

PHARMACY BOARD

Agency Profile

Agency Purpose

The Minnesota Board of Pharmacy was established in 1885 and exists to protect the public from adulterated, misbranded, and illicit drugs, and from unethical or unprofessional conduct on the part of pharmacists or other licensees and registrants. The Board strives to provide a reasonable assurance of professional competency in the practice of pharmacy by enforcing the Pharmacy Practice Act, the State Controlled Substances Act and various other statutes and rules. The Board fulfills its mission through a combination of licensing, inspections, complaint investigation, discipline, consultations and regulatory activities. The Minnesota Prescription Monitoring Program, a tool that prescribers and pharmacists can use to help prevent prescription drug abuse, is also administered by the Board.

At a Glance

Board members: Seven, five pharmacists and two public members, appointed by the Governor

Staff: 12 Full-time employees

Licenses & Registrations Issued

7,546	Pharmacists
498	Pharmacy Interns
8,552	Pharmacy Technicians
1,701	Pharmacies
401	Drug Manufacturers
1,067	Drug Wholesalers
68	Medical Gas Distributors
498	Controlled Substance Researchers
1,456	Pharmacy Preceptors

Inspections

496 inspections of pharmacies, wholesalers, manufacturers, medical gas distributors & controlled substance researchers.

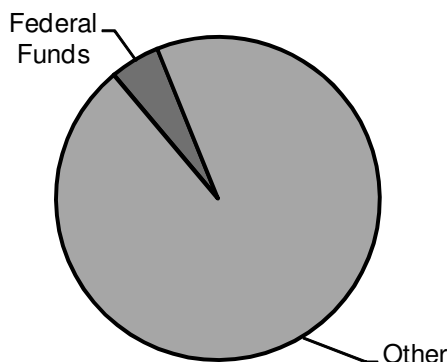
Complaint & Discipline

- Receipt of 85 new jurisdictional complaints
- Resolution of 69 jurisdictional complaints
- 26 disciplinary actions taken
- Monitor 30 individuals under disciplinary order

Prescription Monitoring Program

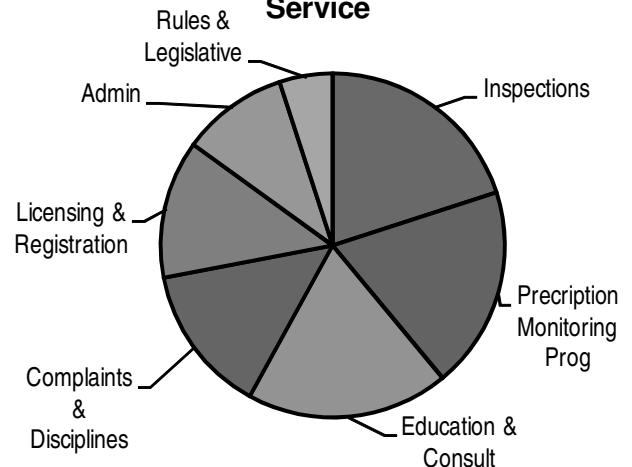
- 6.5 million controlled substance prescriptions projected to be reported annually to PMP
- 2,458 enrolled prescribers and pharmacists
- 16,372 database queries as of 6/30/2010

Est. FY 2010-11 Expenditures by Fund



Source: Consolidated Fund Statement.

Est. FY 2010-11 Expenditures by Service



Source: Board expenses allocated to the services provided by the board.

Strategies

One of the Board's primary strategies is to promote adherence to state and federal laws and rules relating to the practice of pharmacy and to the manufacture and distribution of pharmaceuticals. Another, equally important strategy is to promote the adoption of cutting edge standards of practice that go beyond the minimum requirements specified in the statutes and rules.

Operations

Unlike larger agencies that are divided into administrative areas or divisions, the Board functions as a single operational unit. Nevertheless, the Board's activities can be divided into several areas of focus:

- **Licensing.** Licensing is the Board's "foundation", on which most activities ultimately rest. The ability to license and register individuals and businesses empowers the Board to inspect facilities, investigate complaints, and take disciplinary action when necessary. In addition, the Board is primarily funded by the licensing and registration fees that it collects. Most of the Board's staff members are involved in some aspect of the licensing process. Administrative staff members process applications and work with the National Association of Boards of Pharmacy to make sure that applicants for a pharmacist license have passed the required examinations. Compliance staff members conduct initial inspections of facilities before they are allowed to be licensed.
- **Compliance.** Activities in this area can be further divided as follows:
 - **Inspections.** The Board licenses or registers 2279 in-state pharmacies, drug wholesalers, drug manufacturers, medical gas distributors and controlled substance researchers. Each in-state facility is inspected by a Board Surveyor (aka an Inspector) before it is allowed to open. The Board strives to inspect each pharmacy that it licenses once every two years, at a minimum. However, due to budgetary concerns, the Board did not replace a Surveyor who retired in 2009. This has reduced the number of completed inspections by 20% during FY 2010.
 - **Complaint Investigations.** The Board investigates every jurisdictional complaint that it receives. Most often, a Board Surveyor visits the pharmacy in question, meets with pharmacy staff, reviews the policies and procedures of the pharmacy, and directs pharmacy staff to make necessary changes to policies and procedures. The Surveyor then files a report which is reviewed by the Board's Committee on Professional Standards (COPS). The Committee may dismiss the complaint if it determines that the allegations are without merit or if it is satisfied that the pharmacy will make any changes necessary to minimize future errors. The Committee sometimes determines that offenses were committed that are serious enough to warrant discipline. For cases involving certain issues, such as alleged physical or mental impairment of a licensee, the Board refers the matter to the Attorney General's Office (AGO) for investigation. In such cases, the AGO also issues a report that is reviewed by COPS.
 - **Discipline.** If either COPS or the Board's Executive Director (ED) determines that credible evidence exists that substantiates a serious violation of statutes or rules, the matter is turned into a disciplinary case. The ED works with the AGO to initiate the due process procedures that the Board must follow. The licensee or registrant is directed to appear before a Complaint Review Panel, which weighs the available evidence. In most cases, if the Panel determines that discipline is warranted, it reaches a settlement agreement with the licensee or registrant. Such agreements, which must be approved by the full Board, usually involve the issuance of a disciplinary order which places limitations and conditions on the license or registration of the person or business that was investigated. Several cases per year result in the revocation or voluntary surrender of a license or registration.
 - **Consultations.** The Executive Director and Board Surveyors are licensed pharmacists with, collectively, over 125 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.
- **Policy, Regulatory and Legislative Activities.** As new standards of practice emerge and new technologies are developed, the Board and its staff work to update guidelines, rules and statutes. Guidelines help licensees and registrants use new technologies and procedures in a way that best promotes the health, welfare and safety of citizens. As new technologies and standards of practice become more broadly accepted, the Board

will promulgate rules, as necessary, to replace the guidelines. For certain issues, it is necessary to ask the Legislature and Governor to enact new statutory language. In addition, Board staff very frequently provides technical assistance to legislators and their staff on a variety of issues concerning pharmacy and pharmaceuticals. The Board also works on policy issues with other local, state and federal agencies, including local law enforcement agencies, county attorneys, the state Departments of Human Services and Health, the Minnesota Pollution Control Agency, the Bureau of Criminal Apprehension, the U.S. Drug Enforcement Administration, and the U.S. Food and Drug Administration.

- **Services for the General Public.** In addition to the benefits that the public derives from the activities described above, Board staff provides direct services to the public as well. Staff provides information directly to members of the public in response to inquiries concerning the legal requirements and standards for pharmacy practice. Members of the public can use the Board's online license verification system to verify that individuals and businesses are licensed by the Board and to determine if any disciplinary action has been taken against a licensee or registrant. The Board provides copies of disciplinary orders to the public upon request - at no charge.
- **Prescription Monitoring Program.** The purpose of the Prescription Monitoring Program (PMP) is to promote public health, safety and welfare by detecting the diversion, abuse, and misuse of prescription medications classified as controlled substances under Minnesota statutes and rules. The PMP collects information concerning almost all controlled substance prescriptions dispensed for people residing in Minnesota. Prescribers, pharmacists and certain Medicaid program staff can access this data through a secure online system. The PMP is a tool that these authorized users can employ in order to detect possible "doctor-shopping behavior". (i.e. – obtaining prescriptions from multiple prescribers and having them filled by multiple pharmacies). The Board encourages prescribers and pharmacists who do identify individuals who appear to be engaged in "doctor-shopping" to refer them for appropriate care – either chemical dependency treatment or pain management. Law enforcement officials can obtain data from the system as well, but only after obtaining a court-issued search warrant and serving it on the Board.

Key Activity Goals & Measures

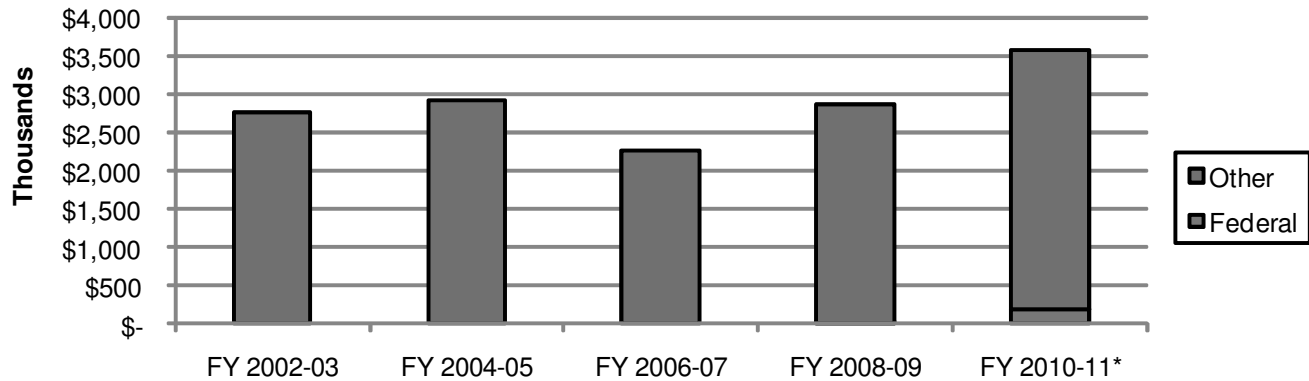
- The Board shares the Minnesota Milestone goal that state citizens will be healthy. By promoting best standards for pharmacy practice and disciplining unethical or incompetent pharmacists, the Board helps achieve the goal of reducing premature deaths. The operations described in the previous section help to reduce the number of medication errors that adversely impact patients. 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.

Budget Trends

The board is responsible for collecting sufficient revenue to cover both direct and indirect expenditures. The board is estimated to collect \$3.196 million in FY 2010-11, which is deposited as non-dedicated revenue into the state government special revenue fund.

From this fund, the board receives a direct appropriation to pay for agency activities such as salaries, rent, costs for disciplinary/contested cases and operating expenditures. It also pays statewide indirect costs through an open appropriation. In FY 2010-11, total expenditures for these purposes are estimated at \$2.904 million. The chart below shows funding trends over the last five biennia for the direct and open appropriation.

Total Expenditures by Fund



* FY 2010-11 is estimated, not actual

Source data for the previous chart is the Minnesota Accounting and Procurement System (MAPS) as of 07/31/10.

FY 2006-07 funding for the Administrative Services Unit moved to the Board of Nursing Home Administrators

Board fees are also responsible for covering a prorated share of support functions provided outside of the Board itself. These include legal support (Attorney General), statewide e-licensing system development and operations (Office of Enterprise Technology), centralized administrative support (Health Boards Administrative Services Unit), funding for services to health professionals (Health Professionals Services Program) and controlled substance program (Prescription Electronic Reporting). In FY 2010-11, some of the health boards' reserves in the state government special revenue fund were also transferred to the general fund. The table below displays direct and open appropriation expenditures, external support costs (prorated share), and the general fund transfers (prorated share) estimated in FY 2010-11.

	FY 2010-11 (in thousands)
Board's Direct and Open Appropriations	\$ 2,904
Board's External Support Costs and Transfers (prorated Share)	
• Attorney General support	106
• E-licensing support	218
• Central administrative service unit	161
• Health professional service program	70
• Prescription Electronic Reporting	124
• General fund transfer	231
Total	3,814
Fees Collected by Board	\$3,196
Prorated Surplus/(Deficit)	(618)

In most years, Board fee revenues exceed direct expenditures and external support costs, and as directed by law, the surplus is used to maintain a reserve in the state government special revenue fund. It should be noted here that the FY 2010-11 transfers to the General Fund, along with unanticipated increases in the support costs discussed above, have resulted in the Board's fee revenue not covering its prorated costs and transfers.

External Factors Impacting Agency Operations

The number of licensees regulated by the Board continues to rise, as do the number of complaints and the complexity of the cases. Also, there is an increase in the use of prescription medications due to an aging

population and a decrease in the amount of reimbursement pharmacies receive for dispensing medications. Given these changes, pharmacies are accelerating the adoption of new technologies and practices in an effort to increase productivity and cut costs. The Board must monitor these developments to ensure that these new technologies and practices do not have an adverse impact on the health, safety and welfare of the public. These developments make inspections and complaint investigations more complicated and time-consuming – and thus more costly.

Contact

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The Web site at: <http://www.pharmacy.state.mn.us> gives visitors easy access to useful information about the Board of Pharmacy. Types of information available through the web site include; general information about the Board, regulatory news and updates, Minnesota rules and statutes, public notices, forms, and online renewals of certain licenses and registrations.

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<i>Dollars in Thousands</i>					
	Current		Forecast Base		Biennium
	FY2010	FY2011	FY2012	FY2013	2012-13
<u>Direct Appropriations by Fund</u>					
State Government Spec Revenue					
Current Appropriation	1,388	1,905	1,905	1,905	3,810
Forecast Base	1,388	1,905	1,744	1,744	3,488
Change		0	(161)	(161)	(322)
% Biennial Change from 2010-11					5.9%
<u>Expenditures by Fund</u>					
Direct Appropriations					
State Government Spec Revenue	1,293	2,009	1,744	1,744	3,488
Open Appropriations					
State Government Spec Revenue	60	45	59	59	118
Statutory Appropriations					
Miscellaneous Special Revenue	0	18	0	0	0
Federal	224	163	0	0	0
Total	1,577	2,235	1,803	1,803	3,606
<u>Expenditures by Category</u>					
Total Compensation	1,133	1,301	1,333	1,363	2,696
Other Operating Expenses	444	934	470	440	910
Total	1,577	2,235	1,803	1,803	3,606
<u>Expenditures by Program</u>					
Pharmacy, Board Of	1,577	2,235	1,803	1,803	3,606
Total	1,577	2,235	1,803	1,803	3,606
Full-Time Equivalent (FTE)	11.1	12.8	13.0	13.0	

PHARMACY BOARD

Agency Revenue Summary

Dollars in Thousands

	Actual FY2010	Budgeted FY2011	Current Law		Biennium 2012-13
			FY2012	FY2013	
<u>Non Dedicated Revenue:</u>					
Departmental Earnings:					
State Government Spec Revenue	1,663	1,533	1,627	1,627	3,254
Other Revenues:					
State Government Spec Revenue	(207)	0	0	0	0
Total Non-Dedicated Receipts	1,456	1,533	1,627	1,627	3,254
<u>Dedicated Receipts:</u>					
Grants:					
Miscellaneous Special Revenue	0	18	0	0	0
Federal	224	163	0	0	0
Total Dedicated Receipts	224	181	0	0	0
Agency Total Revenue	1,680	1,714	1,627	1,627	3,254