



# MINNESOTA BOARD OF PHARMACY

## **Report to the Legislature in Compliance with Minnesota Statutes Section 3D.06 (Sunset Review)**

*Cody Wiberg, Pharm.D.,  
M.S., R.Ph.*

*Executive Director  
Minnesota Board of  
Pharmacy*

*2829 University Avenue SE  
#530  
Minneapolis, MN 55414*

*(651)201-2830  
(651)201-2837 (fax)*

*[cody.wiberg@state.mn.us](mailto:cody.wiberg@state.mn.us)*

**December 2, 2011**

## Contents

|   |    |
|---|----|
| EXECUTIVE SUMMARY.....  | 2  |
| INTRODUCTION .....  | 7  |
| BACKGROUND INFORMATION .....  | 7  |
| INVENTORY OF COMMITTEE, TASK FORCES AND ADVISORY COUNCILS.....      | 18 |
| APPLICATION TO THE BOARD OF THE CRITERIA FOUND IN M.S. § 3D.06..... | 22 |
| PRIORITY BASED BUDGET .....   | 43 |
| APPENDIX A .....  | 46 |
| APPENDIX B .....  | 47 |
| APPENDIX C .....  | 48 |
| APPENDIX D .....  | 49 |
| APPENDIX E.....   | 50 |
| APPENDIX F.....   | 51 |
| APPENDIX G .....  | 52 |
| APPENDIX H .....  | 53 |
| APPENDIX I.....   | 54 |

## COST OF REPORT

[Minnesota Statutes §3.197](#) states that a “report to the legislature must contain, at the beginning of the report, the cost of preparing the report, including any costs incurred by another agency or another level of government”. The estimated cost of preparing this report was **\$8,765**. That is the approximate value, in terms of salary and benefits, of the time that Board staff spent on preparing the report.

## NOTE ON FORMATTING OF REPORT

Please note that this report has been optimized for electronic viewing. Statutory citations and references to certain parts of the report have been formatted as hyperlinks. Hovering the mouse cursor over the underlined text should open a pop-up window with instructions on how to access the relevant Web site or document part.

## EXECUTIVE SUMMARY

The Minnesota Board of Pharmacy has been in continuous existence as a state agency since 1885. There are two primary reasons why it became evident during the late 19th century that the profession of pharmacy needed to be regulated. First, ever more powerful drugs were being either isolated from natural sources or chemically synthesized. These drugs, while offering better treatment options than previously available medicinals, also caused significant adverse drug events if not properly prepared and dispensed. Second, the latter half of the 19th century saw the widespread marketing of “patent medicines” which were promoted by often unscrupulous sellers as “cure-alls” – good for treating everything from a cold to cancer. In reality, the vast majority of these products contained some combination of just three drugs – cocaine, heroin and alcohol. Rather than curing patients, the patent medicines often caused them to become drug addicts or to die. The use of powerful drugs and the unscrupulous sale of drugs are still reasons for regulating both the practice of pharmacy and the distribution of drugs.

The Board’s mission is to promote, preserve, and protect the public health, safety, and welfare by fostering the safe distribution of pharmaceuticals and the provision of quality pharmaceutical care to the citizens of Minnesota. The Board fulfills this mission through the examination and licensure of pharmacists, regulation of the practice of pharmacy, operation of the Minnesota Prescription Monitoring Program, investigation of complaints, issuance of disciplinary orders and inspection of pharmacies, wholesalers, manufacturers and controlled substance research facilities.

[Minnesota Statutes §151.02](#) creates the Minnesota Board of Pharmacy and specifies that it consists of “two public members as defined by [section 214.02](#) and five pharmacists actively engaged in the practice of pharmacy in this state”. [Minnesota Statutes §151.03](#) reads, in part “Members of the board shall be appointed by the governor. The governor shall make appointments to the board that reflect the geography of the state. The board members who are pharmacists must, as a whole, reflect the broad mix of practice types of pharmacists practicing in Minnesota. . . . Any pharmacist on the board who, during incumbency, ceases to be actively engaged in the practice of pharmacy in this state shall be automatically disqualified from membership”.

The staff of the Board consists of the Executive Director, six pharmacy surveyors (or inspectors), one office manager, three senior office and administrative specialists, one office and administrative specialist and one state program administrator coordinator. There is one vacant position for a level 3 information technology specialist.

The major activities performed by the Board and its staff involve: licensing; standard-setting; compliance; provision of technical assistance to elected public officials, other state agencies, federal agencies and units of local government; serving as a resource to the profession and the public concerning issues involving the practice of pharmacy, the distribution of drugs and the abuse of controlled substances; administering the state’s Prescription Monitoring Program and general administration of the agency.

The Board utilizes the following task force and committees: the Committee on Professional Standards, the Complaint Review Panel, the Variance Committee, the Internship Advisory Committee, the Prescription Monitoring Program Advisory Committee and the Continuing Education Advisory Task Force.

Over the past decade, the Board has made a number of changes to improve efficiency. Those changes have been, in part, necessitated by the budget challenges that have had an impact on all state agencies. In addition, the Board recognizes that it has a duty to the public in general, and specifically to the individuals and businesses that we license and register, to operate as efficiently as possible. As a result, the Board was able to operate for a decade, between 2001 and 2011, without an increase in fees. Examples of specific changes are provided in the body of the report.

Many variables affect the general health of the citizens of this state. Many factors are also involved when analyzing the specific impact that pharmaceuticals have on the health of citizens. These factors include the price of pharmaceuticals, access to health insurance that covers prescription drugs, the prescribing practices of practitioners, the extent to which patients correctly comply with medication regimens, the competency of pharmacists, and the policies and procedures followed by pharmacies, drug manufacturers and drug wholesalers. The Board has an influence on some of those factors – but not all of them. Consequently, it is difficult to determine the precise impact that the Board has on the health of citizens. However, the Board has promulgated rules that require its licensees and registrants to follow standards recommended by the United States Pharmacopoeia, the Joint Commission, the Institute for Safe Medication Practices, the Minnesota Alliance for Patient Safety and other organizations involved in health care standard setting. The Board helps to ensure that the standards are followed by conducting routine, unannounced inspections of the in-state facilities that it licenses and by investigating the complaints that it receives from the public. Thus, while the precise impact of the Board is difficult to assess, it is reasonable to assume that, by actively promoting the above-mentioned standards, the Board is having a positive impact on the public health.

Board staff members are frequently consulted by other state agencies about drug-related issues. For example, during the past several years, the Board’s Executive Director has been a member of task forces established by the Minnesota Department of Health that dealt with pandemic influenza, electronic prescribing, diversion of controlled substances by health care professionals, the abuse of prescription drugs and health care workforce shortages. The Board and its staff have worked with or been consulted by the Office of the Attorney General, the Bureau of Criminal Apprehension, the Minnesota Pollution Control Agency, the Department of Veteran’s Affairs, the Department of Revenue, the Department of Human Services, the Department of Health, the Department of Corrections and the other health licensing boards. The Board has also worked with federal agencies, including the Drug Enforcement Administration and the Food and Drug Administration. The Board has worked with local officials, including county prosecutors and sheriffs; city mayors, administrators and police chiefs and a few school district administrators. Other than providing such assistance and advice, the Board does not engage in any activities that are not specifically permitted per the Statutes.

[Minnesota Statutes §16A.1283](#) prohibits a state agency from imposing a new fee or increasing an existing fee unless the new fee or increase is approved by law. Consequently, the Board must seek legislative and gubernatorial approval for any proposed new fees or fee increases.

[Minnesota Statutes §151.06](#) empowers the Board 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 . . .”. [Minnesota Statutes §151.06](#) empowers the Board to “deny, suspend, revoke, or refuse to renew any registration or license required under this chapter” based upon one of approximately a dozen grounds. That section also empowers the Board to “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”.

Minnesota Statutes [§§214.10](#) and [214.103](#) require the Board to investigate any jurisdictional complaint and empower the Board to attempt to reach a stipulated agreement with a licensee or registrant when the Board has established that it has grounds for imposing discipline. If the allegations are substantiated, the Board may impose discipline on the licensee or registrant involved. The Board must handle all disciplinary activities in accordance with the relevant provisions of the [Administrative Procedures Act \(Chapter 14\)](#).

[Minnesota Statutes §151.06, subd. 5](#) states that the Board “may impose a civil penalty not exceeding \$10,000 for each separate violation, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant of any economic advantage gained by reason of the violation, to discourage similar violations by the licensee or registrant or any other licensee or registrant, or to reimburse the board for the cost of the investigation and proceeding, including, but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board members' per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members”.

The number of complaints received by the board increased in two of the last three complete fiscal years. This appears to be turning into a trend. Although we are only five months into FY 2012, the Board has already received 157 complaints. A complaint data chart found in the body of the report shows a drop in fiscal year-end open cases in FY 2008 and FY 2009 – and an increase in FY 2010 and 2011. During the 2007 Session, the Legislature increased the Board’s appropriation so that an additional pharmacy surveyor could be hired. Having that additional surveyor on staff was the main reason that the number of year-end open cases dropped. Unfortunately, due to budget concerns, the Board did not replace a surveyor that retired in mid-2009. The lack of that surveyor explains the increase in open cases in FY 2010 and 2011. During the 2011 Special Session, the Legislature once again increased the Board’s appropriation and another surveyor was added to the Board’s staff on November 22, 2011. That should once again reduce the number of year-end open complaints.

As authorized by statute, the Board has promulgated the rules found in [Chapter 6800](#) of the Minnesota Rules. The Board’s goal whenever it promulgates rules is to promote the health, safety and welfare of the public in a manner that minimizes the regulatory burden faced by licensees and registrants. In order to attain that goal, the Board encourages public participation in the rule-making process.

The Board makes every effort to comply with federal and state laws and applicable rules regarding equality of employment opportunity and the rights and privacy of individuals and the state law and applicable rules of any state agency regarding purchasing guidelines and programs for historically underutilized businesses.

Board employees follow the statutes, rules and policies regarding conflicts of interest that apply to all state employees. Upon initial employment, staff members are given a notebook that contains as many as 15 statutes, rules or policies that they must follow. They are required to submit a signed document affirming that they have read and understand the materials in the notebook. The Board’s Executive Director and Office Manager hold meetings at least annually to verbally review the materials in the notebooks with staff. In addition, the Board Members and the Executive Director adhere to the relevant statutes regarding public officials. They are defined under [Minnesota Statutes §10A.01](#) as

“public officials” and are therefore subject to various provisions of [Chapter 10A](#).

Abolishing the Board of Pharmacy, without making provisions for the efficient continuation of many of its functions, would put the State of Minnesota at odds with several significant federal laws and rules - and would potentially result in the loss of approximately \$150 million in federal funding. The specific federal laws and rules involved are the Food, Drug and Cosmetic Act, the Controlled Substances Act and certain sections of the Social Security Act relating to Medicare and Medicaid.

Unlike larger agencies, the Board does not have numerous programs, some of which might be deemed to be of higher priority than others. The Board expends funds in just seven areas. Furthermore, the activities in some areas are intertwined with the activities in other areas. Also, due to the budget constraints faced by all state agencies over the past decade, the Board has already reduced expenditures in some areas and found ways to work more efficiently in other areas. In short, the Board has long since “cut out the fat” and, at times, has had to “cut into the bone”. For these reasons, the Board does not perform any functions that are not a priority and that can be cut from its budget.

[Minnesota Statutes §214.055](#) requires the Board to collect fees sufficient to cover expenditures. The fees that are collected are deposited in the State Government Special Revenue Fund (SGSRF). Like most of the health licensing boards, the Pharmacy Board usually collects more fees than it is allowed to expend. Those excess fees are, in theory, kept in the SGRF in case the Board has unexpected expenditures. However, most of the Board’s reserves have been transferred to the General Fund over the past eight years, leaving virtually no “cushion”. The Board has a very tight budget so, unlike larger agencies, it has less ability to respond to unexpected expenses by shifting monies from one area to another. An alternative approach would be for the Board to have the authority to expend the fees it collects without being tied to a specific legislative appropriation. Since fees are established by the legislature and since Minnesota Management and Budget would monitor Board expenditures, adequate external control mechanisms would be in place to ensure that the Board continued to operate in a fiscally sound manner.

Minnesota statutes §§[214.10](#) and [214.103](#) require legal and certain investigative services be provided by the Attorney General’s Office (AGO). The Boards of Dentistry, Medical Practice and Nursing have implemented a system in which Board staff draft certain legal documents (rather than the AGO). The AGO reviews the documents for accuracy and compliance with law. According to those Boards, this practice has resulted in a 50% decrease in the time from receipt of complaint to a review before the Board - at no change in the cost to the Boards. A logical expansion of this practice would be for the health-licensing boards to retain their own legal counsel and investigative staff rather than contracting with the AGO; thus, eliminating a layer of involvement. Legal and investigative services would be shared among the health-related licensing boards on a fee for use basis. Based on the experience with drafting of notices, complaint resolution time would be reduced, and public safety enhanced.

Consolidating all of the health licensing boards into a single, “umbrella” organization would almost certainly result in no costs savings or increases in efficiency. The boards all regulate different professions and work closely with different national organizations. Consequently, the licensing processes used by one board resemble, but are not identical, to the processes used by the other boards. In addition, due to the budget problems faced by all state agencies, the boards have not always expanded staff to keep pace with increased licensing activities. In the case of the Board of Pharmacy, licensing staff sometimes has to work overtime during peak licensing periods. For these reasons, consolidation of the boards would not result in a decrease in the number of staff members working on

licensing.

Similarly, most states that place health licensing boards into an umbrella organization continue to employ individuals to administer and staff the individual boards. Those individuals have policy expertise in the area regulated by the board they administer. Those states also continue to employ individuals to serve as inspectors and complaint investigators. Consequently, consolidation of the boards would likely not result in a decrease in the number of staff members employed by the boards. To the contrary, consolidation might very well introduce a new layer of bureaucracy – the upper-level management and staff necessary to supervise the umbrella organization as a whole. These conclusions are supported by a report prepared in 2003 at the request of Minnesota’s health licensing boards and by a 1999 report of the Office of the Legislative Auditor.



## INTRODUCTION

As Executive Director of the Minnesota Board of Pharmacy, I am submitting this report to the Sunset Commission in compliance with [Minnesota Statutes §3D.06](#), which requires the chief administrative officer of a state agency that is subject to sunset review to report to the Sunset Commission:

- (1) information regarding the application to the agency of the criteria in [section 3D.10](#);
- (2) a priority-based budget for the agency;
- (3) an inventory of all boards, commissions, committees, and other entities related to the agency; and
- (4) any other information that the agency head considers appropriate or that is requested by the commission.

This report contains all of the required information, but not in the order listed above. Background information concerning the mission, history, members, officers, staff, activities, and budget of the Board will be provided first. That will be followed by an inventory of the committees and task forces that are utilized by the Board. Information regarding the application to the agency of the criteria found in [Minnesota Statutes §3D.10](#) will then be provided. The report will conclude with a priority-based budget and several appendices.

## BACKGROUND INFORMATION

### Mission Statement

The Minnesota Board of Pharmacy exists to promote, preserve, and protect the public health, safety, and welfare by fostering the safe distribution of pharmaceuticals and the provision of quality pharmaceutical care to the citizens of Minnesota. The Board fulfills this mission through the examination and licensure of pharmacists, the regulation of the practice of pharmacy, the operation of the Minnesota Prescription Monitoring Program, the investigation of complaints, the issuance of disciplinary orders and the inspection of licensed pharmacies, wholesalers, and manufacturers.

History: why the Board was established and the continued existence of the need that it was created to address

The Minnesota Board of Pharmacy has been in continuous existence as a state agency since it was created by the Legislature in 1885. [Minnesota Statutes §3D.10](#) asks for an “identification of the . . . problem or need that the agency . . . was intended to address”. Identifying the need that the Board was intended to address will require providing a brief history of the regulation of pharmacy in this country. “Pharmacy is an old profession that traces its history back at least 4,000 years ago, when people who prepared medications were different from those who decided what medications people needed to use. Even in the early years of the pharmacy profession, the distinction between medication prescribers and medication preparers was noted in the law, due to the need to avoid conflicts of interest. As American pharmacy began to formally develop in the early 19<sup>th</sup> Century, the need to regulate the profession became evident, and by the end of that century most states had enacted pharmacy practice acts with boards of pharmacy empowered to make and enforce rules for the profession”. (From <http://pharmacy.auburn.edu/pcs/onlinedemo/jurisprudence/pdf/lesson01.pdf>)



There are two primary reasons why it became evident during the 19<sup>th</sup> century that the profession of pharmacy needed to be regulated. First, ever more powerful drugs were being either isolated from natural sources or chemically synthesized. These drugs, while offering better treatment options than previously available medicinals, also caused significant adverse drug events (ADE) if not properly prepared and dispensed. Second, the latter half of the 19<sup>th</sup> century saw the widespread marketing of “patent medicines” which were promoted by often unscrupulous sellers as “cure-alls” – good for treating everything from a cold to cancer. In reality, the vast majority of these products contained some combination of just three drugs – cocaine, heroin and alcohol. Rather than curing patients, the patent medicines often caused them to become drug addicts or to die.

The need for pharmacists to be both formally trained and regulated became apparent at roughly the same time. Consequently, the University of Minnesota established a College of Pharmacy in 1892 that initiated a program consisting of two years of professional studies leading to the doctor of pharmacy degree. The educational requirements have increased over the years so that current graduates must complete a minimum of six years of study to earn the doctor of pharmacy degree. As mentioned above, the Legislature created the Minnesota Board of Pharmacy in 1885, empowering the Board to regulate both the practice of pharmacy and the distribution of drugs and poisons. The Legislature recognized that the public needed protection from adulterated, misbranded, and illicit drugs, and from incompetent, unethical, illegal or unprofessional conduct on the part of pharmacists.

The same basic reasons for regulating the practice of pharmacy and the distribution of drugs continue to this day. Many pharmaceuticals that are dispensed today are even more powerful and potentially dangerous than the drugs that were developed in the late 19<sup>th</sup> century. According to the report *Preventing Medication Errors*, released by the Institute of Medicine in 2006, “in any given week four out of every five U.S. adults will use prescription medicines, over-the-counter drugs, or dietary supplements of some sort, and nearly one-third of adults will take five or more different medications”. The report estimates that “there are at least 1.5 million preventable adverse drug events that occur in the United States each year”, many of which are attributable to the dispensing of drugs by pharmacists. The report estimates that, in addition to the suffering and even death that ADEs cause, they cost the country billions of dollars per year. It is safe to assume that if the boards of pharmacy that exist in each of the fifty states did not regulate the practice of pharmacy, even more ADEs would occur.

Similarly, the unscrupulous sale of drugs also continues, albeit in a different manner from what occurred in the late 19<sup>th</sup> century. During the 1980’s, certain prescription drug marketing practices, while being in some ways beneficial, also introduced pricing differentials that contributed to the diversion of large quantities of pharmaceuticals into a secondary grey market. These practices included the distribution of free drug samples, the distribution of coupons that could be used to purchase drugs at reduced cost, and the sale of deeply discounted drugs to hospitals and other health care entities. The resulting grey market provided a means through which mislabeled, adulterated, expired, subpotent and counterfeit drugs were able to enter the nation's drug distribution system. As a result, Congress passed the Prescription Drug Marketing Act (PDMA) of 1987, which President Ronald Reagan signed into law on April 22, 1988. When signing the bill, President Reagan remarked that he supported “the expressed goal of this legislation, which is to reduce potential public health risks that may result from the distribution of mislabeled, subpotent, counterfeit, or adulterated prescription drugs in the secondary source market, the so-called diversion market”. One provision of the PDMA requires all drug wholesalers to be licensed and regulated by the states, in accordance with guidelines prescribed by the Act. Most states, including Minnesota, have designated pharmacy boards to license drug wholesalers.

## Membership and officers

[Minnesota Statutes §151.02](#) creates the Minnesota Board of Pharmacy and specifies that it consists of “two public members as defined by [section 214.02](#) and five pharmacists actively engaged in the practice of pharmacy in this state”. Each pharmacist must have had at least five consecutive years of practical experience as a pharmacist immediately preceding appointment. [Minnesota Statutes §151.03](#) reads, in part “Members of the board shall be appointed by the governor. The governor shall make appointments to the board that reflect the geography of the state. The board members who are pharmacists must, as a whole, reflect the broad mix of practice types of pharmacists practicing in Minnesota. . . . Any pharmacist on the board who, during incumbency, ceases to be actively engaged in the practice of pharmacy in this state shall be automatically disqualified from membership”.

The following are the current members of the Board. A complete listing of all individuals who have served as members of the Board of Pharmacy since 1950 can be found in [Appendix I](#).

| <b>MN Board of Pharmacy Current Members (November, 2011)</b> |                        |
|--|------------------------|
| <b>Name and Address</b>                                      | <b>Terms</b>           |
| <b>James M. Koppen, President</b>                            | 4/09 – 1/13            |
| 14719 Cross Lake Road  |                        |
| Pine City, MN 55063  | <b>(pharmacist)</b>    |
| <b>Laura Schwartzwald, Vice-President</b>                    | 4/10 – 1/14            |
| Guidepoint Pharmacy #101                                     |                        |
| 108 S 6th Street Suite 1                                     |                        |
| Brainerd, MN 56401   | <b>(pharmacist)</b>    |
| <b>Kay L. Hanson</b>   | 7/04 - 3/08            |
| 9208 Dunbar Knoll N.   | 3/08 – 1/12            |
| Brooklyn Park, MN 55443                                      | <b>(pharmacist)</b>    |
| <b>Ikram-UI-Huq</b>  | 6/06 – 4/10            |
| 8749 134th Street  | 4/10 – 1/14            |
| Apple Valley, MN 55124                                       | <b>(public member)</b> |
| <b>Karen Bergrud</b>   | 5/07 – 6/11            |
| 503 Fairway Court North                                      | 6/11 – 1/15            |
| Stewartville, MN 55976                                       | <b>(pharmacist)</b>    |
| <b>Stuart T. Williams</b>                                    | 6/11 – 1/15            |
| Henson & Efron, PA   |                        |
| 220 S. 5th St. Suite 1800                                    |                        |
| Minneapolis, MN 55402-4503                                   | <b>(public member)</b> |
| <b>Bob Goetz</b>   | 11/11 – 01/12          |
| 2495 Wildwood Ridge  |                        |
| Red Wing, MN 55066   | <b>(pharmacist)</b>    |

[Minnesota Statutes §151.05](#) requires the Board to “annually elect one of its members as president and one of its members as vice-president, and a pharmacist, who may or may not be a member, as secretary”. As noted in the table above, Mr. James Koppen currently serves as the Board’s President

and Ms. Laura Schwartzwald serves as the Vice President. On an annual basis, after conducting a performance review, the Board decides whether or not the Executive Director should continue serving as the Board’s Secretary. The Board’s current Executive Director/Secretary, Dr. Cody Wiberg, has served since September 21, 2005. A complete list of the Board’s Executive Directors and Secretaries, dating back to 1911, is available in [Appendix I](#). Note that Minnesota Statutes §214.04, subd. 3 states that: “the executive director of each health-related board . . . shall be the chief administrative officer for the board but shall not be a member of the board. The executive director . . . shall maintain the records of the board, account for all fees received by it, supervise and direct employees servicing the board, and perform other services as directed by the board”.

### Board Staff

[Minnesota Statutes §151.06](#), subd. 1(a)(8) empowers the Board to “employ necessary assistants and adopt rules for the conduct of its business”. [Chapter 214](#) also contains provisions that allow the health-licensing boards to hire staff. In addition to the Executive Director, the Board of Pharmacy currently employs six pharmacy surveyors (or inspectors), one office manager (OM), three senior office and administrative specialists (OASS), one office and administrative specialist (OAS) and one state program administrator coordinator (SPAC). There is one vacant position for a level 3 information technology specialist (ITS3). The following table lists the current employees of the Board. A chart of organizational relationships can be found in [Appendix A](#). The duties performed by the staff members will be described in the next section of this report.

| <b>Minnesota Board of Pharmacy Staff</b> |                                     |
|--|-------------------------------------|
| <b>Staff Member</b>                      | <b>Position</b>                     |
| Cody Wiberg                              | Executive Director                  |
| Pat Eggers                               | Office Manager                      |
| Candice Fleming                          | Pharmacy Surveyor                   |
| Stu Vandenberg                           | Pharmacy Surveyor                   |
| Les Kotek                                | Pharmacy Surveyor                   |
| Michele Mattila                          | Pharmacy Surveyor                   |
| Karen Schreiner                          | Pharmacy Surveyor                   |
| Steven Huff                              | Pharmacy Surveyor                   |
| Barbara Carter                           | PMP Manager (SPAC)                  |
| (vacant)                                 | Information Technology Specialist 3 |
| Sojourner Killingsworth                  | PMP Coordinator (OASS)              |
| Lee Ann Olson                            | Licensing Specialist (OASS)         |
| Jennifer Fischer                         | Licensing Specialist (OASS)         |
| Collette Zelinsky                        | Receptionist (OAS)                  |

### Activities

The major activities performed by the Board and its staff involve: licensing; standard-setting; compliance; provision of technical assistance to elected public officials, other state agencies, federal agencies and units of local government; serving as a resource to the profession and the public concerning issues involving the practice of pharmacy, the distribution of drugs and the abuse of controlled substances; administering the state’s Prescription Monitoring Program and general

administration of the agency (e.g budget planning, purchasing, human resource issues, et cetera).

### Licensing

The Board licenses pharmacists, pharmacies, drug and medical gas manufacturers, drug and medical gas wholesalers, and medical gas distributors. It registers pharmacy technicians, pharmacy interns, pharmacy preceptors and controlled substance researchers. Licensing tasks are largely performed by the licensing specialists, who process applications and make sure that licenses are issued in a timely manner. When issuing initial licenses and registrations, staff must verify certain information by obtaining and reviewing documents such as birth certificates, college transcripts, articles of incorporation, et cetera. Staff must also verify that out-of-state facilities are licensed by the state in which they are located and must obtain copies of any disciplinary orders that the facilities have been subject to. When all information has been verified and when the appropriate fees have been paid, staff prints and mails out license or registration certificates. For renewals, staff sends out renewal notices, processes returned applications and issue the appropriate certificate. (As noted below, some renewals are primarily completed online).

The Executive Director reviews applications for out-of-state pharmacies, manufacturers and wholesalers to ensure that certain legal requirements have been met. The office manager and receptionist also perform some tasks associated with licensing. The surveyors review the applications and plans for all new in-state pharmacies to ensure that requirements for security, patient counseling, and safe compounding and dispensing will be met. Every new in-state pharmacy, drug wholesaler, drug manufacturer, medical gas distributor and controlled substance research lab is inspected by a surveyor before it is allowed to open. Pharmacists and technicians can renew their licenses using the online services section of the Board's Web site. The following chart shows the licenses and registrations issued by the Board during the past ten years. Please note that the total number of licensees and registrants has increased every year, with an overall increase of 53.2% during that time frame.

| License/registration type             | Number licensed or registered by year |               |               |               |               |               |               |               |               |               |
|---------------------------------------|---------------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                       | 2001                                  | 2002          | 2003          | 2004          | 2005          | 2006          | 2007          | 2008          | 2009          | 2010          |
| Pharmacist                            | 5,638                                 | 5,853         | 6,023         | 6,226         | 6,357         | 6,502         | 6,629         | 6,980         | 7,294         | 7,546         |
| Technician                            | 4,707                                 | 5,354         | 5,843         | 6,269         | 6,581         | 6,830         | 7,336         | 8,114         | 8,288         | 8,552         |
| Pharmacy                              | 1,369                                 | 1,409         | 1,471         | 1,502         | 1,586         | 1,601         | 1,649         | 1,669         | 1,693         | 1,701         |
| Drug Wholesaler                       | 725                                   | 773           | 837           | 870           | 885           | 903           | 936           | 974           | 1,018         | 1,067         |
| Drug Manufacturer                     | 249                                   | 239           | 247           | 260           | 266           | 268           | 288           | 322           | 361           | 401           |
| Medical Gas Distributors              | 35                                    | 35            | 44            | 40            | 39            | 40            | 39            | 47            | 56            | 68            |
| Controlled Substance Researcher       | 113                                   | 193           | 348           | 422           | 425           | 375           | 371           | 387           | 404           | 498           |
| Pharmacy Intern                       | 495                                   | 605           | 646           | 672           | 755           | 891           | 1,006         | 1,166         | 1,435         | 1,436         |
| Preceptors                            | 810                                   | 913           | 977           | 985           | 1,067         | 1,596         | 1,432         | 1,421         | 1,397         | 1,456         |
| <b>Totals</b>                         | <b>16,142</b>                         | <b>17,376</b> | <b>18,439</b> | <b>19,250</b> | <b>19,966</b> | <b>21,012</b> | <b>21,693</b> | <b>23,088</b> | <b>23,955</b> | <b>24,735</b> |
| <b>Year-to-year per cent increase</b> |                                       | 7.64%         | 6.12%         | 4.40%         | 3.72%         | 5.24%         | 3.24%         | 6.43%         | 3.76%         | 3.26%         |

## *Standard Setting*

[Minnesota Statutes §214.001](#) states, in part, that the “legislature finds that the interests of the people of the state are served by the regulation of certain occupations. The legislature further finds . . . that it is desirable for boards composed primarily of members of the occupations so regulated to be charged with formulating the policies and standards governing the occupation”. Notwithstanding this language, the reality with most professions, including pharmacy, is that standards of practice evolve over time through a process involving many interested parties. Individual pharmacists, companies that own pharmacies, drug manufacturers and wholesalers, colleges of pharmacy, professional associations, accreditation organizations, the federal government, the state Legislature and the Board of Pharmacy all play a role in setting standards for the profession. The Board strives to work cooperatively with all other interested parties, while always being mindful that its primary duty is to serve and protect the public.

One of the ways in which the Board helps set standards of practice involves the promulgation of rules. Since one of the specific criteria for review found in [Minnesota Statutes §3D.10](#) is “an assessment of the agency’s rule-making process”, a discussion of the Board’s rule-making process can be found in the section of this report that addresses the application of the §3D.10 criteria to the Board’s operations.

The Board also helps set standards of practice in other ways. The Board occasionally issues interpretations of Minnesota statutes and rules involving the practice of pharmacy. This typically occurs when either the language of the statute or rule is ambiguous or when some new development (e.g. introduction of a new type of technology) is not adequately addressed in existing statutes or rules. Before issuing such interpretations, the Board usually solicits input from the profession and the public and also seeks legal advice from the Office of the Attorney General.

The Board makes recommendations to the Legislature concerning statutory changes that may be necessary to address evolving standards of practice. The Board sometimes makes such recommendations after being asked by a legislator for technical assistance. Sometimes the Board makes recommendations without being asked for such assistance, usually when the Board becomes aware of an issue that is not adequately addressed in current statutes and rules.

The Board and its staff members also help set standards by working, in a variety of ways, with professional associations, accreditation organizations, educational institutions and state and federal agencies. The Board is an active member of the National Association of Boards of Pharmacy (NABP), an organization to which all state boards of pharmacy belong. The Board has offered input into the NABP Model Practice Act and, over the years, board members and staff have participated on NABP committees and task forces. The Board is also an active member of the Alliance of States with Prescription Monitoring Programs, the National Association of State Controlled Substances Authorities, the Citizen Advocacy Center and the Council on Licensure, Enforcement and Regulation. Board members and staff have also participated on task forces and advisory committees established by the Minnesota Department of Health, the Minnesota Bureau of Criminal Apprehension, the Minnesota Pharmacists Association, the Minnesota Alliance for Patient Safety and the Accreditation Council for Pharmacy Education.

## *Compliance*

As mentioned above, the Board's primary mission is to protect the public from adulterated, misbranded, and illicit drugs, and from incompetent, unethical, illegal or unprofessional conduct on the part of pharmacists or other licensees and registrants. The compliance activities undertaken by the Board and its staff are integral to carrying out that mission. Compliance activities include routine inspections of the in-state facilities licensed by the Board, the granting of rule variances, investigation of complaints and, when necessary, discipline.

**Inspections.** [Minnesota Statutes §151.06](#) empowers the Board 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”. Nearly every board of pharmacy across the United States employs compliance officers to carry out such inspections because the proper storage and handling of pharmaceuticals is critical to their safe use. The Board's pharmacy surveyors conduct routine, unannounced inspections of in-state pharmacies, drug wholesalers, drug manufacturers, medical gas distributors and controlled substance research labs or offices. When an inspector finds that a facility is not in compliance with state or federal statutes or rules regarding its operations, the facility receives a notice which identifies the specific violations and suggests appropriate corrective action. A surveyor will follow up with another unannounced inspection to confirm that the facility has come into compliance with the statute or rule that had been violated. If the facility has not corrected the deficiency to the satisfaction of the surveyor, he or she will report that fact to the Executive Director who then brings the matter before the Board's Committee on Professional Standards for consideration of possible disciplinary action. (A description of the Committee is found below). A surveyor will sometimes find a violation which puts the public at significant and imminent risk of harm. In such cases, the surveyor will immediately report the matter to the Executive Director (in addition to suggesting corrective actions to the facility). This process is in keeping with the Board's philosophy of working cooperatively with licensees and registrants in order to encourage voluntary compliance with the statutes and rules. The Board prefers to resort to discipline only when such cooperation cannot be obtained or when very significant violations have occurred.

The Board's goal is for every licensed facility located within the state to have an unannounced, routine inspection at least once every two years. However, the Board has not been able to meet that goal for quite some time – for several reasons. The use of new technologies and the adoption of tougher standards by national accrediting and standard setting organizations have made inspections more time-consuming. As just one example, the United States Pharmacopeia (USP) adopted significant new standards for sterile compounding in 2004. The standards were developed after a Food and Drug Administration (FDA) study found that a third of compounded sterile preparations had product deficiencies. The USP is a scientific organization that sets standards for the quality, purity, identity, and strength of drugs manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the FDA. However, the FDA rarely enforces those standards for pharmacies since, in most states, the board of pharmacy enforces them. Accrediting organizations also require pharmacies to follow those standards. Inspecting pharmacies that engage in sterile compounding takes much longer than it used to before USP adopted these new standards.

Staffing issues have also made it difficult to meet the inspecting goal mentioned above. Over the past half dozen years, the Legislature has required the Board to implement a major new controlled substance monitoring program and to complete several studies and reports. The increased workload has meant that one of the surveyors has had to take over some responsibilities concerning variance



processing and complaint investigations that used to be handled by the Executive Director. In 2007, the Legislature authorized an increase in the Board’s appropriation so that an additional surveyor could be hired. That led to an increase in the number of completed inspections in 2008 and 2009. However, a surveyor retired in 2009 and could not be replaced due to budgetary concerns. As might be expected, the number of completed inspections once again decreased. As mentioned above, during the 2011 Special Session the Legislature increased the Board’s appropriation to allow for the hiring of a surveyor to replace the one who retired in 2009. That will lead to an increase in the number of inspections completed, but will still not allow the Board to reach its inspection goal. However, the Board is considering a plan to equip surveyors with specialized tablet computers that would allow them to use an electronic inspection form and automatically upload the forms, via a mobile data network, to the Board’s licensing database. This would allow the surveyors to spend less time in the office entering inspection data into the database. The following chart shows the number of inspections completed by year between 2004 and 2010.

**Number of facility inspections**

| Year                                   | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
|--|------|------|------|------|------|------|------|
| Number of in-state licensed facilities | 2100 | 2142 | 2106 | 2141 | 2192 | 2211 | 2279 |
| Number of facility inspections         | 849  | 781  | 737  | 526  | 636  | 684  | 518  |

**Variations.** [Minnesota Statutes §151.06](#) makes it the “duty of the board to make and publish uniform rules . . . for carrying out and enforcing the provisions” of Chapter 151. Consequently, the Board has adopted the rules that are found in [Chapter 6800](#) of the Minnesota Rules. (A discussion of the Board’s rule-making process is included below, in the section regarding the application to the Board of the criteria found in Minnesota Statutes §3D.10). There are several provisions in [Minnesota Statutes Chapter 14](#) that concern the issuance of variances (i.e. exceptions) to the rules. Due to the introduction of new technologies and to changes in the standards of practice, the Board receives variance requests on a regular basis. The Board’s Variance Committee, which is described below, reviews the variance requests and makes recommendations to the full Board. The requests are almost always granted, but the Board often places conditions on the variance that are crafted to make sure that new technologies and procedures are used in a manner that does not endanger the public.

**Complaint investigation.** Minnesota Statutes §§[214.10](#) and [214.103](#) require the Board to investigate every jurisdictional complaint that it receives. The Board’s Executive Director reviews each complaint shortly after it is received to determine if the Board does have jurisdiction. Almost all complaints received are jurisdictional, but the Board occasionally receives complaints about issues over which it has no authority (e.g some individuals have complained about the prices charged by a pharmacy for prescription drugs but the Board has no authority to regulate prices). All jurisdictional complaints are logged into the Board’s licensing and regulatory database by one of the licensing specialists.

Most complaints received by the Board involve either dispensing errors or allegations that a pharmacist is not practicing up to acceptable standards. Those complaints are investigated by one of the pharmacy surveyors, who usually meets with pharmacy staff, reviews the policies and procedures of the pharmacy and directs pharmacy staff to make necessary changes to policies and procedures to come into compliance with the statutes and rules. The surveyor then files an investigative report, along with any evidence collected, with the Executive Director. The Executive Director places the matter before the Board’s Committee on Professional Standards (see below, in the section that provides the required inventory of committees and task forces, for a description of the activities of the Committee).



Complaints of this type are usually dismissed because either the investigation has not substantiated the allegations or the infraction can be handled in a non-disciplinary manner. When a complaint is dismissed, the complainant receives a letter explaining the handling of their complaint.

The Board also receives complaints alleging that a licensee or registrant is chemically dependent, has stolen narcotics or stimulants from his or her employer, has reported to work under the influence of alcohol, is mentally or physically unable to safely practice pharmacy, has engaged in sexually inappropriate activity with patients or has been charged with a serious crime. The Board typically asks the Office of the Attorney General (AGO) to investigate such complaints. The Board has authority under [Minnesota Statutes §214.103](#) to issue subpoenas and occasionally does issue them for the cases investigated by the AGO. At the conclusion of the investigation, the AGO submits an investigative report to the Board's Executive Director, who then places the matter before the Committee on Professional Standards. The Committee usually ends up referring these types of complaints to the Board's Complaint Review Panel (CRP) for consideration of disciplinary action. (A description of the activities of the CRP can be found below in the section that provides the required inventory of committees and task forces).

**Discipline.** The Board prefers to resolve complaints through non-disciplinary means, if possible. As mentioned above, the Board's general approach is to work cooperatively with licensees and registrants in order to encourage voluntary compliance with the statutes and rules. However, some infractions are so egregious that discipline is warranted. As an example, several years ago the Board disciplined five pharmacists and a pharmacy for knowingly filling thousands of prescriptions for narcotics and other frequently abused drugs based on purported prescriptions that they should have known were not issued for valid medical purposes. One individual died of a narcotic overdose, although it was not possible to determine that the drugs which caused the overdose were dispensed by the Minnesota pharmacists involved. The Board most commonly disciplines pharmacists who have stolen narcotics or stimulants from their employer and then abused them. When imposing discipline, the Board follows all of the due process procedures required under [Minnesota Statutes Chapter 14](#).

*Provision of technical assistance to elected public officials, other state agencies, federal agencies and units of local government.*

Board staff provides objective, nonpartisan technical assistance to legislators and their staff and to the Office of the Attorney General. In addition, staff has been consulted by the Minnesota Departments of Health, Human Services, Corrections, Public Safety and Veteran's Affairs and by the Minnesota Pollution Control Agency on a variety of pharmacy or drug-related issues. Examples of activities and issues that staff members have worked on over the past half dozen years include:

- Legislature
  - Scheduling of controlled substances, including synthetic designer drugs
  - Preventing prescription drug abuse
  - Regulation of pseudoephedrine to prevent methamphetamine abuse
  - Pharmaceutical waste
  - Repackaging of prescription drugs for nursing home residents
  - Regulating pharmacy benefit managers
  - Marketing practices of pharmaceutical manufacturers
  - Generic substitution for epilepsy drugs
  - Allowing medication returns from jails

- Pharmacist “conscience clause”
- Definition of ‘practice of pharmacy”
- Tamper-resistant prescription pads
- Attorney General’s Office
  - Provision of information concerning a variety of drug and pharmacy-related issues about which citizens have complained to the AGO
- Health Department
  - Antiviral Subgroup – pandemic influenza
  - Electronic Prescribing Workgroup
  - Health Workforce Shortage Study Work Group
  - Drug Diversion Task Force
  - Tribe declared public health emergencies related to substance abuse
- Human Services
  - Federally required annual assessment of patient counseling by pharmacists
  - Provision of pharmacy services in state-run community behavioral health hospitals
- Minnesota Pollution Control Agency
  - Pharmaceutical waste
- Public Safety
  - Regulation of pseudoephedrine to prevent methamphetamine abuse
- Corrections
  - Provision of pharmacy services to state prisons
- Veteran’s Affairs
  - Provision of pharmacy services to state veteran’s homes

The Board works, as necessary, with the United States Drug Enforcement Administration (DEA) in the investigation of cases involving the diversion and abuse of controlled substances. For example, the Board and the DEA recently exchanged information that lead to the arrest and prosecution of an individual who used his drug wholesaling business to illegally sell narcotics to street dealers and addicts. The Board also revoked the individual’s drug wholesaler license.

The Board has also conducted joint investigations with the United States Food and Drug Administration (FDA). For example, the Board and the FDA took action against a pharmacy that was compounding contaminated ophthalmic solutions that caused patients across the country to develop serious eye infections and even blindness. The FDA worked on getting the solution recalled and the Board used its authority to require the pharmacy to meet more stringent sterile compounding standards that had been adopted by the United States Pharmacopeia at about the time this incident happened.

The Board’s staff is contacted regularly by local law enforcement agencies and county attorney offices that have questions about the state’s schedules of controlled substances. The Board has worked with the mayors and city administrators of several rural communities to ensure continued access to pharmacy services when the only pharmacy in those communities closed down. Board staff has been contacted by several school district administrators who have had questions about the proper storage and administration of student medications.

*Serving as a resource to the profession and the public concerning issues involving the practice of pharmacy, the distribution of drugs and the abuse of controlled substances*

Board staff responds to questions received from the public and from the individuals and businesses that the Board licenses and registers. The Board receives many such questions every day. The questions typically concern the laws and rules enforced by the Board. Licensees and registrants also frequently ask the Board's professional staff to review proposed policies and procedures, pharmacy construction plans and innovative practice ideas. The Executive Director and the pharmacy surveyors collectively have over 200 years of experience working in a variety of pharmacy practice settings. That experience, plus a thorough knowledge of the federal and state laws and rules applicable to drug distribution and pharmacy practice, make the Board's professional staff a valuable resource to licensees and registrants.

#### *Administering the state's Prescription Monitoring Program*

The abuse and diversion of prescription drugs is a significant and persistent problem in the United States. Data from an annual survey conducted by the federal Substance Abuse and Mental Health Services Administration (SAMHSA) reveals that approximately 6.9 million individuals aged 12 or older are nonmedical users of controlled prescription drugs (opioid pain relievers, tranquilizers, sedatives, or stimulants). While the number of non-medical users has remained relatively stable over the past 5 years, the number of treatment admissions and deaths from overdoses of controlled prescription drugs has increased significantly.

As part of an effort to address prescription drug abuse in this state, Governor Tim Pawlenty signed legislation on May 5, 2007 that created [Minnesota Statutes §152.126](#). That legislation had very broad, bipartisan support in the Legislature. This section of statutes required the Minnesota Board of Pharmacy to establish an electronic system for the reporting of schedule II, III and IV controlled substance prescriptions dispensed to residents of the state. The Board subsequently implemented the Minnesota Prescription Monitoring Program (PMP), making Minnesota the 34<sup>th</sup> state to establish such a program. (Currently, every state but New Hampshire and Missouri either has a controlled substances monitoring program in place or on the drawing board). Daily data collection from dispensers of controlled substances began on January 4, 2010 with authorized access to the data commencing on April 15, 2010.

As of November 2011, almost 5,600 authorized prescribers and pharmacists, having direct access to timely prescription history data, have conducted over 160,000 queries of the more than 6.6 million records currently stored in the secure database. These queries have helped to determine appropriate medical treatment and interventions, or in some cases have detected "doctor shopping" behaviors. In addition, the data helps to identify patients who could benefit from referral to a pain-management specialist or those who are at risk for addiction and may be in need of substance abuse treatment.

Medical Examiners and Coroners, in an effort to determine an individual's cause of death, have requested more than 50 reports on decedents from the PMP since its implementation.

Through the PMP, personnel from the Minnesota Department of Human Services, Restricted Recipient Program, performed approximately 3,000 queries of the database to identify recipients whose usage of controlled substances warrants restrictions to a single primary care physician, a single outpatient pharmacy, or a single hospital. This helps reduce fraud and abuse in Medicaid, Minnesota Care and other programs administered by DHS.

Additionally, through the PMP, individuals engaged in potentially unlawful possession and/or diversion of controlled substances have also been identified. Law enforcement officials have served more than 100 search warrants on the PMP, requesting an individual's controlled substance prescription history to support an investigation.

The PMP is not funded through General Fund tax revenues. Instead, it is funded through the licensing fees collected by the Board of Pharmacy and by the boards that license healthcare professionals who are authorized by law to prescribe controlled substances. In addition, the Board has received nearly \$800 thousand dollars in federal grants (which were first authorized by the Bush Administration and later reauthorized by the Obama Administration). The Board has also received \$39,000 in grants from the National Association of State Controlled Substances Authorities.

### *General administration of the agency*

[Minnesota Statutes §214.04](#), subd. 3 states, in part, that the “executive director of each health-related board . . . shall be the chief administrative officer for the board but shall not be a member of the board. The executive director . . . shall maintain the records of the board, account for all fees received by it, supervise and direct employees servicing the board, and perform other services as directed by the board”. Consequently, the Board's Executive Director, assisted by the Office Manager, performs the tasks that are necessary for the general administration of the agency. These tasks include: developing a budget to be submitted to the Board, the Governor and the Legislature for approval; ensuring that Board expenditures are in line with the approved budget; ensuring that state procurement and contracting rules are followed; managing Board staff members; enforcing state personnel policies; maintaining the Board's records and other tasks as necessary to ensure the smooth daily operation of the Board's office.

## INVENTORY OF COMMITTEE, TASK FORCES AND ADVISORY COUNCILS

### Committee on Professional Standards

The Committee on Professional Standards (Committee) reviews the investigative reports and evidence submitted by the Board's pharmacy surveyors or by the investigators of the Attorney General's Office (AGO) Health-Licensing Division. [Minnesota Statutes §214.103, subd. 8](#) states, in part, that 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”. In order to meet these requirements, the Committee consists of two members of the Board, the Executive Director and the chief pharmacy surveyor. In addition, the Assistant Attorney General assigned to the Board attends all meetings of the Committee. (Consequently, all complaints are reviewed by a representative of the AGO – even when the complainant has not requested such review).

The Board members serve on this Committee on a rotating basis and the Committee meets six to eight times per year (depending on the number of complaints that need to be reviewed). On average, the meetings last between two to four hours. The Executive Director, the chief pharmacy surveyor and one office specialist spend a portion of their time preparing for the Committee's meetings and completing required paperwork. Consequently, part of the costs associated with the Committee consists of a portion of the salaries and benefits paid to those individuals. The Board members are each paid a \$55

per diem and are reimbursed for mileage. The AGO charges the Board for the services of the assistant attorney general who provides legal counsel to the Committee. Case materials are provided to the Committee members in electronic format whenever possible in order to minimize printing and postage costs.

Since complaint investigation data is considered private under [Minnesota Statutes §13.41](#), the meetings of the Committee are not open to the public. The Committee dismisses a complaint if the investigation has not substantiated the allegations or if the infraction can be handled in a non-disciplinary manner. If the Committee determines that disciplinary action against a licensee or registrant might be warranted, the Executive Director works with the Assistant Attorney General to initiate the due process procedures required under [Minnesota Statutes Chapter 14](#). This typically includes an appearance by the licensee or registrant before a Complaint Review Panel.

### Complaint Review Panel

The Complaint Review Panel (Panel) consists of two Board members, with members serving on a rotating basis. Panels meet six to eight times per year, depending on the number of disciplinary cases that need to be handled. The Board's Executive Director serves as staff to the Panel and an Assistant Attorney General serves as counsel. Consequently, part of the costs associated with the Committee consists of a portion of the salary and benefits paid to the Executive Director. The Board members are each paid a \$55 per diem and are reimbursed for mileage. The AGO charges the Board for the services of the Assistant Attorney General who provides legal counsel to the Panel. Case materials are provided to the Panel members in electronic format whenever possible in order to minimize printing and postage costs.

A licensee or registrant who appears before the Panel receives a Notice of Conference (NOC) that is prepared by the Assistant Attorney General and reviewed by the Executive Director. The NOC informs the licensee or registrant of the date and time of the Panel meeting, of the allegations made against them, and of their right to be represented by an attorney. It also provides them with other information required to ensure that they understand their due process rights. The Panel may dismiss the complaint if the testimony and evidence provided by the licensee or registrant, as weighed against the investigative reports and evidence submitted by the Board's pharmacy surveyors or by the investigators of the AGO, persuades the members that the allegations have not been substantiated or that the infraction can be handled in a non-disciplinary manner. If the Panel determines that discipline is warranted, it will attempt to resolve the matter by proposing a Stipulation and Consent Order (SCO) to the licensee or registrant. Assuming that the licensee or registrant agrees to the discipline proposed by the Panel, the SCO is presented to the full Board for consideration. If the full Board approves the SCO, it is served on the licensee or registrant who must then comply with the terms of the Order. Very rarely, a licensee or registrant will not agree to a SCO and the Board initiates a contested-case hearing before an administrative law judge.

### Variance Committee

As mentioned above, the Board regularly receives requests for variances to the rules that it administers. At one time, all variance requests were considered by the full Board at one of its regularly scheduled business meetings. However, due to an increased number of variance requests, the Board decided to establish a Variance Committee to review such requests and make recommendations to the full Board. The Variance Committee consists of two Board members, the chief pharmacy surveyor, two other

surveyors and the Board's Executive Director. The Board members and the pharmacy surveyors serve on a rotating basis. Part of the costs associated with the Committee consists of a portion of the salaries and benefits paid to the Board staff members that participate. The Board members are each paid a \$55 per diem and are reimbursed for mileage.

The Variance Committee meets approximately eight times per year for a period of four to six hours per meeting. The individuals and businesses requesting a variance often attend the meeting to provide information to the Committee. The Variance Committee makes its recommendations to the Board based on the standards established in Minnesota Rules Part 6800.9900, subp. 3:

Subp. 3. **Decision on variance.** The board shall grant a variance if it determines that:

- A. the variance will not adversely affect directly or indirectly, the health, safety, or well-being of the public;
- B. the alternative measures to be taken, if any, are equivalent or superior to those prescribed in the part for which the variance is requested; and
- C. compliance with the part for which the variance is requested would impose an undue burden upon the applicant.

The recommendations of the Variance Committee are presented to the Board at the next regularly scheduled Business meeting. (The chief pharmacy surveyor and one of the Office Specialists prepare the Variance Committee Report that is presented to the Board). Certain variances are deferred to the full Board (e.g. controversial variance requests or requests made by a pharmacy at which one of the Board members works). Also, any Board member can pull a variance request from the Variance Committee Report and have it discussed by the full Board. After the Board meeting, the chief pharmacy surveyor and one of the office specialists send letters to the individuals and businesses who have requested variances, notifying them of the Board's decision. Most variance requests are granted, but it is common for the Board to establish conditions for approval, as authorized by [Minnesota Statutes § 14.055, subdivision 2](#).

#### Internship Advisory Committee

As mentioned above, the Board registers pharmacy interns, who are students enrolled in colleges of pharmacy who receive experiential training in actual practice settings. Working under the supervision of licensed pharmacists, interns are involved in compounding drug preparations, filling prescriptions, evaluating and monitoring drug therapy and educating patients. [Minnesota Statutes §151.101](#) requires the Board to "prescribe standards and requirements for interns, pharmacist-preceptors, and internship training". The Board adopted [Minnesota Rules 6800.5600](#) to form the Internship Advisory Committee (IAC) "to advise the board on the administration of parts 6800.5100 to 6800.5600", which are the parts of the rules that set standards in this area. The IAC meets on an ad hoc basis, primarily to update the Board's Internship Competency Manual and to advise the Board concerning potential rule changes involving internships. (The Internship Competency Manual lists the specific competencies that interns are expected to master during their required 1,600 hours of practical training).

Pursuant to [Minnesota Rules 6800.5600](#), the IAC includes "practicing pharmacists, pharmacist-educators, pharmacist-interns, and representatives of the board". The Committee is staffed by the Board's Executive Director and the chief pharmacy surveyor. Consequently, part of the costs associated with the Committee consists of a portion of the salaries and benefits paid to those individuals. The



Board members who serve on the Committee are each paid a \$55 per diem and are reimbursed for mileage. All other members are volunteers who receive no compensation.

#### Continuing Education Advisory Task Force

[Minnesota Statutes §214.12](#) permits licensing agencies to “promulgate by rule requirements for renewal of licenses designed to promote the continuing professional competence of licensees”. The Board has adopted rules that require pharmacists and pharmacy technicians to complete continuing education. The Board adopted [Minnesota Rules 6800.1600](#) to form the Continuing Education Advisory Task Force (CEATF) which advises the Board on issues concerning continuing education. The CEATF reviews CE programs submitted by individual pharmacists and technicians to determine if they meet the standards found in [Minnesota Rules 6800.1500](#). The CEATF also reviews the applications that are submitted by individuals and organizations who are applying to become Board-approved providers of continuing education.

The CEATF consists of two Board members, the Board’s Executive Director, a pharmacy surveyor and representatives of the Minnesota Pharmacists Association, the Minnesota Society of Health-System Pharmacists and the University of Minnesota College of Pharmacy. It meets quarterly and prepares a report that is reviewed and approved by the Board at one of its regularly scheduled business meetings. Part of the costs associated with the CEATF consists of a portion of the salaries and benefits paid to the Board’s Executive Director and pharmacy surveyor. The Board members who serve on the Task Force are each paid a \$55 per diem and are reimbursed for mileage. All other members are volunteers who receive no compensation.

#### Prescription Monitoring Program Advisory Committee

[Minnesota Statutes §152.126](#) requires the Board to administer an electronic system for receiving certain information for most controlled substances dispensed within the state. The system, which became fully operational in April of 2010, is called the Minnesota Prescription Monitoring Program (PMP). A detailed description of the PMP is provided in the next section of this report. Subdivision 3 of the above mentioned section of statute requires the Board to “convene an advisory committee” . . . “to advise the board on the development and operation of the electronic reporting system”. Consequently, the Board has established the PMP Advisory Committee (PMPAC) which, pursuant to the statutes, consists of representatives of the Minnesota Departments of Health and Human Services, each health-related licensing board that licenses prescribers, the Minnesota Medical Association, the Minnesota Pharmacists Association, the Minnesota Nurses Association, the Minnesota Dental Association, a consumer privacy advocate and a consumer or patient rights organization.

During the planning and implementation stages of the Prescription Monitoring Program, the PMPAC met on a regular basis. Currently, the PMPAC meets once or twice each year to receive updates from the Board’s staff and to offer advice concerning the operation of the program and potential statutory changes. The PMPAC is staffed by the Board’s PMP Manager and one of the Office Specialists. In addition, the Board’s Executive Director attends the meetings. Consequently, most of the costs associated with the Committee consist of a portion of the salaries and benefits paid to those staff members. All members of the PMPAC are volunteers and receive no compensation for their services.



## APPLICATION TO THE BOARD OF THE CRITERIA FOUND IN M.S. § 3D.06

### The efficiency and effectiveness with which the agency operates

Although [Minnesota Statutes §3D.06](#) includes the “effectiveness” with which an agency operates in this criterion, it would seem that “effectiveness” is more related to the second criterion, which requires an assessment of the extent to which the mission, goals and objectives of the agency have been met. Consequently, this portion of the report will focus on the efficiency with which the Board operates. Over the past decade, the Board has made a number of changes to improve efficiency. Those changes have been, in part, necessitated by the budget challenges that have affected all state agencies. However, the Board recognizes that it has a duty to the public in general, and specifically to the individuals and businesses that we license and register, to operate as efficiently as possible. As a result, the Board was able to operate for a decade, between 2001 and 2011, without an increase in fees.

During the past ten years, the Board has taken the following actions to increase efficiencies and/or decrease costs:

- Stopped mailing paper copies of the quarterly newsletter to licensees and registrants. The newsletter is now published on the Board’s Web site and an e-mail is sent to licensees and registrants to alert them of the online availability of the latest edition. This has saved staff time and reduced printing and postage costs.
- Developed an online renewal process that allows pharmacists and pharmacy technicians to renew their license or registration through a secure portion of the Board’s Web site. An e-mail is sent to pharmacists and technicians alerting them that they need to renew. Over 90% of pharmacists and 75% of technicians have chosen to renew online. This has saved staff time and reduced printing and postage costs.
- The Board provides notices to licensees and registrants whenever possible via e-mail, directing them to obtain additional information on the Board’s Web site. This has saved staff time and reduced paper, postage and printing costs.
- The Board has gone to paperless meetings, with meeting materials currently distributed to Board members on secured flash drives. This has saved staff time and reduced paper, printing and postage costs. To further increase efficiencies, Board staff is currently working to develop a process by which members can access the materials over a secure Internet link – eliminating the need to mail even the flash drives.
- The Board has also changed how business meetings are run by introducing a consent agenda to handle routine and non-controversial issues. Combined with going to paperless meetings, this has resulted in Board meetings being reduced in length from the previous five to six hours to the current two to three hours.
- The Board had Voice-Over-Internet phones (VOIP) installed which has allowed for the use of more sophisticated voice messaging. Voice messages are converted to audio computer files and attached to e-mails that are sent to the appropriate staff member. The VOIP system has also allowed for the use of an interactive voice response system that more efficiently routes calls to the appropriate staff member.
- The Board used to provide pharmacy interns and certain pharmacist licensure applicants with bound copies of the state’s pharmacy statutes and rules. The Board now directs these individuals to review the statutes and rules on the Legislature’s Web site. This has saved staff time and reduced postage costs and the costs associated with purchasing the bound copies.

- The Board has stopped directly administering all licensing examinations. Several decades ago, the Board administered several exams: one to test an applicant's knowledge of pharmaceuticals, medicinal chemistry, calculations and other subjects; a practical examination designed to assess the applicant's compounding competency; and a law exam. Exams were only administered twice a year. Beginning in the 1970's, the Board adopted the use of standardized, written examinations developed by the National Association of Boards of Pharmacy (NABP) - but continued to administer practical and state law exams. About a decade ago, the Board stopped administering the state law exam, when NABP developed the Multistate Pharmacy Jurisprudence Examination. The Board dropped the practical examination in 2004. Consequently, pharmacist license applicants currently take only two computer-based, psychometrically validated exams that are developed by NABP and administered at testing centers under contract to NABP. They can take the examinations at any time and at testing centers located in several parts of the state. This has saved staff time and reduced paper and printing costs. In addition, it allows pharmacist license applicants far greater flexibility in regards to taking the licensing examinations.
- Board Surveyors make every effort to coordinate complaint investigations with routine facility inspections. For example, if a Surveyor has to investigate a complaint in Brainerd, he/she will stay in the general area for up to several days and also conduct inspections of other pharmacies. That makes for more efficient use of their time and decreases travel costs.
- The Board recently adopted a large package of rule changes, many of which were designed to reduce the regulatory burden faced by the individuals and businesses that the Board licenses. Some of the rule changes will also reduce the workload of the Board's staff. In particular, licensees will have to submit significantly fewer rule variance requests. That, of course, means that Board staff will be processing fewer variance requests.
- The Board has contracted with vendors to provide information technology services related to the Board's licensing database and the Prescription Monitoring Program. It is much cheaper and more efficient to have the vendors do most of this work rather than trying to have it all done in house. The vendors provide similar services to other state agencies around the country, thus achieving economies of scale that our Board cannot achieve. However, the interaction between these two systems, coupled with a Board plan to implement an electronic document management system, lead the Board to seek an increased appropriation to hire an information technology specialist 3. The Legislature and Governor approved this request during the 2011 Special Session.

The health-related licensing boards have taken joint action to increase the efficiency with which we perform our duties. Although we are independent state agencies, we work together in a variety of ways, including:

- Our offices are all located in the same building at 2829 University Ave SE in Minneapolis. With the assistance of the Department of Administration, we recently negotiated a new seven-year lease with the building owner that actually reduced our lease payments. We also jointly lease and share three conference rooms and two rooms that house shared printers. (One of those rooms also serves as a centralized mail room).
- We jointly purchase and share certain IT equipment such as network servers, printers and copiers, a folding and envelope stuffing machine, audiovisual equipment, recording systems and an electronic public notice board that is located in the lobby of the building.
- We jointly fund an Administrative Services Unit (ASU) which is staffed by individuals with

expertise in accounting and financial management, human resources, contracts, purchasing and information technology. ASU employs six full-time staff members, one 0.7 FTE temporary staff member and one 0.6 FTE staff member to provide services to the 18 Health-Related Licensing Boards and their 170 employees. (Please note that two of the full-time staff members and the temporary 0.7 FTE staff member are IT specialists and, consequently, are technically now employees of the Office of Enterprise Technology – although they continue to do work for the Boards and their salaries are still jointly paid by the Boards). Jointly funding the ASU means that each Board does not have to hire staff with expertise in these areas. Some of the larger Boards have IT specialists that focus exclusively on Board-specific projects. The IT specialists assigned to ASU provide programming and desktop support to smaller boards and administer the IT equipment, servers and networks used by all of the Boards. The Boards' have been told that the Small Agency Resource Team (SmART) that is run by the Department of Administration was modeled after our ASU.

- We jointly fund the Health Professionals Services Program (HPSP), which provides the Boards with an alternative method for monitoring health care professionals whose ability to safely practice is impaired by chemical dependency or by physical or mental illness. In the past, Board of Pharmacy staff had to directly monitor such professionals - with only limited resources. Chemical dependency and health care treatment records were reviewed by the Board's Executive Director. The Board's staff also scheduled toxicology screens and tracked the results using spreadsheets. The case workers at HPSP now perform such duties, following impaired health professionals and ensuring that they have appropriate evaluation, treatment and monitoring. Those case workers have special training and expertise in performing these duties. Please note that the HPSP is authorized by [Minnesota Statutes §214.31](#).
- The Executive Directors of the Boards hold a monthly meeting of the Executive Director's Forum. During these meetings, the Executive Directors discuss issues of mutual concern and hear reports from the Boards' Management and Policy Committees and Information Technology Work Group. Representatives of the Attorney General's Office and the Health Professionals Services Program attend the ED Forums and give reports on issues that commonly affect all of the Boards. ASU staff members also provide information to the Executive Directors concerning accounting, financial, human resources, contracting and information technology issues. The Boards' office managers hold a similar monthly meeting.
- [Minnesota Statutes §214.025](#) reads: "The health-related licensing boards may establish a Council of Health Boards consisting of representatives of the health-related licensing boards and the Emergency Medical Services Regulatory Board. When reviewing legislation or legislative proposals relating to the regulation of health occupations, the council shall include the commissioner of health or a designee". The Boards have, in fact, established the Council of Health Boards (CHB), which consists of the Executive Director and one member of each of the health licensing boards and the EMSRB. [Minnesota Statutes §214.001](#) permits the chair of a standing committee in either house of the legislature to request information from the CHB on proposals relating to the regulation of health occupations. The CHB has provided the Legislature with many reports concerning proposals to regulate health occupations. The CHB also acts as an additional forum at which the Boards can discuss issues of mutual concern.
- As mentioned above, the Board of Pharmacy and most of the boards that license prescribers jointly fund the Minnesota Prescription Monitoring Program.

## The extent to which the mission, goals and objectives of the agency have been met

The mission of the Board is to promote, preserve, and protect the public health, safety, and welfare by fostering the safe distribution of pharmaceuticals and the provision of quality pharmaceutical care to the citizens of Minnesota. The Board fulfills this mission through the examination and licensure of pharmacists, the regulation of the practice of pharmacy, the operation of the Minnesota Prescription Monitoring Program, the investigation of complaints, the issuance of disciplinary orders and the inspection of licensed pharmacies, wholesalers, and manufacturers.

As required, the Board prepared an *Agency Profile* that was included as part of the budget that Governor Dayton submitted to the Legislature earlier this year. (The *Agency Profile* can be viewed at: [www.state.mn.us/mmb/pharmacy.pdf](http://www.state.mn.us/mmb/pharmacy.pdf)). In the *Agency Profile*, the Board established the following “Key Activity Goals & Measures”:

- The Board shares the Minnesota Milestone goal that state citizens will be healthy. By promoting best standards for pharmacy practice and disciplining unethical or incompetent pharmacists, the Board helps achieve the specific goal of reducing premature deaths. The Board believes that the activities mentioned above help to reduce the number of medication errors that adversely impact patients. However, due to the *many* variables that affect the health of citizens, it is difficult to determine the precise impact of the Board’s activities in this area.
- Help reduce “doctor-shopping” behavior and the abuse of prescription drugs. Reducing the abuse of prescription drugs should result in fewer cases of accidental overdoses and even motor vehicle and other accidents caused by impaired individuals. This is a goal of the Minnesota Prescription Monitoring Program (PMP), which only became fully operational on April 15, 2010. The Board does not yet have enough data to demonstrate the impact that the PMP might be having in this area. We do know that a very similar program that the Iowa Board of Pharmacy has been running for the past couple of years has resulted in a decrease of “doctor-shopping” in that state. The Board expects similar results in Minnesota. The Board is tracking data that is indicative of “doctor shopping”, namely the number of individuals who receive prescriptions from six or more prescribers and have them filled at six or more pharmacies within a six month period of time.

As mentioned above, many variables affect the general health of the citizens of this state. Many factors are also involved when analyzing the specific impact that pharmaceuticals have on the health of citizens. These factors include the price of pharmaceuticals, access to health insurance that covers prescription drugs, the prescribing practices of practitioners, the extent to which patients correctly comply with medication regimens, the competency of pharmacists, and the policies and procedures followed by pharmacies, drug manufacturers and drug wholesalers. The Board has an influence on some of those factors – but not all of them. Consequently, it is difficult to determine the precise impact that the Board has on the health of citizens.

However, the Board has promulgated rules that require its licensees and registrants to follow standards recommended by the United States Pharmacopoeia, the Joint Commission, the Institute for Safe Medication Practices, the Minnesota Alliance for Patient Safety and other organizations involved in health care standard setting. The Board helps to ensure that the standards are followed by conducting routine, unannounced inspections of the in-state facilities that it licenses and by investigating the complaints that it receives from the public. In addition, the Board only licenses pharmacists who have graduated from colleges of pharmacy that meet the standards of the Accreditation Council for

Pharmacy Education. Thus, while the precise impact of the Board is difficult to assess, it is a reasonable to assume that, by actively promoting the above-mentioned standards, the Board is having a positive impact on the public health.

Identification of activities of the agency that are in addition to those granted by statute, the authority for those activities and the extent to which those activities are needed

Board staff members are frequently consulted by other state agencies about drug-related issues. For example, during the past several years, the Board's Executive Director has been a member of task forces established by the Minnesota Department of Health that dealt with pandemic influenza, electronic prescribing, diversion of controlled substances by health care professionals, the abuse of prescription drugs and health care workforce shortages. The Board and its staff members have worked with or been consulted by the Office of the Attorney General, the Bureau of Criminal Apprehension, the Minnesota Pollution Control Agency, the State Department of Veteran's Affairs, the Department of Revenue, the Department of Human Services, the Department of Health, the Department of Corrections and the other health licensing boards. The Board has also worked with federal agencies, including the Drug Enforcement Administration and the Food and Drug Administration. The Board has worked with local officials, including: county public health officials, prosecutors and sheriffs; city mayors, administrators and police chiefs; and a few school district administrators. The Board believes that the other state agencies that have requested assistance and advice have been acting within their statutory authority. Also, while [Minnesota Statutes §151.06](#) doesn't specifically empower or direct the Board to provide consultation to these other agencies, the Board assumes that the Legislature would want state agencies to share expertise with one another. Other than providing such assistance and advice, the Board does not engage in any activities that are not specifically permitted per the Statutes.

Authority of the agency relating to fees, inspections, enforcements and penalties

[Minnesota Statutes §16A.1283](#) prohibits a state agency from imposing a new fee or increasing an existing fee unless the new fee or increase is approved by law. Consequently, the Board must seek legislative and gubernatorial approval for any proposed changes in fees.

In regards to inspections, [Minnesota Statutes §151.06](#) empowers the Board 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”

This power is limited in certain circumstances by [Minnesota Statutes §151.26](#), which states, in part:

“Nothing in this chapter shall subject a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine, to inspection by the State Board of Pharmacy, nor prevent the person from administering drugs, medicines, chemicals, or poisons in the person's practice, nor prevent a duly licensed practitioner from furnishing to a patient properly packaged and labeled drugs, medicines, chemicals, or poisons as may be considered appropriate in the treatment of

such patient; unless the person is engaged in the dispensing, sale, or distribution of drugs and the board provides reasonable notice of an inspection”.

In regards to enforcements, there are several relevant sections of statutes. [Minnesota Statutes §151.06](#) empowers the Board to “deny, suspend, revoke, or refuse to renew any registration or license required under this chapter, to any applicant or registrant or licensee” based upon one of approximately a dozen grounds. That section also empowers the Board to “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”.

In addition, Minnesota Statutes [§609B.130](#) reads:

“Under section [151.06](#), the Board of Pharmacy shall deny, suspend, revoke, or refuse to renew any registration or license required under chapter 151 to any applicant, registrant, or licensee upon any of the following grounds:

- (1) in the case of a pharmacist, conviction in any court of a felony;
- (2) in the case of a pharmacist, conviction in any court of an offense involving moral turpitude;
- (3) conviction of theft of drugs, or the unauthorized use, possession, or sale thereof; or
- (4) in the case of a pharmacist, aiding suicide or aiding attempted suicide, as established by 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](#)”.

[Minnesota Statutes §151.38](#) requires the Board to embargo drugs if it finds or has probable cause to believe that any drug or medicine is adulterated, or so misbranded as to be dangerous or fraudulent, or is being sold, delivered, or offered for sale in violation of certain labeling requirements found in [Section 151.361](#). (An embargo prevents the sale or distribution of the drug in question). If the Board determines that a drug is, in fact, misbranded or adulterated, it must “within 30 days, petition the district court in whose jurisdiction the article is embargoed for an order of condemnation”.

Minnesota Statutes §§[214.10](#) and [214.103](#) require the Board to investigate any jurisdictional complaint and empower the Board to attempt to reach a stipulated agreement with a licensee or registrant when the Board has established that it has grounds for imposing discipline. In the event that a stipulated agreement cannot be reached, the Board is empowered to initiate a contested case hearing before an administrative law judge. A complaint alleging sexual contact or sexual conduct with a client must be forwarded to the Office of the Attorney General for an investigation. If the allegations are substantiated, the Board may impose discipline on the licensee or registrant involved. The Board must handle all disciplinary activities in accordance with the relevant provisions of the Administrative Procedures Act ([Chapter 14](#)).

Pursuant to [Minnesota Statutes §214.10](#), the Board may “issue subpoenas and compel the attendance of witnesses and the production of all necessary papers, books, records, documents, and other evidentiary material. Any person failing or refusing to appear or testify regarding any matter about which the person may be lawfully questioned or produce any papers, books, records, documents, or other evidentiary materials in the matter to be heard, after having been required by order of the board or by a subpoena of the board to do so may, upon application to the district court in any district, be ordered to comply therewith”.



Minnesota Statutes §151.06, subd. 5 states that the Board “may impose a civil penalty not exceeding \$10,000 for each separate violation, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant of any economic advantage gained by reason of the violation, to discourage similar violations by the licensee or registrant or any other licensee or registrant, or to reimburse the board for the cost of the investigation and proceeding, including, but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board members' per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members”.

Whether less restrictive or alternative methods of performing any function that the agency performs could adequately protect or provide service to the public

As noted above, the Board’s primary functions are: licensing; standard-setting; compliance; provision of technical assistance to elected public officials, other state agencies, federal agencies and units of local government; serving as a resource to the profession and the public concerning issues involving the practice of pharmacy, the distribution of drugs and the abuse of controlled substances; administering the state’s Prescription Monitoring Program (PMP) and general administration of the agency. Of these functions, only licensing, compliance and administration of the PMP might be considered “restrictive”. Those three areas are addressed below. The Board has an open approach to standard-setting which involves working cooperatively with educational institutions, professional associations, other state agencies, federal agencies, accreditation organizations and other interested parties. Likewise, the general administration of the agency and the provision of technical assistance to elected public officials, other government agencies, the profession and the public are in no way restrictive.

*Licensing*

The Board licenses pharmacists, pharmacies, drug manufacturers, drug wholesalers, medical gas manufacturers, and medical gas wholesalers and distributors. In the Board’s judgment, less restrictive alternatives would not adequately protect the public. As mentioned above, there are at least 1.5 million preventable adverse drug events that occur in the United States each year, many of which are attributable to the dispensing of drugs by pharmacists. In addition, it is critical for the health and safety of the public that drugs and medical gases be properly manufactured, stored and distributed. Licensing helps to ensure that only properly trained and qualified individuals will either practice pharmacy or be responsible for the operation of pharmacies, manufacturers and wholesalers.

Three possible alternatives to licensure are registration, certification and the caveat emptor approach of no regulation at all. Every developed country on the planet has rejected the third approach. Each of the states in this country, plus the United States territories of Puerto Rico, the Virgin Islands and Guam, have boards of pharmacies that are members of the National Association of Boards of Pharmacy. In addition, the pharmacy regulatory agencies of eight of the Canadian provinces and of Australia and New Zealand are associate members of NABP. All of the states in this country require pharmacists and pharmacies to be licensed. Most of the states license or register drug manufacturers and all of them license drug wholesalers. Most of the states conduct routine, unannounced inspections of the facilities that are licensed.

Registration, in its purest form, provides only for a mechanism by which the registrants can be tracked.



There are no requirements concerning education, training or demonstration of competence. Certification officially recognizes particular individuals as being qualified but, in its purest form, allows those who are not certified to offer the same services. Neither of these approaches is sufficient when it comes to regulating the production, distribution and dispensing of drugs which have the power to cure or the power to kill, depending on how they are used.

Tort law in this country recognizes that drugs are “unavoidably unsafe products”. The *Restatement (Second) of the Law of Torts* explains that there “are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs”. This is because almost any drug that is powerful enough to have an effect on a physiological process can also cause unwanted side-effects. It is imperative that drugs are used in a manner that maximizes benefits while minimizing the inherent risks. Consequently, licensure is more appropriate than the less restrictive alternatives mentioned above.

The Board registers pharmacy technicians, pharmacy interns, preceptors and controlled substance researchers. By both statute and rule, pharmacy technicians must work under the immediate and personal supervision of a pharmacist. The same is true for interns, by rule. Consequently, registration is appropriate for technicians and interns, rather than the more restrictive licensure option. Controlled substance researchers who conduct research involving humans are either licensed health care professionals or they work under the supervision of such professionals. The other controlled substance researchers that the Board registers conduct research only on animals. Thus, registration is an appropriate option for controlled substance researchers. Certification is not an option for technicians, interns or researchers because they have access to controlled substances – that is, drugs such as morphine, Valium and even marijuana and heroin. It is necessary to have a mechanism for tracking individuals who have access to such drugs. Unfortunately, it is not uncommon for these individuals to divert the drugs for their personal use or for sale to others.

### *Compliance*

The compliance activities of the Board involve routine inspections, processing of variance requests, complaint investigations and disciplinary activities. In the judgment of the Board there are no less restrictive alternatives to routine inspections, complaints investigations and disciplinary activities that would adequately protect the public. The Board does not exist because of the vast majority of licensees and registrants who practice in a competent, safe, ethical and lawful manner. It exists because of the small percentage who do not. Given that they are handling drugs that are “unavoidably unsafe products”, that small percentage of licensees and registrants can cause a significant amount of harm to the citizens of this state.

Unannounced inspections by Board Surveyors routinely reveal infractions of the statutes and rules, most of which are minor. However, those inspections also reveal problems that are an immediate threat to the public. As just one of many examples, during a recent routine inspection of a pharmacy, Board Surveyors found that drugs for administration by injection, which must be sterile to prevent the risk of potentially life-threatening infections, were not being compounded in accordance with United States Pharmacopeia standards for sterile compounding. The Surveyors immediately instructed the pharmacist-in-charge to cease compounding sterile products until those standards were met. Had there been no routine inspection of this pharmacy, the first notice the Board might have received was a complaint alleging that a patient of the pharmacy had died after having an unsterile product administered.

Minnesota Statutes §§[214.10](#) and [214.103](#) require the Board to investigate every jurisdictional complaint. In the judgement of the Board, the Legislature quite correctly concluded that citizens should have the ability to file such complaints. Citizens also have the option of filing malpractice suits against health care professionals. However, relying on malpractice suits *alone* to address incompetent, unethical and unsafe professionals is not a good alternative. Having complaints investigated by experts can potentially result in corrective action being taken before a situation becomes so bad that people are severely injured. This sort of preventative strategy can help reduce the costs associated with medical errors and malpractice litigation.

The Board reserves disciplinary action for the more egregious cases that come to its attention. For minor infractions, the Board issues informal warnings and provides suggestions to the licensees or registrants as to how they can come into compliance. The Board's Surveyors then follow up at a later date to ensure that the suggestions have been followed. Licensees and registrants are most commonly disciplined for stealing controlled substances for their own use or to sell to others. The Board has also disciplined pharmacists for serious breaches of patient data privacy laws, sexual misconduct, drinking alcohol while on duty, inappropriately working with illicit Internet sites to dispense controlled substances to individuals without legally valid prescriptions, repeated failure to come into compliance with regulations and other serious infractions.

#### *Prescription Monitoring Program*

At least 35 states currently administer a prescription monitoring program. (Please see above for a complete description of Minnesota's PMP). Some states take an "active" approach to controlled substance prescription monitoring and some, including Minnesota, take a more "passive" approach. In the "active" states, staff of the agency housing the PMP actively engage in "data-mining" and try to identify individuals who appear to be doctor-shopping. If an individual is so identified, the agency will send a letter to each prescriber and pharmacist from whom the individual received service. Some of those states also try to identify inappropriate prescribing by practitioners or dispensing by pharmacies, reporting such individuals to the appropriate licensing board. One possible adverse consequence of using a more "active" approach is the possibility of a "chilling effect" on appropriate prescribing. (That is, some practitioners may be more reluctant to prescribe controlled substances even when appropriate - for fear of having their prescribing practices questioned).

The Board's PMP staff does not engage in data-mining for the purpose of identifying doctor-shoppers or inappropriate prescribing and dispensing. Instead, the data collected by the Board is made available to prescribers, pharmacists and certain Department of Human Services (Medicaid) staff who apply for access. Law enforcement officials can obtain data upon presenting the Board with a search warrant and medical examiners have authority to request reports as well. In the judgment of the Board, Minnesota's approach appropriately balances the need to identify doctor-shoppers and to prevent the "chilling effect" mentioned above.

#### *Other Considerations*

[Minnesota Statutes §214.055](#) requires the Board to collect fees sufficient to cover expenditures. The fees that are collected are deposited in the State Government Special Revenue Fund (SGSRF). The Board may expend only those funds that are appropriated by the legislature, regardless of the amount of fees that are collected. Like most of the health licensing boards, the board usually collects more fees

than it is allowed to expend. Those excess fees are, in theory, kept in the SGSRF in case the Board has unexpected expenditures (e.g. a contested case hearing that ends up in the court system and thus consumes a larger portion of the board's budget for disciplinary cases than was anticipated). However, most of the Board's reserves have been transferred to the General Fund over the past eight years, leaving virtually no "cushion". The Board has a very tight budget so, unlike larger agencies, it has less ability to respond to unexpected expenses by shifting monies from one area to another. An alternative approach would be for the Board to have the authority to expend the fees it collects without being tied to a specific legislative appropriation. Since fees are established by the legislature and since Minnesota Management and Budget would monitor Board expenditures, adequate external control mechanisms would be in place to ensure that the Board continued to operate in a fiscally sound manner.

Minnesota statutes §§[214.10](#) and [214.103](#) require legal and certain investigative services be provided by the Attorney General's Office (AGO). The Boards of Dentistry, Medical Practice and Nursing have implemented a system in which Board staff draft certain legal documents (rather than the AGO). The AGO reviews the documents for accuracy and compliance with law. According to those Boards, this practice has resulted in a 50% decrease in the time from receipt of complaint to a review before the Board - at no change in the cost to the Boards. A logical expansion of this practice would be for the health-licensing boards to retain their own legal counsel and investigative staff rather than contracting with the AGO; thus, eliminating a layer of involvement. Legal and investigative services would be shared among the health-related licensing boards on a fee for use basis. Based on the experience with drafting of notices, complaint resolution time would be reduced, and public safety enhanced.

Extent to which the jurisdiction of the agency and the programs administered by the agency overlap or duplicate those of other agencies, the extent to which the agency coordinates with those agencies, and the extent to which the programs administered by the agency can be consolidated with the programs of other state agencies

While there are other health licensing boards, the Minnesota Board of Pharmacy is the only state agency empowered to do the following (see Minnesota Statutes §§[151.06](#) and [152.02](#)):

- regulate the practice of pharmacy;
- regulate the manufacture, wholesale, and retail sale of drugs within this state;
- regulate the identity, labeling, purity, and quality of all drugs and medicines dispensed in this state . . .;
- enter and inspect . . . 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 . . . secure samples or specimens of any drugs, medicines, medical gases, or veterinary drugs or devices after paying or offering to pay for such sample . . . inspect and make copies of any and all records of shipment, purchase, manufacture, quality control, and sale of these items . . .;
- examine and license as pharmacists all applicants whom it shall deem qualified to be such;
- license wholesale drug distributors;
- deny, suspend, revoke, or refuse to renew any registration or license required under this chapter, to any applicant or registrant or licensee for one of 13 specified reasons;
- register as pharmacy technicians all applicants who the board determines are

- qualified to carry out the duties of a pharmacy technician;
- regulate and define additional substances, not listed in the statutes, which contain quantities of a substance possessing abuse potential and add them to the appropriate controlled substance schedule in rule;
- add substances to or delete or reschedule substances listed in the controlled substance schedules, by rule;
- coordinate the state's schedules of controlled substances with the federal schedules;
- administer the Minnesota Prescription Monitoring Program.

Although the other health licensing boards are also engaged in licensing, complaint investigation, disciplinary activities and (in some cases) inspections, they have jurisdiction over professions different than those for which the Board has jurisdiction. Thus none of the functions of the Board overlap or duplicate those of other agencies.

Most of the health licensing boards handle licensure examinations by working with national organizations that develop and administer examinations. Many of the boards use licensure transfer programs administered by those same organizations. In the case of the Board of Pharmacy, the organization is the National Association of Boards of Pharmacy (NABP). The NABP developed and periodically updates two psychometrically validated pharmacist licensure examinations – the North American Pharmacist Licensure Examination and the Multistate Pharmacy Jurisprudence Examination. In addition, NABP administers the Licensure Transfer Program that allows pharmacists to more easily become licensed in a different state.

Consolidating all of the health licensing boards into a single, “umbrella” organization would almost certainly result in no costs savings or increases in efficiency. The boards all regulate different professions and work closely with different national organizations. Consequently, the licensing processes used by one board resemble, but are not identical, to the processes used by the other boards. In addition, due to the budget problems faced by all state agencies, the boards have not always expanded staff to keep pace with increased licensing activities. In the case of the Board of Pharmacy, licensing staff has sometimes had to work overtime during peak licensing periods. For these reasons, consolidation of the boards would not result in a decrease in the number of staff members working on licensing.

Similarly, most states that place health licensing boards into an umbrella organization continue to employ individuals to administer and staff the individual boards. Those individuals have policy expertise in the area regulated by the board they administer. Those states also continue to employ individuals to serve as inspectors and complaint investigators. Consequently, consolidation of the boards would likely not result in a decrease in the number of staff members employed by the boards. To the contrary, consolidation might very well introduce a new layer of bureaucracy – the upper-level management and staff necessary to supervise the umbrella organization as a whole.

These conclusions are supported by a report prepared in 2003 at the request of Minnesota's health licensing boards. (A copy of that report, which is titled *Health Licensing Boards and Governance Structure*, will be provided to the Commission). The author concluded that the literature review and research she did to prepare the report supported some of the Minnesota Legislative Auditor's (OLA) 1999 findings, namely: “We found no convincing evidence that any particular organizational arrangement or process provides an assured solution to any given problem associated with occupational regulation.”

A finding of the OLA report was that: “. . . we do not think Minnesota has a crisis in occupational regulation. In our view, Minnesota today simply has many of the same occupational regulation issues that have persisted here and in most other states for decades”. The OLA report also states that to: “be regulated, an occupation ought to require knowledge, skills, or abilities that are teachable and testable; the skills should be taught in accredited programs; these programs should be distinguishable from related occupational or professional programs; and the occupation should have its own trade or professional association”. The profession of pharmacy meets all of these criteria.

The OLA report further states (emphasis added):

‘Previous studies of occupational regulation have focused on the efficiency with which the boards are administered and envisioned that large state agencies could provide administrative services more efficiently than many small boards. The merit of this idea has been called into question by the fact that over the years the health boards have distanced themselves from the Department of Health *and set up a joint administrative services unit, an arrangement that appears to be working well in providing a limited number of services.*

There are undoubtedly further opportunities for more collaboration among the boards and improvements in efficiency, but *our analysis does not conclude that administrative efficiency is the primary problem with occupational regulation*”.

Finally, the OLA report highlights that occupational regulation has been the subject of scrutiny in this state for at least the past three decades. The Legislature created sunrise legislation in [Chapter 214](#) back in 1976. In 2001, the Legislature modified the sunrise provisions to allow the “chair of a standing committee in either house of the legislature” to “request information from the Council of Health Boards (CHB) on proposals relating to the regulation of health occupations”. The CHB has prepared many reports concerning emerging health occupations since that time.

According to the OLA report, the Department of Administration conducted a major study of occupational regulation in the mid-1970’s and recommended (emphasis added):

“replacing all autonomous regulatory boards with advisory boards housed in various state departments. Following the study, a Senate Government Operations Committee task force on occupational regulation was established to follow up on the report’s recommendations. *The task force did not agree with the suggestion that the independent boards be abolished, although it recommended strengthening the relationship between boards and host departments that provided administrative services. Over the years, however, the relationship between boards and host agencies has become attenuated rather than strengthened, especially for the boards affiliated with the Minnesota Department of Health. Copying and data processing, a major concern in the Department of Administration report, have become less expensive in the last 20 years and the economies available from centralization of these services have greatly diminished or vanished altogether*”.

The OLA report also states the following:

“In the 1990s, there have been two interim committees of the Legislature, one in the House and one in the Senate, that studied the issue of occupational regulation and took testimony. However, neither committee proposed legislative reforms that were passed into law”.

In summary, the question of occupational regulation has been reviewed several times over the past 35 years and the result in each instance has been to leave the health-licensing boards as autonomous agencies. The health licensing boards work even more closely together now than they did when the OLA report was issued in 1999. If the economies of centralization had been “greatly diminished” by 1999, they truly have “vanished altogether” today. A summary of that OLA report is available at: [www.auditor.leg.state.mn.us/ped/pedrep/9905sum.pdf](http://www.auditor.leg.state.mn.us/ped/pedrep/9905sum.pdf).

As described above, the health licensing boards already work together in a variety of ways that have increased efficiencies and reduced costs. Since there is no evidence that using a governance model different than one currently used by the boards will further increase efficiencies or reduce costs, the Board of Pharmacy would recommend that the Legislature not risk the disruption that would likely occur during a transition to a new governance model.

Promptness and effectiveness with which the agency addresses complaints concerning entities or other persons affected by the agency, including an assessment of the Board's administrative hearings process

The charts below provide information concerning the Board’s complaint and disciplinary cases since fiscal year 2007. The number of complaints received by the board increased in two of the last three complete fiscal years. This may be turning into an accelerating trend. Although we are only five months into FY 2012, the Board has already received 157 complaints. The complaint data chart shows a drop in fiscal year-end open cases in FY 2008 and FY 2009 – and an increase in FY 2010 and 2011. During the 2007 Session, the Legislature increased the Board’s appropriation so that an additional pharmacy surveyor could be hired. Having that additional surveyor on staff was the main reason that the number of year-end open cases dropped. Unfortunately, due to budget concerns, the Board did not replace a surveyor that retired in mid-2009. The lack of that surveyor explains the increase in open cases in FY 2010 and 2011. During the 2011 Special Session, the Legislature once again increased the Board’s appropriation and another surveyor was added to the Board’s staff on November 22, 2011. That should once again reduce the number of year-end open complaints.

While the Board of Pharmacy occasionally initiates a contested case hearing when a licensee or registrant does not want to sign a stipulation and consent order, the Board has not had to conduct a hearing before an administrative law judge for many years. Most discipline cases involve pharmacists and technicians who have stolen narcotics or stimulants from their employers, either for their own use or to sell to others. In nearly all of those cases, the theft has been captured on security video or the employer has gotten the individual to voluntarily sign a confession. Confronted with such evidence, most accused individuals choose to sign a stipulation and consent order (SCO) after meeting with the Board’s Complaint Review Panel. The few who have not initially signed a SCO have eventually done so - before a hearing was necessary.

An Assistant Attorney General advises the Board in all complaint and disciplinary matters. This helps ensure that all due process requirements of Minnesota Statutes [Chapters 14](#) and [214](#) are followed. This is another reason that the Board has rarely had to hold a contested case hearing before an ALJ and has also not had any disciplinary orders appealed to the Minnesota Court of Appeals for years.

Although the Board issues disciplinary orders for only 15 – 20% of the complaints that it receives, most of the other cases are dismissed only after the licensee or registrant agrees to take appropriate corrective action. As noted above, the Board prefers to handle less serious infractions by working with the licensee or registrant to come into voluntary compliance with the statutes, rules and standards of practice.

### Disciplinary Data

| Minnesota Board of Pharmacy | FY 2007 | FY 2008 | FY 2009 | FY 2010 | FY 2011 |
|-----------------------------|---------|---------|---------|---------|---------|
| Disciplinary Orders Issued  | 16      | 21      | 12      | 15      | 22      |

### Complaint Data

| Minnesota Board of Pharmacy                    | FY 2007 | FY 2008 | FY 2009 | FY 2010 | FY 2011 |
|--|---------|---------|---------|---------|---------|
| Complaints Received                            | 64      | 86      | 104     | 86      | 125     |
| <b>Complaints by Type of Primary Complaint</b> |         |         |         |         |         |
| Billing problem                                | 3       | 2       | 2       |         | 0       |
| Chemical dependency or drug diversion          | 8       | 5       | 19      | 16      | 15      |
| Dispensing error                               | 30      | 51      | 34      | 31      | 36      |
| Dispensing outdated drug                       | 1       | 1       | 0       | 0       | 1       |
| Dispensing without authorization               | 0       | 2       | 6       | 8       | 7       |
| Failure to counsel or inappropriate counseling | 1       | 3       | 2       | 2       | 2       |
| Nursing home kickback – attempt                | 1       | 0       | 1       | 1       | 0       |
| Other  | 10      | 16      | 32      | 22      | 52      |
| Physical/mental impairment                     | 1       | 1       | 2       | 2       | 1       |
| Practicing without a license                   | 2       | 0       | 0       | 0       | 3       |
| Unprofessional Conduct                         | 5       | 5       | 5       | 3       | 7       |
| Violation of privacy                           | 2       | 0       | 1       | 1       | 1       |
| Complaints Open on June 30th                   | 41      | 21      | 22      | 46      | 40      |
| Complaints Closed by June 30th                 | 23      | 106     | 100     | 49      | 130     |

### Assessment of the agency's rulemaking process and the extent to which the agency has encouraged participation by the public in making its rules and decisions and the extent to which the public participation has resulted in rules that benefit the public

As authorized by statute, the Board has promulgated the rules found in [Chapter 6800](#) of the Minnesota Rules. The Board's goal whenever it promulgates rules is to promote the health, safety and welfare of the public in a manner that minimizes the regulatory burden faced by licensees and registrants. In order to attain that goal, the Board encourages public participation in the rule-making process.

Rules recently adopted by the Board are illustrative. (See the September 6, 2011 edition of the *State Register* at: [www.comm.media.state.mn.us/bookstore/stateregister/36\\_07.pdf](http://www.comm.media.state.mn.us/bookstore/stateregister/36_07.pdf)). This package of rule changes was intended to reduce the regulatory burden in certain areas, to update rules rendered obsolete by changes in technology and pharmacy practice, to implement changes in pharmacy



technician registration that were requested by most of the organizations representing pharmacies in the state and to respond to issues brought to the Board's attention by the general public.

The Board took three years to make these rule changes. Part of the reason that the Board took that long was because it wanted to give licensees, registrants and the general public the opportunity to have thorough input into the process. Although not required by statute or rule, the Board formed three advisory committees, composed primarily of members recommended by professional and trade organizations or by the University of Minnesota College of Pharmacy. One of the committees focused exclusively on changes to the rules involving pharmacy technician registration, one focused exclusively on changes to rules involving pharmacy interns and one focused on the remainder of the proposed rule changes. Those three committees met several times to review rule drafts and to make recommendations for changes in language. The Board did, in fact, make language changes in response to the input from the advisory committees.

Since approximately forty individuals requested it, the Board also conducted a rules hearing presided over by Administrative Law Judge Eric Lipman. The rules hearing automatically triggered additional comment periods, during which the Board received a number of comments from a variety of individuals and groups. Many of the comments were well-taken and the Board accordingly made changes in the proposed rule language. Judge Lipman found that the Board had missed the deadline for mailing out certain documents by up to six days but determined that those errors "did not deprive any person or entity of an opportunity to participate meaningfully in the rule-making process". The judge also found five legal defects, four of which were actually due to the Board's attempt to modify proposed language in response to comments received during the rules hearing. Judge Lipman found that the modified language had introduced ambiguity into the proposed rule language. Consequently, the Board again modified the rule language so that the ambiguity was eliminated while still addressing, as much as possible, the concerns made by commenters.

During this rule-making process, the Board periodically sent out notices to all of the individuals on its list of persons interested in rule proposals. In addition, the Board sent out e-mails to the over 13,000 licensees and registrants for whom we have an e-mail address. The Board also published key documents on its Web site, which are still available at: [www.pharmacy.state.mn.us/rulemake2010.htm](http://www.pharmacy.state.mn.us/rulemake2010.htm).

The Board is confident that public participation in its rule-making process results in rules that benefit the public. The above-mentioned rule change involving pharmacy technician registration requirements is one example. Although they work under the direct supervision of a pharmacist, technicians perform certain tasks in the compounding and dispensing process that, if not done correctly, could seriously harm a patient. And yet, until the Board adopted its recent rule changes, the only requirement for technician registration was to be 16 years old. The recently adopted rules concerning technicians were drafted to reflect a consensus reached between the Board, the University of Minnesota College of Pharmacy and various organizations representing different portions of the profession, including: the Minnesota Pharmacists Association, the Minnesota Society of Health-System Pharmacists, the Minnesota Retailers Association, the Minnesota Grocer's Association and the National Association of Chain Drug Stores. All of these organizations feel that increasing technician registration requirements was necessary to better ensure public safety.

Extent to which the agency has complied with federal and state laws and applicable rules regarding equality of employment opportunity and the rights and privacy of individuals, and state law and applicable rules of any state agency regarding purchasing guidelines and programs for historically underutilized businesses

The Board is aware of and diligently tries to follow all of the above-mentioned laws and rules. As required, the Board has adopted an affirmative action plan, a copy of which will be provided at the Commission's request.

The Board takes the privacy of individuals very seriously and has taken appropriate steps to safeguard non-public data. For example, the laptop computers that some Board staff use are encrypted so that, if lost, any data on the laptops would not be accessible. The vendor that the Board contracts with to collect data for the Prescription Monitoring Program uses state-of-the-art encryption and other security measures to protect that data. For example, the servers on which the data is stored are located in a building surrounded by a barb-wire topped fence and patrolled by armed guards. The Board does not release any documents or data that are considered to be non-public under state and federal laws.

Several of the staff members working for the Administrative Services Unit are specialists in contracting and procurement. Board staff works with them (and sometimes directly with Department of Administration staff) to ensure that all purchasing and contracting requirements are met – including any that involve historically underutilized businesses.

Extent to which the agency issues and enforces rules relating to potential conflicts of interest of its employees

The Board has not issued its own rules relating to potential conflicts of interest of its employees. However, Board employees do follow the statutes, rules and policies regarding conflicts of interest that apply to all state employees. (For example, see [Minnesota Statutes §43A.38](#) – Code of Ethics for Employees in the Executive Branch). Upon initial employment, staff members are given a notebook that contains as many as 15 statutes, rules or policies that they must follow. They are required to submit a signed document affirming that they have read and understand the materials in the notebook. The Board's Executive Director and Office Manager hold meetings at least annually to verbally review the materials in the notebooks with staff.

In addition, the Board Members and the Executive Director adhere to the relevant statutes regarding public officials. They are defined under [Minnesota Statutes §10A.01](#) as “public officials” and are therefore subject to various provisions of [Chapter 10A](#). Also, [Minnesota Statutes §214.10](#) contains the following provision, which Board members do follow: “A board member who has a direct current or former financial connection or professional relationship to a person who is the subject of board disciplinary activities must not participate in board activities relating to that case”. The Executive Director reviews these statutes with each newly appointed Board member as part of the orientation process. The Board members are also given a copy of a document from the Attorney General's Office that is titled *Board Members' Handbook of Legal Issues*. The *Handbook* explains the legal issues that Board members must consider and goes over a number of relevant laws, including those involving ethics and conflicts of interest. If there are any questions about the possibility of a conflict-of-interest, the Board seeks advice from the Attorney General's Office.

Extent to which the agency complies with chapter 13 and follows records management practices that enable the agency to respond efficiently to requests for public information

The Board strives to follow all applicable provisions of [Chapter 13](#) and to follow records management practices that allow for efficient responses to requests for public information. As one example, the Board is required to collect reports from drug manufacturers and wholesalers that detail certain payments that they make to practitioners (primarily physicians). Those reports are designated as public data under [Minnesota Statutes §151.47](#). Beginning in late 2006, a series of articles in professional journals and the lay press sparked significant interest in those reports. Consequently, all reports submitted prior to that time were scanned into Adobe documents and placed on the Board's Web site. (See [www.pharmacy.state.mn.us/main\\_pay.htm](http://www.pharmacy.state.mn.us/main_pay.htm)). The Board subsequently required manufacturers to download a spreadsheet template and submit the data electronically. The spreadsheets are also posted on the Board's Web site and are easier to search than the Adobe documents. (The spreadsheet can be accessed at: <http://www.pharmacy.state.mn.us/forms/gifts.xls>).

One of the online services offered by the Board is licensure verification. Anyone can access this service at: [www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx](http://www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx). A user of this service can verify the licensure or registration of any individual or business that the Board licenses or registers, with the exception of controlled substance researchers. In addition, individuals can view or download forms, applications, checklists, meeting minutes and a variety of other documents from the Web site.

For the past several years, the Board's disciplinary orders, which are public documents, have been automatically scanned into Adobe documents after they are fully executed. In addition, when older disciplinary orders are requested, they are also scanned. Consequently, the Board now typically responds to requests for disciplinary orders by sending an e-mail to the requestor to which the order is attached. The Board plans to implement an electronic document management system (EDMS) within the next two or three years. The EDMS will be integrated with the Board's licensing system. That will allow individuals to directly download disciplinary orders while they are completing a licensure or registration verification.

The Board plans to expand online services to allow for electronic submission of: initial license/registration applications; continuing education reporting certificates and other documents. That expansion, coupled with the implementation of the EDMS, will mean that nearly all Board documents will be generated and stored electronically – increasing the efficiency with which the Board responds to requests for public information.

As noted above, the Board also takes very seriously its obligation to protect non-public data and to comply with the sections of [Chapter 13](#) that require the safe-guarding of such data.

Effect of federal intervention or loss of federal funds if the agency is abolished

Abolishing the Board of Pharmacy, without making provisions for the efficient continuation of many of its functions, would put the State of Minnesota at odds with several significant federal laws and rules - and would potentially result in the loss of approximately \$150 million in federal funding. The specific federal laws and rules involved are the Food, Drug and Cosmetic Act, the Controlled Substances Act and certain sections of the Social Security Act relating to Medicare and Medicaid.

*Food, Drug and Cosmetic Act*

[21 USC Section 353](#), the part of the Food, Drug and Cosmetic Act (FDCA) that distinguishes between prescription and non-prescription drugs, states in part (and with emphasis added):

“(b)(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug; *shall be dispensed only (i) upon a written prescription of a **practitioner licensed by law** to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, . . .* The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale”.

Unless a practitioner is licensed by law, it is illegal under this section of the FDCA for a prescription drug to be dispensed to any person. If the boards that license physicians, physician assistants, advance nurse practitioners, dentists, podiatrists and optometrists were abolished and if the state no longer licensed those practitioners, Minnesotans would not have legal access to prescription drugs (unless they were prescribed by practitioners licensed in other states or the federal government somehow waived this legal requirement).

While this language does not include the word “licensed” before the word “pharmacist”, all states licensed pharmacists when this language was passed in 1952. It is a fairly safe assumption that Congressional intent was for licensed pharmacists to fill the prescriptions written by licensed practitioners. Other sections of the FDCA do specify that pharmacists must be licensed in order to perform certain activities such as compounding. (See [21 USC Section 353a](#)).

[21 USC Section 353](#) also contains the Prescription Drug Marketing Act provisions of the FDCA which were signed into law by President Ronald Reagan in 1988. One portion of this section reads (emphasis added):

“No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person *is licensed by the State* in accordance with the guidelines issued under subparagraph (B)”.

In Minnesota, as in many states, the Board of Pharmacy licenses drug wholesalers. Consequently, if the Board was abolished and if the state stopped licensing drug wholesalers, those wholesalers could not operate within Minnesota. Again, Minnesotans would have difficulty accessing needed prescription drugs.

## *Controlled Substances Act*

Relevant provisions of the regulations promulgated by the U.S. Drug Enforcement Administration under authority of the federal Controlled Substances Act include (with emphasis added):

- [21 CFR Section 1306.03](#):

### **Section 1306.03 Persons entitled to issue prescriptions.**

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances **by the jurisdiction in which he is licensed to practice his profession** and

(2) either registered or exempted from registration pursuant to [Secs. 1301.22\(c\)](#) and [1301.23](#) of this chapter.

Unless a practitioner is licensed and also authorized to practice a profession, prescriptions for controlled substances (like opioid pain relievers) can't be issued. If the agencies that license physicians, physician assistants, advance nurse practitioners, dentists, podiatrists and optometrists were abolished and if the state no longer licensed those practitioners, Minnesotans would not have legal access to controlled substances (unless they were prescribed by practitioners licensed in other states of the federal government somehow granted a waiver to this regulation).

- [21 CFR Section 1306.06](#) and [21 CFR Section 1300.01\(b\)\(33\)](#):

### **Section 1306.06 Persons entitled to fill prescriptions.**

A prescription for a controlled substance **may only be filled by a pharmacist**, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

Section 1300.01(b)(33)

(33) The term *pharmacist* means any pharmacist **licensed by a State** to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

If the Board of Pharmacy was abolished and if the state no longer licensed pharmacists, controlled substance prescriptions could not be legally dispensed by pharmacies located within the Minnesota.

## *Social Security Act*

Considerations involving the Social Security Act include:

- **42 U.S.C. 1396r-8(g)(1)(A)**

This section requires state Medicaid agencies to perform retrospective drug utilization review as a condition for receiving federal matching dollars for prescription drugs. The agencies must have a DUR board which meets the following standards (emphasis added):

“The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

- (i) The clinically appropriate prescribing of covered outpatient drugs.
- (ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.
- (iii) Drug use review, evaluation, and intervention.
- (iv) Medical quality assurance.

The membership of the DUR Board shall be made up of at least 1/3 but no more than 51 percent ***licensed*** and actively practicing ***physicians*** and at least 1/3 ***licensed*** and actively practicing ***pharmacists***”.

Consequently, the Minnesota Department of Human Services has a DUR Board that includes Minnesota licensed physicians and pharmacists. If the boards of Medical Practice and Pharmacy were abolished and if the state no longer licensed physicians and pharmacists, the federal match for prescriptions drugs, which is currently approximately \$150 million, would be in jeopardy.

In addition, each state has to have a **State Plan** approved by CMS. Minnesota’s State Plan currently contains the following language (emphasis added):

**The following providers are eligible for payment for dispensing prescribed drugs:**

- (1) A *pharmacy that is licensed by the Minnesota Board of Pharmacy*
- (2) An out of state pharmacy that complies with the licensing and certification requirements of the state

Unless CMS agreed to a State Plan Amendment that eliminated the licensure requirement, Minnesota would not receive federal matching funds for prescription drugs if the Board of Pharmacy was abolished and if the state stopped licensing pharmacies.

Section 6401 (a) of the Affordable Care Act amended section 1866(j) of the Social Security Act to require screening of Medicare providers. Note that the screening requires a licensure check. Related regulations are as follows (emphasis added):



**CFR 445.412, “Verification of provider licenses”:**

The State Medicaid agency must

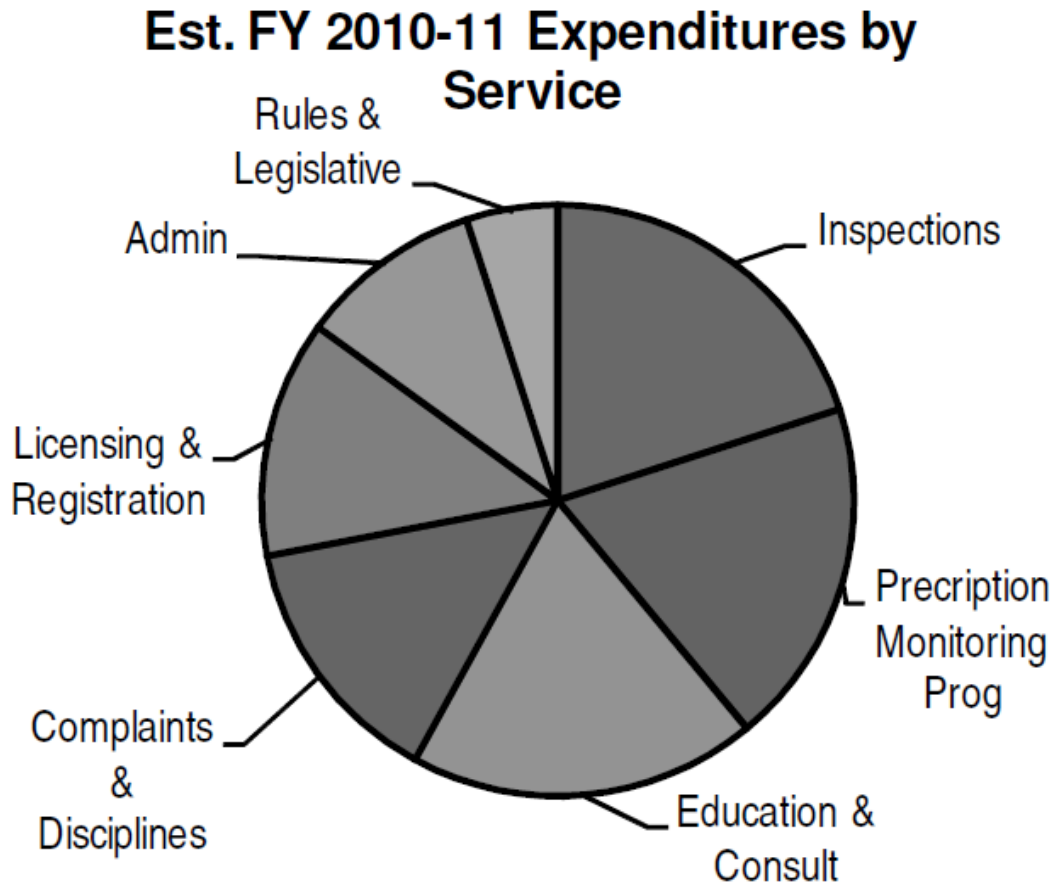
- (a) Have a method for verifying that any provider purporting to be *licensed* in accordance with the laws of any State *is licensed* by such State
- (b) Confirm that the provider’s license has not expired and that there are no current limitations on the provider’s license

Per these requirements, a health care provider that wishes to participate in Medicaid must be licensed by the state. If the boards that license health care providers that participate in Medicaid are abolished and some other provision is not made for their licensure, those providers will not be able to participate in Medicaid. Similar provisions apply for Medicare. Consequently, senior citizens, disabled individuals and many children – who are the primary enrollees in Medicare and Medicaid – would have greatly reduced access to health care services.

The Board was recently awarded a **federal grant** of approximately \$375,000 by the U.S. Department of Justice, Bureau of Justice Assistance. The purpose of the grant is to make enhancements to the Minnesota Prescription Monitoring Program, which was described in detail above. If the Board were abolished the state would lose that grant money – unless operation of the PMP was transferred to another agency. Even if the PMP were transferred, that grant money might be in jeopardy because it was specifically awarded to the Board and might not be transferable to another state agency.

## PRIORITY BASED BUDGET

The following graph is taken from the Board of Pharmacy Agency Profile that was included in the budget that Governor Dayton submitted to the Legislature earlier this year.



Unlike larger agencies, the Board does not have numerous programs, some of which might be deemed to be of higher priority than others. As the chart depicts, the Board expends funds in just seven areas. Furthermore, the activities in some areas are intertwined with the activities in other areas. For example, routine inspections may uncover practice violations that might be handled by providing education and consultation to the licensee or, for more severe violations, might result in the initiation of the complaint and disciplinary processes. Also, due to the budget constraints faced by all state agencies over the past decade, the Board has already reduced expenditures in some areas and found ways to work more efficiently in other areas. In short, the Board has long since “cut out the fat” and, at times, has had to “cut into the bone”. As mentioned above, the Board did not replace a Surveyor who retired in 2009 due to budget concerns and there was a corresponding decline in the number of inspections completed and an increase in the number of year-end open complaint investigations. For these reasons, the Board does not perform any functions that are not a priority. The following information explains why the Board considers all of its activities to be important.

Roughly half of the Board’s budget is expended on the core activities of licensing, inspections,

complaint investigation and disciplinary actions - activities that the Board has been engaged in since it was established in 1885. As noted in the previous section, elimination of licensing would put the State of Minnesota at odds with several significant federal laws and rules - and would potentially result in the loss of approximately \$150 million in federal funding. Licensing fees are also the basis for the Board's funding. The Board is currently receiving over 20 complaints per month from the public. Many of the complaints involve pharmacists and technicians who are significantly impaired due to chemical dependency or mental illness. Investigation of other complaints often reveals practice violations which, though they are not so severe as to warrant discipline, do require corrective action on the part of the licensee. Routine inspections also frequently reveal practice violations that need to be corrected to reduce the risk of patient harm. For these reasons, the Board's most important priorities are licensing, inspections, complaint investigations and disciplinary activities.

Most of the expenditures spent on administration are for renting the Board's office and purchasing equipment and supplies. The health related licensing boards recently negotiated a new lease that actually lowered rents. The Board has also taken steps to control expenditures on equipment and supplies. However, equipment does wear out and supplies are consumed. Without having an office to work in and adequate equipment and supplies, the Board could not function. Consequently, this area of the budget is also a priority.

The Executive Director (ED) and Board Surveyors are licensed pharmacists with, collectively, over 200 years of experience working in a variety of pharmacy settings. As such, their advice is sought on a daily basis by pharmacists and other licensees and registrants. The ED and Surveyors provide consultations on issues that are often extremely technical and complex. For example, Surveyors regularly work with pharmacists, architects and engineers to provide advice concerning compliance with the United States Pharmacopeia Chapter 797 standards for sterile compounding. The goal of all consultations is to promote both adherence to laws and rules and the adoption of cutting edge standards of practice and technology that help protect the health, welfare and safety of citizens. There are a few private sector consultants who are experts in certain areas of pharmacy practice and Board staff already refers some inquiries to those consultants. However, if the ED and Surveyors stopped responding to those daily requests for advice, it is likely that the public would be at increased risk of harm. It is also likely that the Board would receive additional complaints regarding dispensing errors and adverse drug events. In the judgment of the Board, it is better to provide consultation and education "up front" in order to prevent errors than it is to investigate a complaint after the error has occurred. Consequently, while it might be possible to divert some expenditure in this area to inspections, the Board believes that some priority must be given to consultation and education.

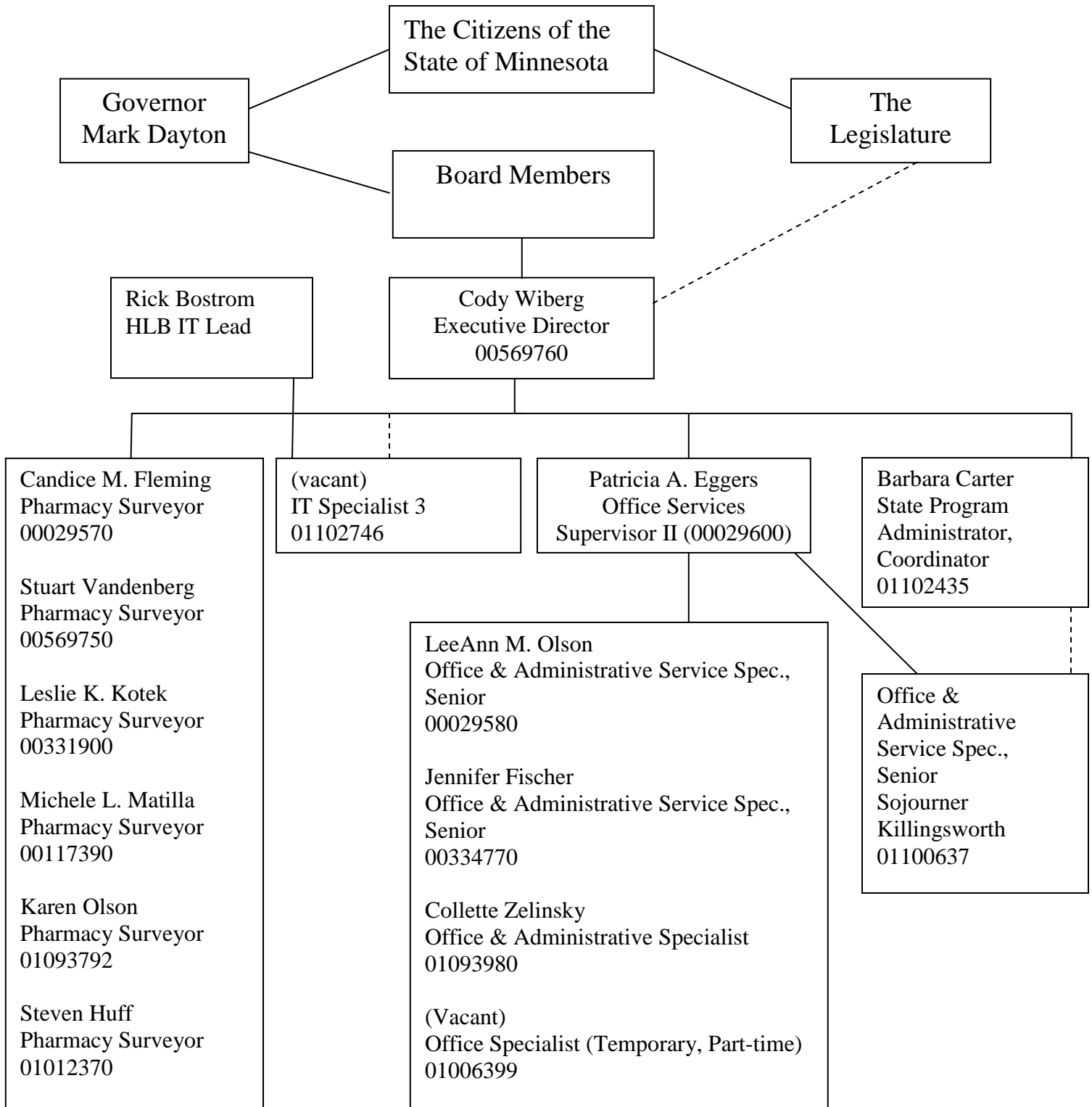
Most of the expenditures in the rules and legislative area are for the time spent by the Executive Director responding to legislative requests for technical assistance and preparing legislatively mandated reports. It is the Board's understanding that it must provide such technical assistance to legislators when it is requested. That being the case, the levels of expenditures in this area will be entirely dependent on the number of requests for technical assistance and reports that are received and the complexity of the issues involved. Presumably, members of the Legislature would want the Board to make responding to their requests for technical assistance a priority.

The Prescription Monitoring Program (PMP) is the newest of the Board's functions, having become fully operational in April of 2010. The PMP was created by an act of the Legislature that enjoyed broad bipartisan support. It has also proven to be a very popular program, with over 5,500 pharmacists and prescribers enrolled as users. Law enforcement has served the Board with over 180 search

warrants, with some cases targeting organized rings of individuals who procure drugs to sell on the street. As mentioned earlier in the report, prescription drug abuse has reached epidemic proportions in the United States – and Minnesota has not been spared. Consequently, the Board considers the PMP to also be an important priority.

As it has done in the past, the Board will continue to routinely assess its operations in order to develop more efficient policies and procedures and to limit increases in expenditures. However, the Board cannot significantly reduce expenditures below current levels. The Legislature and Governor appear to have concurred with this assessment by authorizing an increase in the Board's fees and appropriation during the 2011 Special Session.

**APPENDIX A**  
**Organizational Relationships**  
 Current as of November 11, 2011



**APPENDIX B**  
**Links to the Board's Web sites**

**Link to the Board's Main Web site:**

[www.pharmacy.state.mn.us](http://www.pharmacy.state.mn.us)

**Direct link to the Minnesota Prescription Monitoring Program Web site:**

<http://pmp.pharmacy.state.mn.us/>



**APPENDIX C**  
**A Six Year History of FTE Staffing Levels**

| Minnesota Board of Pharmacy | FY<br>2007 | FY<br>2008 | FY<br>2009 | FY<br>2010 | FY<br>2011 | FY<br>2012 |
|-----------------------------|------------|------------|------------|------------|------------|------------|
| <b>FTE Staffing Levels</b>  | 10         | 11.3       | 11.3       | 10.3       | 12.3       | 14         |

| <b>Notes</b>  |
|---|
| 1. During the 2007 Session, the Legislature increased the Board's appropriation to allow for the hiring of an additional Pharmacy Surveyor. In addition, the Legislature directed the Board to implement the Prescription Monitoring Program. A part-time staff member was hired to assist in the implementation                                      |
| 2. A Pharmacy Surveyor retired at the end of FY 2009 and was not replaced at the time due to budget concerns.   |
| 3. During the 2010 Session, the Legislature approved a permanent source of state funding for the Prescription Monitoring Program. This allowed for the hiring of the two full-time staff members needed to <i>minimally</i> run the PMP.  |
| During the 2011 Special Session, the Legislature approved the Board's first fee increase in a decade and increased the Board's appropriation so that the Board could replace the Surveyor who retired in 2009 and hire an Information Technology Specialist 3 (to work with our licensing database and PMP vendors on enhancements to those systems). |

**APPENDIX D**  
**A Six Year History of All Funding**

| Minnesota Board of Pharmacy<br>Six Year History of Funding | Fiscal Year        |                    |                    |                    |                    |                    |
|--|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
|  | 2006               | 2007               | 2008               | 2009               | 2010               | 2011               |
| Federal Grant Revenues                                     | \$0                | \$0                | \$0                | \$8,468            | \$224,332          | \$163,099          |
| Other Grant Revenues                                       | \$0                | \$0                | \$0                | \$0                | \$0                | \$36,010           |
| Fees Revenues  | \$1,441,783        | \$1,478,013        | \$1,575,281        | \$1,643,853        | \$1,455,764        | \$1,700,893        |
| Civil Penalty Revenues                                     | \$500              | \$1,100            | \$4,300            | \$50,700           | \$500              | \$5,100            |
| <b>Total Revenues</b>                                      | <b>\$1,442,283</b> | <b>\$1,479,113</b> | <b>\$1,579,581</b> | <b>\$1,703,021</b> | <b>\$1,680,596</b> | <b>\$1,905,102</b> |
| Direct Regular Expenditures                                | \$1,103,773        | \$1,128,361        | \$1,381,016        | \$1,409,672        | \$1,292,725        | \$1,363,356        |
| Indirect Regular Expenditures                              | \$128,294          | \$136,726          | \$138,963          | \$172,270          | \$221,884          | \$281,184          |
| Prescription Monitoring Program Expenditures               | \$0                | \$0                | \$0                | \$8,468            | \$224,332          | \$181,289          |
| <b>Total Expenditures</b>                                  | <b>\$1,232,067</b> | <b>\$1,265,087</b> | <b>\$1,519,979</b> | <b>\$1,590,410</b> | <b>\$1,738,941</b> | <b>\$1,825,829</b> |
| <b>Surplus or Shortfall</b>                                | <b>\$210,216</b>   | <b>\$214,026</b>   | <b>\$59,602</b>    | <b>\$112,611</b>   | <b>-\$58,345</b>   | <b>\$79,273</b>    |

## APPENDIX E

### **A List of All Advisory Councils Whose Primary Function is to Advise the Organization**

The Board of Pharmacy has no Advisory Councils. The Board does have a Continuing Education Advisory Task Force and an Internship Advisory Committee that are described fully in the body of the report.

## APPENDIX F

### **Citation to the Statute Creating the Organization and to other Statutes Governing or Administered by the Organization; Citation to the Administrative Rules Adopted by the Organization**

Certain sections of statutes apply to all state agencies and are not listed here. The following chapters and sections of **statutes** create the duties and powers of the Board of Pharmacy and/or are administered by the Board.

1. [Minnesota Statutes Chapter 151](#) is the primary chapter that creates the Board and that the Board administers.
2. [Minnesota Statutes Chapter 214](#) contains provisions that apply to all health licensing boards, including the Board of Pharmacy.
3. [Minnesota Statutes Chapter 152](#) is the state's Controlled Substances Act. Some of the Board's powers and duties derive from portions of this chapter.
4. [Minnesota Statutes §609B.130](#) contains provisions relating to certain disciplinary actions and references back to Section 151.06.
5. [Minnesota Statutes Chapter 319B](#) contains provisions relating to professional firms of which the Board must be cognizant.
6. [Minnesota Statutes §299A.297](#) requires the Commissioner of Public Safety to “provide information and assistance upon request to the State Board of Pharmacy with respect to the board's enforcement of chapter 152”.
7. A number of other sections of statutes reference the Board but they are not administered by the Board, nor do they govern the Board. (e.g. – there are sections that define controlled substances as those that are either listed in Chapter 152 of the statutes or that are listed in the rules promulgated by the Board in Chapter 6800).

The **rules** promulgated by the Board of Pharmacy are found in [Minnesota Rules Chapter 6800](#).

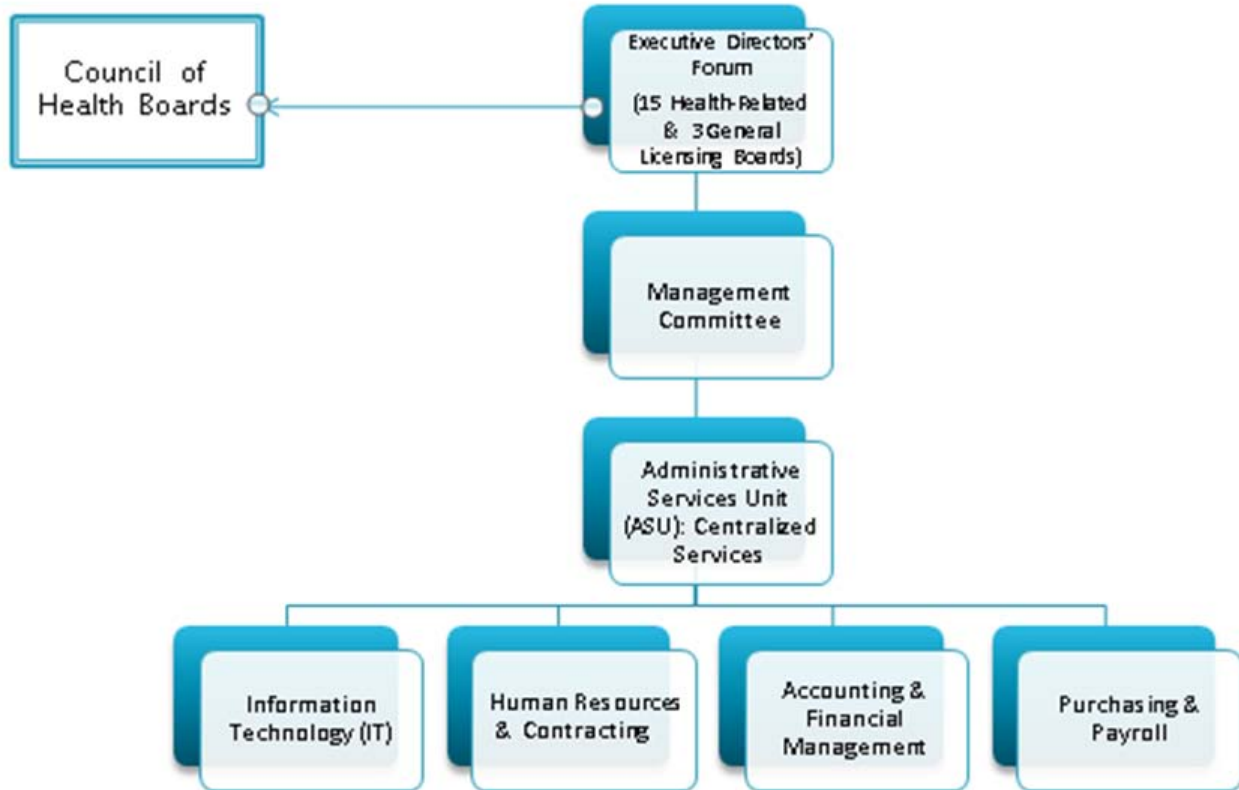
## APPENDIX G

### **A Copy or Link to any other Governance Documents Adopted by the Agency**

The Board has not adopted any such documents.

## APPENDIX H

### Structural Relationships: Council of Health Boards, Executive Director's Forum, Management Committee and Administrative Services Unit





# APPENDIX I

## Historical Data Concerning Board Members and Executive Directors

| MINNESOTA BOARD OF PHARMACY MEMBERS SINCE 1950 |              |                     |                 |
|--|--------------|---------------------|-----------------|
| TERM START                                     | TERM END     | NAME                | MEMBER REPLACED |
| January-50                                     | July-55      | ANGUS TAYLOR        |                 |
| May-51   | January-56   | HAROLD CARPENTER    | B. DETERLING    |
| December-52                                    | May-54       | RAYMOND CALLANDER   | PASTERNAKI      |
| January-53                                     | June-57      | HARRY CARLSON       |                 |
| January-54                                     | April-56     | JOHN HARMS          | VICTOR FEIT     |
| May-54   | March-58     | IVAN PETERSON       | R CALLANDER     |
| July-55  | February-60  | ANGUS TAYLOR        |                 |
| January-56                                     | January-61   | FLOYD ALCOTT        | H CARPENTER     |
| April-56                                       | January-59   | ROBERT BERG         | J HARMS         |
| June-57  | September-61 | JAMES GARDNER       | H CARLSON       |
| March-58                                       | January-63   | IVAN PETERSON       |                 |
| January-59                                     | January-64   | MAX BEARMAN         | R BERG          |
| February-60                                    | April-61     | OSCAR OLSON         | A TAYLOR        |
| January-61                                     | April-61     | FLOYD ALCOTT        |                 |
| April-61                                       | September-62 | NORMAN TELANDER     | O OLSON         |
| April-61                                       | January-66   | WILLIAM F. APPEL    | F ALCOTT        |
| September-61                                   | January-62   | JOHN NELSON         | J GARDNER       |
| January-62                                     | January-67   | JOHN NELSON         |                 |
| September-62                                   | January-65   | MAURICE HILLESTAD   | N TELANDER      |
| January-63                                     | January-68   | JOHN QUISTGARD      | I PETERSON      |
| January-64                                     | January-69   | MAX BEARMAN         |                 |
| January-65                                     | January-70   | KITTY ALCOTT        | M HILLESTAD     |
| January-66                                     | January-71   | BENJAMIN SEIFERT    | W APPEL         |
| January-67                                     | January-72   | JOHN NELSON         |                 |
| January-68                                     | January-73   | JOHN QUISTGARD      |                 |
| January-69                                     | June-74      | LOWELL ANDERSON     | MAX BEARMAN     |
| January-70                                     | January-75   | ROY OLSON           | K ALCOTT        |
| January-71                                     | January-76   | BENJAMIN SEIFERT    |                 |
| January-72                                     | January-77   | KITTY ALCOTT        | J NELSON        |
| January-73                                     | January-78   | THOMAS R BERG       | J QUISTGARD     |
| January-74                                     | January-79   | MICHAEL HART        | L ANDERSON      |
| January-74                                     | June-79      | THOMAS M JONES      | 1ST PUBLIC MBR  |
| January-74                                     | January-78   | ROSETTA STARK       | 1ST PUBLIC MBR  |
| January-75                                     | May-80       | MARCUS FREDERICKSON | ROY OLSON       |
| January-75                                     | May-80       | LOUISE KORTZ        | BEN SEIFERT     |
| January-77                                     | January-81   | KITTY ALCOTT        |                 |
| January-78                                     | April-82     | THOMAS R BERG       |                 |
| January-78                                     | April-82     | OVE WANGENSTEEN     | R STARK         |

|             |             |                                  |                 |
|-------------|-------------|----------------------------------|-----------------|
| June-79     | March-83    | GARY P BLUME                     | T JONES         |
| June-79     | March-83    | MICHAEL HART                     |                 |
| May-80      | January-84  | LESTER HACKNER                   | L KORTZ         |
| May-80      | January-84  | JOSEPH ZASTERA                   | FREDERICK-SON   |
| February-81 | January-85  | ARNOLD D DELGER                  | K ALCOTT        |
| April-82    | January-86  | ROGER VADHEIM                    | THOMAS BERG     |
| April-82    | January-86  | OVE WANGENSTEEN                  |                 |
| March-83    | January-87  | MICHAEL HART                     |                 |
| March-83    | January-87  | PATRICIA LIND                    | G BLUME         |
| January-84  | January-88  | JOSEPH ZASTERA                   |                 |
| January-84  | January-88  | B PATRICIA DELAPOINTE            | L HACKNER       |
| January-85  | February-89 | GEORGE MEDICH                    | A DELGER        |
| January-86  | January-90  | OVE WANGENSTEEN                  |                 |
| January-86  | January-90  | HENRY CAPIZ                      | R VADHEIM       |
| January-87  | May-91      | DORIS CALHOUN                    | M HART          |
| January-87  | May-91      | PATRICIA LIND                    |                 |
| January-88  | March-92    | JOSEPH ZASTERA                   |                 |
| January-88  | March-92    | B PATRICIA DELAPOINTE            |                 |
| February-89 | April-93    | GEORGE MEDICH                    |                 |
| January-90  | January-94  | HENRY CAPIZ                      |                 |
| January-90  | January-94  | OVE WANGENSTEEN                  |                 |
| May-91      | January-95  | DENISE M GROEHLER                | D CALHOUN       |
| May-91      | January-95  | CAROL PETERSON                   | P LIND          |
| March-92    | January-96  | HOWARD JUNI                      | J ZASTERA       |
| March-92    | January-96  | WENDY SIMENSON                   | P DELAPOINTE    |
| April-93    | January-97  | DON GIBSON                       | G MEDICH        |
| January-94  | January-98  | CARL BENSON                      | H CAPIZ         |
| January-94  | January-98  | JEAN LEMBERG                     | OVE WANGENSTEEN |
| January-95  | January-99  | DENISE FRANK (Formerly GROEHLER) |                 |
| January-95  | January-99  | CAROL M. PETERSON                |                 |
| January-96  | January-00  | CHARLES COOPER                   | HOWARD JUNI     |
| January-96  | January-00  | JEFFERY LINDOO                   | WENDY SIMENSON  |
| January-97  | January-01  | DON GIBSON                       |                 |
| January-98  | January-02  | JEAN LEMBERG                     |                 |
| January-98  | January-02  | CARL BENSON                      |                 |
| June-99     | January-03  | CAROL PETERSON                   |                 |
| June-99     | January-03  | VERNON KASSEKERT                 | DENISE FRANK    |
| March-00    | January-04  | BETTY L. JOHNSON                 | JEFFERY LINDOO  |
| March-00    | January-04  | CHARLES COOPER                   |                 |
| January-01  | January-05  | THOMAS DICKSON                   | DONALD GIBSON   |
| February-02 | January-06  | JEAN LEMBERG                     |                 |
| February-02 | January-06  | GARY SCHNEIDER                   | CARL BENSON     |
| July-03     | January-07  | VERNON KASSEKERT                 |                 |
| July-03     | January-07  | CARLETON CRAWFORD                | CAROL PETERSON  |

|             |            |                    |                   |
|-------------|------------|--------------------|-------------------|
| June-04     | January-08 | BETTY JOHNSON      |                   |
| June-04     | January-08 | KAY HANSON         | CHARLES COOPER    |
| April-05    | January-09 | THOMAS DICKSON     |                   |
| June-06     | April-10   | GARY SCHNEIDER     |                   |
| June-06     | January-10 | IKRAM-UL-HUQ       | JEAN LEMBERG      |
| May-07      | January-11 | CARLETON CRAWFORD  |                   |
| May-07      | January-11 | KAREN BERGRUD      | VERN KASSEKERT    |
| March-08    | January-12 | KAY HANSON         |                   |
| March-08    | July-11    | STACEY JASSEY      | BETTY JOHNSON     |
| April-09    | January-13 | JAMES KOPPEN       | TOM DICKSON       |
| April-10    | January-14 | LAURA SCHWARTZWALD | GARY SCHNEIDER    |
| June-11     | January-15 | STUART WILLIAMS    | CARLETON CRAWFORD |
| November-11 | January-12 | BOB GOETZ          | STACEY JASSEY     |

| <b>Minnesota Board of Pharmacy Executive Directors Since 1911</b> |                         |                         |
|---|-------------------------|-------------------------|
| <b>EXECUTIVE DIRECTOR</b>   | <b>BEGAN EMPLOYMENT</b> | <b>ENDED EMPLOYMENT</b> |
| Charles T. Heller, Sr.  | 1911 or thereabouts     | 1913                    |
| Edward A. Tupper  | 1913                    | 1920                    |
| Martin Johnson  | 1920                    | 2/1/1923                |
| John W. Dargavel  | 2/1/1923                | 2/1/1934                |
| Hugo H. Peterson  | 2/1/1934                | 2/1/1935                |
| Edward J. Prochaska   | 2/1/1935                | 2/1/1940                |
| Frank W. Moundry  | 2/1/1940                | 5/1/1957                |
| Harry W. Carlsen  | 5/1/1957                | 5/9/1958                |
| Angus H. Taylor   | 5/13/1958               | 7/29/1959               |
| Arthur L. Eide  | 7/29/1959               | Jul-65                  |
| Paul G. Grussing  | Jul-65                  | 11/6/1973               |
| David E. Holmstrom  | Nov-73                  | 9/20/2005               |
| Cody Wiberg   | 9/21/2005               | Present                 |