prescription Electronic Reporting System

Approved at the January 30, 2008 Board Meeting

Prepared By Cody Wiberg, Pharm.D., R.Ph. – Executive Director

INTRODUCTION

The Board of Pharmacy is submitting this report to the Legislature in compliance with subdivision 3(c) of M.S. §152.126.

During the 2007 Regular Session, the Legislature passed a health and human services omnibus appropriations bill, which the Governor signed into law on May 25, 2007. Article 11, section 7 of the bill requires the Minnesota Board of Pharmacy to establish a controlled substances prescription electronic reporting system (CSPERS) for most schedule II and III controlled substance prescriptions dispensed in this state. (Appendix B). At present, at least 36 other states have an operational or planned CSPERS. (Appendix E).

The bill also directs the Board to convene a Prescription Electronic Reporting Advisory Committee (PERAC) for the purpose of advising the Board on the development and operation of the CSPERS. After contacting the organizations mentioned in the bill, the Board appointed 12 members to the PERAC (Appendix A). The PERAC met on November 15, 2007 and on January 22, 2008. The focus of these first meetings was on potential changes to Minnesota Statutes §152.126. The PERAC reviewed a draft of this report and of the grant application that will be submitted to the U.S. Department of Justice. The Board of Pharmacy reviewed and approved this report at its January 30, 2008 meeting.

RECOMMENDED CHANGES TO M.S. §152.126

After considering the recommendations of the PERAC, and for the reasons given below, the Board recommends the following changes to M.S. §152.126. (Note that draft legislation is provided in Appendix C).

1. The change made at lines 6 and 7 of Appendix C would add schedule IV controlled substances to the program. PERAC members believe that exclusion of schedule IV drugs might result in prescribers using such drugs when drugs in schedules II or III might be more appropriate. Also, schedule IV includes the benzodiazepines (e.g. Valium).
2. The change made at lines 13 through 15 of Appendix C would remove veterinarians from the definition of a dispenser that is included in M.S. §152.126. The vast majority of outpatient prescriptions in Minnesota are filled by pharmacies, most of which already use electronic systems to dispense medications and bill third party payers. Veterinarians typically do not electronically transmit insurance claims for the drugs that they dispense. Furthermore, per the Board of Veterinary Medicine, it is very unusual for clients to seek out controlled substance prescriptions for illegitimate reasons. In fact, it is relatively uncommon for veterinarians to dispense controlled substances.
3. Members of both the PERAC and the Board of Pharmacy are concerned that the CSPERS might have a chilling effect on the legitimate prescribing of controlled substances for the treatment of pain. The change beginning on line 19 of Appendix C would add a subdivision that refers to M.S. §152.125, which is Minnesota's Intractable Pain Act. This new subdivision would emphasize that no prescriber will be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance in accordance with the provisions of M.S. § 152.125. The following observations are offered in support of adding the proposed subdivision to the law.

The U.S. Substance Abuse and Mental Health Services Administration (SAMSHA) recently

issued a report to Congress on controlled substances monitoring programs. The report has a section concerning access to pain treatment, which begins:

> "Evidence that some CSMPs (controlled substances monitoring program) may exert a negative impact on patients' access to pain treatment was consistent across the literature review, the data analysis, and the information gathered from key informants. The negative effect was particularly pronounced in jurisdictions where a CSMP required the use of a special prescription form, and/or where the CSMP covered Schedule II but not Schedule III analgesics".

In reading the entire section, it becomes clear that the number of prescriptions filled for schedules II and III opioid analgesics are lower in states with a controlled substances monitoring program. Whether that is due to a decrease in inappropriate prescriptions or to a decrease in the issuance of prescriptions for the legitimate treatment of pain is not clear. Therefore, it is possible that the decrease in schedules II and III prescriptions noted in the SAMSHA report could be the result of a chilling effect on the on the legitimate prescribing of controlled substances for the treatment of pain.

As required by the Legislature during the 2007 Regular Session, the Minnesota Board of Medical Practice (BMP) established a Workgroup on Appropriate Prescribing of Controlled Substances for the Management of Pain. The members of the Workgroup are also concerned about the potential for a chilling effect. In their November 10, 2007 report to the BMP, they state:

> "Recent Minnesota legislation requiring that Class II and III controlled substances be recorded and monitored in an electronic, real-time database continues to have the potential to create a 'chilling effect' on health care providers' willingness to use controlled substances when they are medically necessary, and thus should be monitored closely by the legislature".

Several years ago, the Minnesota Boards of Medical Practice, Nursing and Pharmacy issued a *Joint Statement on Pain Management* (Appendix D). In the preamble to the statement, the Board's noted that the

> "effects of unmanaged pain are serious and wide-ranging and, yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs".

Also, the Federation of State Medical Boards of the United States has adopted a *Model Policy for the Use of Controlled Substances for the Treatment of Pain.* The *Model Policy* notes that fears of "investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain".

4. The change at lines 23 and 24 of Appendix C would delay implementation of the CSPERS from January 1, 2009 until January 1, 2010. The CSPERS enabling legislation states: "This section is effective July 1, 2007, or upon receiving sufficient nonstate funds to implement the prescription electronic reporting program, whichever is later". Assuming that the Board is awarded a federal grant, the earliest the money will be disbursed is October 1, 2008. In fact, the Board will not even be notified about the awarding of grants until August or September of 2008. Consequently, it will not be possible to finalize a contract with a vendor until at least October of 2008. It

would be overly optimistic to think that a vendor could implement an electronic reporting system in less than three months. Furthermore, pharmacies will need time to make needed changes to their prescription processing systems. Finally, since the Board will be collecting and storing sensitive data on millions of prescriptions, it is essential that the system be thoroughly tested before it goes live.

5. The change made at lines 25 through 27 of Appendix C would remove the reporting exemption for prescriptions dispensed for less than a 48 hour supply. Staff from the Minnesota Department of Human Services (DHS) note that one of the patterns of prescription use or abuse that they have observed in the Minnesota Health Care Program (MHCP) involves recipients who go to the emergency room on weekends or evenings to obtain a 1 or 2 day supply of controlled substances and yet also have monthly prescriptions for schedule II, III or IV controlled substances filled. DHS staff believes that many of those prescriptions are obtained by people who are seeking additional narcotics for inappropriate reasons.
6. The change beginning at line 41 of Appendix C would add representatives of professional dental and nursing associations to the Prescription Electronic Reporting Advisory Committee. This is an appropriate change since nurse practitioners prescribe a significant proportion of the prescriptions dispensed in this state and dentists often prescribe controlled substances for pain. That fact was recognized by including the Boards of Nursing and Dentistry on the PERAC, but professional dental and nursing associations were inadvertently left out in the original bill.
7. The changes made at lines 58 through 72 of Appendix C concern the data that dispensers will be required to submit to the Board. A prescription number would help better organize the CSPERS database. The address of the patient would help to distinguish between those individuals who share the same name and birth date. The days supply will help users of the system to determine if an individual for whom a prescription was dispensed used the controlled substance more quickly than was prescribed. Finally, the Board will need the flexibility to make changes to data elements. Other states that have controlled substance monitoring systems use vendors to collect data and maintain databases. Most vendors use standards developed by the American Society for Automation in Pharmacy, but some may be able to use standards developed by the National Council on Prescription Drug Programs. NCPDP standards are used by virtually every pharmacy in the country that electronically transmits prescription claims to third party payers. Using NCPDP standards would make transmission of data to the Board nearly effortless to most pharmacies. However, as noted, most vendors currently use ASAP standards. In addition, the federal agency that issues grants for prescription monitoring programs will look more favorably on the applications from states that use ASAP standards. In fact, the grant announcement specifies that enabling statutes or regulations should include provision for "the submission of data elements consistent with standards established by the American Society for Automation in Pharmacy".
8. The change made at lines 89 and 90 is necessary because the existing language is too limiting. Many controlled substances are stimulants that are prescribed for narcolepsy or attention deficit disorders. Other controlled substances are prescribed for anxiety and sleep disorders. The existing language refers only to standards used for the treatment of pain. Permissible users of the CSPERS will be interested in obtaining information about individuals who may be inappropriately seeking prescriptions for controlled substances other than those used for pain relief.
9. The change made at lines 109 and 110 of Appendix C "cleans up" the statute. The existing language uses the term "practitioner" which is not defined in Chapter 152. The proposed language uses "prescriber", which is defined in §152.126.
10. The change made at line 153 of Appendix C eliminates the requirement that the Board evaluate the CSPERS for cost-effectiveness. It may be possible to determine whether or not the CSPERS

is "negatively impacting" the appropriate prescribing of controlled substances. However, determining cost-effectiveness would be difficult and perhaps impossible. Some of the variables that would have to be considered include: controlled substance prescriptions dispensed; prescriptions for drugs used in place of controlled substances; administration of controlled substances in emergency rooms, clinics and other outpatient facilities; outpatient visits and hospitalizations related to the use of controlled substances (or the failure to appropriately use them); and chemical dependency treatment. Since many other factors have an impact on those variables, trying to isolate the impact of the CSPERS would not be easy.

11. The change at line 156 would delay the completion of the evaluation by one year, since implementation of the CSPERS would be delayed by one year if recommendation number four is accepted.

PRELIMINARY IMPLEMENTATION PLANS

The next step in the implementation process will be to submit a grant application to the United States Department of Justice, Bureau of Justice Assistance (BJA). That agency administers the only federal program that currently awards grants to states with controlled substances electronic monitoring programs. (The grant program specified in the federal legislation known as the National All Schedule Prescription Electronic Reporting Act, or NASPER, has never been funded by Congress).

The program administered by the BJA is known as the Harold Rogers Prescription Drug Monitoring Program. Harold Rogers grants can be used to "plan, establish and build a data collection and analysis system; develop an infrastructure to support programmatic activities; facilitate the exchange of information and collected prescription data among states; facilitate the establishment of collaborations; develop a training program for system users; produce and disseminate educational materials; and assess the efficiency and effectiveness of the program".

Since Minnesota does not have an existing monitoring program but does have enabling legislation, the state will be eligible for a 24 month implementation grant of up to $400,000. The deadline for submitting a grant application is February 14, 2008. As mentioned above, those states which are awarded grants will not receive them until after October 1, 2008. Minnesota probably has a good chance of receiving a grant since only one state had their application rejected last year.

Once the grant application has been submitted, Board staff will next turn their attention to the process that will ultimately lead to the selection of a vendor. Specifically, the Board will prepare and publish a Request for Information (RFI), asking that vendors with experience in implementing and operating CSPERS provide information about their services and products. The responses to the RFI may be of use to Board staff if a Request for Proposal (RFP) is drafted. However, responding to the RFI will not provide any advantage to respondents in the event that the Board does publish a RFP for competitive contracting.

The Board will almost certainly need to issue a RFP and enter into a contract with a vendor. Most states with a CSPERS do contract with vendors. Also, the Board of Pharmacy does not currently employ any information technology (IT) staff. The Board does have access to the services of IT staff that is shared by all of the health-licensing boards. In addition, the Board will need to hire its own, dedicated IT staff to work on both the CSPERS project and on other tasks.

Board staff will begin work on the RFP while the application for the federal grant is pending. Assuming that Minnesota is awarded a grant, the Board will publish the RFP and negotiate a contract

with the selected vendor. Once a contract is in place, the system will be designed, necessary hardware will be purchased and installed and training will be offered to the users of the system. It is probable that at least some pharmacies will also need to upgrade their pharmacy software and/or hardware so that they are able to transmit data to the Board in the correct format.

Once the system is operational, Board staff will next publish a RFP for the purpose of contracting with a vendor that has the ability to evaluate the impact of the CSPERS on the prescribing and use of controlled substances. The Board will take into consideration the recommendations for evaluation that were made by the Board of Medical Practice Workgroup on Appropriate Prescribing of Controlled Substances for the Management of Pain. When the results of that evaluation are available, they will be forwarded to the Legislature, as required by the statute.

Note that the Board of Pharmacy will seek input from the Prescription Electronic Reporting Advisory Committee during all stages of the development and operation of the CSPERS.

FISCAL CONSIDERATIONS

As mentioned above, Minnesota is eligible to receive a 24 month implementation grant of up to $400,000. After the CSPERS is implemented, and assuming the Harold Rogers Program is still in existence, the state would be eligible for another 24 month grant of up to $400,000. However, the second grant would have to be used for the enhancement of the existing system. No more than 25% of the second grant can be used for the day-to-day operational costs of the CSPERS. Consequently, state financial support for the system will be required within two years of its start date. There are at least several possible options for the Legislature to consider:

- Authorize an increase in the fees that the Board of Pharmacy charges its licensees and registrants. The Legislature would have to also grant authority to the Board to spend the additional funds collected. This approach is the normal method by which health-licensing boards raise revenues and make expenditures. However, the service provided by this program will primarily be utilized by practitioners licensed by other boards. (By legal definition, "practitioners" are those health professionals authorized by law to prescribe drugs). For example, in Kentucky, 92% of the requests for patient profiles come from prescribers. Consequently, it does not seem appropriate for Board of Pharmacy licensees and registrants to bear all of the costs. This is also a concern of the Minnesota Pharmacist's Association.
- Authorize an increase in the licensing fees that the Board of Pharmacy charges manufacturers of controlled substances. This narrows the impact to those licensees of the Board that produce the controlled substances that are of concern. However, since there are very few such licensees, their fees would have to dramatically increase.
- Authorize the transfer of funds from the health licensing boards that regulate practitioners (i.e. prescribers) to the Board of Pharmacy. (If the recommendations listed above are adopted, veterinarians would not be reporting to or using the system, therefore the Board of Veterinary Medicine would presumably not be required to transfer any funds). The pharmacies licensed by the Board of Pharmacy would also need to have their fees increased. (But the increase would not be as high as it would be if only Pharmacy Board licensees paid for the program). This would spread the cost out to all practitioners and facilities that would derive benefit from the program. However, it is somewhat more complicated than having funds come only from Board of Pharmacy

fees.

- Authorize the transfer of funds from the general fund to the Board of Pharmacy. Ultimately, the public will benefit from this program to the extent that it reduces the illicit use of prescription drugs.

Long-term costs would involve: licensing, maintenance and upgrade of the software and hardware needed to run the system; at least one additional clerical staff person to handle the data requests that would come in from users of the system; and possibly printing, mailing and faxing costs. If the Board receives a large number of data requests, more than one clerical staff person may be required.

In addition, the Board of Pharmacy will need authority to hire an information technology staff person by the middle of 2008 (i.e. before federal grants are received). As mentioned above, the Board currently has no dedicated IT staff, instead relying on the services of two IT staff members that are shared by 18 other licensing boards. The Board is in the process of upgrading its licensing database and has plans to integrate a scanning system into the database in order to create as "paperless" an office as possible. The Board anticipates that the IT staff member will spend about 50% of his/her time working on the CSPERS and the other 50% working on the Board's other IT needs. Consequently, the Board recognizes that it would be appropriate that 50% of the salary of the IT staff member be paid for out of existing Board funds.

APPENDIX A

PRESCRIPTION ELECTRONIC REPORTING ADVISORY COMMITTEE ROSTER

Minnesota Statutes §152.126 requires the Board of Pharmacy to form a "Prescription Electronic Reporting Advisory Committee" (PERAC) consisting of 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 consumer privacy or security advocate; and
7. a consumer or patient rights organization.

The Board consulted with the organizations named in the statute and appointed the following individuals to the PERAC:

Consumer Privacy or Security Advocate
Richard Neumeister
Minnesota Board of Dentistry
Mary Liesch, Complaints & Compliance Supervisor
Minnesota Board of Medical Practice
Alfred Anderson, M.D., D.C.
Minnesota Board of Nursing
Susan E. Lamotte, RN, CNM, MS; APN Consultant
Minnesota Board of Optometry
Beth DeSpiegelaere, O.D.
Minnesota Board of Podiatric Medicine
Keith Hovland, Executive Director
Minnesota Board of Veterinary Medicine
John King, DVM, Executive Director
Minnesota Department of Health
Jim Golden, Director, Division of Health Policy
Minnesota Department of Human Services
Ron Nail, Surveillance and Integrity Review Services
Minnesota Medical Association
David Thorson, M.D.
Minnesota Pharmacists Association
Liz Carpenter, Vice President, Public Affairs
Minnesota Senior Federation (consumer advocacy group)
Lee Graczyk, Issues Director

APPENDIX B

2007 REGULAR SESSION LAW, CHAPTER 147, ARTICLE 11, SECTION 7

Sec. 7. [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. A dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care.

(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. 2. Prescription electronic reporting system. (a) The board shall establish by January 1, 2009, 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 consumer privacy or security advocate; and

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

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

(7) date the prescription was written;

(8) date the prescription was filled;

(9) name and strength of the controlled substance;

(10) quantity of controlled substance prescribed; and

(11) quantity of controlled substance dispensed.

(b) The dispenser must submit the required information by a procedure and in a format established by the board.

(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 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 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.

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.

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

APPENDIX C

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~~ through 5, and those substances defined by the board pursuant to section 152.02, subdivision 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~~ a dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions pursuant to 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. 2. **Treatment of intractable pain.** This section is not intended to limit or interfere with the legitimate prescribing of controlled substances for pain. Therefore, no prescriber shall be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance in accordance with the provisions of section 152.125.

Subd. ~~2~~ 3. **Prescription electronic reporting system.** (a) The board shall establish by January 1, 2010 ~~January 1, 2009~~, an electronic system for reporting the information required under subdivision ~~4~~ 5 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~~ 4. **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;
~~(6)~~ (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~~ 5. **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;
~~(5)~~ (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 such 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~~ 6. 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~~ 7. 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~~ 8. 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~~ 10. 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.

APPENDIX D

MINNESOTA BOARDS OF MEDICAL PRACTICE, NURSING AND PHARMACY JOINT STATEMENT ON PAIN MANAGEMENT

Pain management is a significant issue in health care today. Estimates of Americans experiencing pain range from 50-75 million persons annually. Thirty to fifty percent of patients undergoing cancer treatment experience pain. The effects of unmanaged pain are serious and wide-ranging and, yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs. Factors cited in the under-treatment of pain include concerns about causing addiction or tolerance; inadequate knowledge of controlled substances and pain management; fear of scrutiny and discipline by regulatory agencies; inadequate assessment; and patient reluctance to report pain or to take pain medications.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines on pain management state, "Patients have the right to appropriate assessment and management of pain." (Emphasis added). It is, therefore, incumbent upon Minnesota physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the Minnesota Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If pain is reported, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize these risks;
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

APPENDIX E

SUMMARRY OF STATE CONTROLLED SUBSTANCE MONITORING PROGRAMS

As of April of 2007 there were at least 33 states with operational or planned monitoring programs (See map on next page)

Controlled substance schedules required to be reported by dispensers:

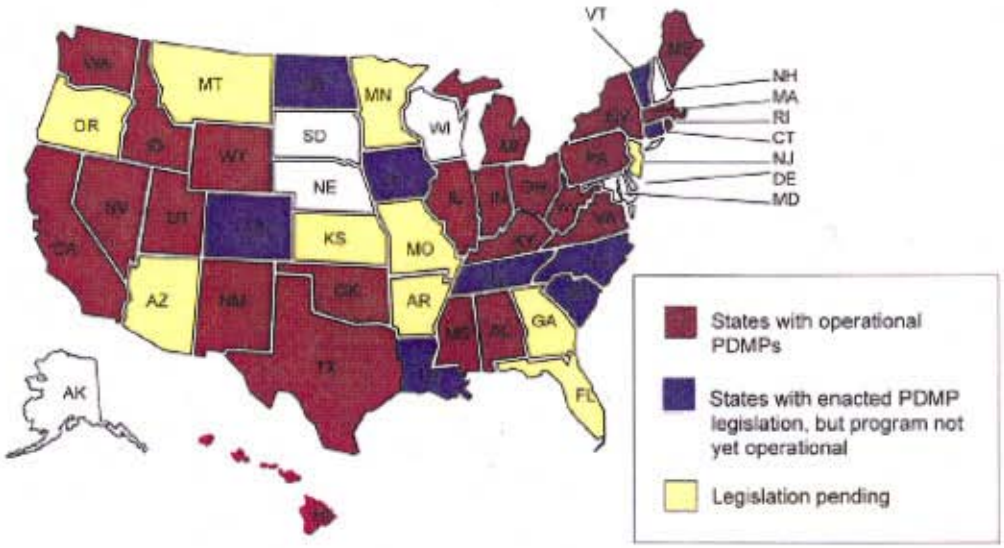
a. Schedules II – V: 16 states
b. Schedules II – IV: 10 states
c. Schedule II only: 4 states
d. Schedule II plus benzodiazepines: 1 state
e. Schedules II and III: 1 state
f. "Limited Triplicate": 1 state

Since November of 2006, at least four states, including Minnesota, have passed legislation:

a. Florida
b. Kansas – established a task force to develop a plan
c. Minnesota
d. North Dakota

The earliest program was enacted in 1972 in Pennsylvania. One was enacted in 1980's, 10 were enacted in the 1990's, and 21 enacted in 2000 or later. The earlier programs did not involve electronic reporting.

Status of State Prescription Drug Monitoring Programs (PDMPs)



National Alliance for Model State Drug Laws

Prepared by the National Alliance for Model State Drug Laws, current through April 17, 2007.

Washington's PMP applies to licensed practitioners and is used for disciplinary purposes or for disciplinary board supervision of a practitioner's practice.