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Pharmacy, Board of

http://mn.gov/health-licensing-boards/pharmacy/

AT A GLANCE (All data is for FY 2013)

Board Members and Staff

- 7 board members (five pharmacists and two public members) appointed by the Governor
- 19 full-time employees

Licenses & Registrations Issued

- 7,841 Pharmacists
- 1,347 Pharmacy Interns
- 10,486 Pharmacy Technicians
- 1,792 pharmacies
- 484 drug manufacturers
- 1,158 drug wholesalers
- 101 medical gas distributors
- 23 controlled substance researchers

Inspections

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

Complaint & Discipline

- Receipt of 118 new jurisdictional complaints
- Resolution of 76 jurisdictional complaints
- 10 disciplinary actions taken

Prescription Monitoring Program (PMP)

- 6.9 million controlled substance prescriptions projected to be reported annually to PMP
- 10,417 enrolled PMP Users
- 402,129 database queries



Historical Spending



Source: Consolidated Fund Statement

PURPOSE

The Minnesota Board of Pharmacy was established in 1885. Its mission is to preserve and protect the public health, safety, and welfare of Minnesotans by promoting the safe distribution of pharmaceuticals and the provision of quality pharmacy care.

The Board fulfills this mission through examination and licensure of pharmacists, regulation of the practice of pharmacy, inspection of licensed facilities, investigation of complaints, and the issuance of disciplinary orders and agreements for corrective action. Board staff also helps educate pharmacists and others about laws, rules and best standards of practice.

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.

The Board contributes to the following state wide outcomes:

- All Minnesotans have optimal health
- People in Minnesota are safe
- Efficient and accountable government services

Small Agency Profile

BUDGET

The activities of the board are largely funded by license fees collected from individuals and businesses regulated by the Board. The Board has also received federal and private grants that have been used to make enhancements to the Prescription Monitoring Program. The Board does not receive any appropriations from the general fund.

The board is responsible for collecting sufficient revenue to cover both direct and indirect expenditures. The Board collected \$2,383,000.00 in FY 2013. This revenue was 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 2013, total expenditures for these purposes were \$2,296,000.00.

STRATEGIES

The Board's primary strategy is to promote adherence to state and federal laws and rules relating to the practice of pharmacy and the manufacture and distribution of drugs. 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.

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 1,839 in-state pharmacies, drug wholesalers, drug manufacturers, medical
 gas distributors and controlled substance researchers. Each in-state facility is inspected by a Board Surveyor before it is
 allowed to open. Subsequent inspections, which are unannounced, are also periodically conducted.
 - Complaint Investigations. The Board investigates every jurisdictional complaint 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 Complaint Review Panel (CRP). The CRP may dismiss the complaint if it determines that the allegations are without merit or if it satisfied that the pharmacy will make any changes necessary to minimize the risk of future errors. The CRP 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 the CRP.
 - Discipline. If either the CRP or the Board's Executive Director (ED) determines that the evidence 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 Committee on Professional Standards, which weighs the available evidence. In most cases, if the Committee 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.
 - Consultations. The Executive Director, Deputy Director and Board Surveyors are licensed pharmacists with, collectively, nearly 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, DD and Surveyors provide consultations on issues that are often extremely technical and complex. 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 guidances, rules and statutes. Guidances 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 guidances. 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 drugs. 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 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 abuse or misuse of controlled substances. Controlled substances are drugs that have a high potential for abuse and addiction, such as narcotics and stimulants. The PMP collects information concerning almost all controlled substance prescriptions dispensed for people residing in Minnesota. Prescribers, pharmacists and certain Medicaid 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. (Obtaining prescriptions from multiple prescribers and having them filled by multiple pharmacies). The Board encourages prescribers and pharmacists who 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. Recent legislation requires the Board to begin providing prescribers and pharmacies with unsolicited reports, derived from the PMP database, concerning individuals who may be doctor-shopping.

Type of Measure	Name of Measure	Previous	Current	Dates
Quantity	Percentage of in-state facility inspections	27.7%	28.8%	FY 2011
	completed annually			FY 2013
Quantity	Percentage of complaints investigated and	89.4%	67.5%	FY 2012
	resolved within 12 months			FY 2013
Result	Number of individuals who receive	2,881	2,667	7/1/2011 -
	prescriptions from five or more prescribers and have them filled at five or more			12/31/2011
				7/1/2012 –
	pharmacies within a six month period of time			12/31/2012

RESULTS

Sections of MN Statutes Chapters 151 (<u>https://www.revisor.mn.gov/statutes/?id=151</u>), 152 (<u>https://www.revisor.mn.gov/statutes/?id=152</u>) and 214(<u>https://www.revisor.mn.gov/statutes/?id=214</u>) provide the Board of Pharmacy with legal authority to carry out its duties.

(Dollars in Thousands)

Expenditures By Fund

	Actua FY12	al FY13	Actual FY14	Estimate FY15	Forecast FY16	Base FY17	Govern Recomme FY16	
1201 - Health Related Boards	1,704	2,235	2,388	2,939	2,792	2,792	2,906	2,947
2000 - Restricted Misc Special Rev	17	0	18	2	1	1	1	1
3000 - Federal	31	61	76	275	133	133	133	133
Total	1,751	2,296	2,481	3,216	2,926	2,926	3,040	3,081
Biennial Change Biennial % Change				1,650 41		155 3		424 7
Governor's Change from Base Governor's % Change from Base								269 5
Expenditures by Program								
Program: Pharmacy Board of	1,751	2,296	2,481	3,216	2,926	2,926	3,040	3,081
Total	1,751	2,296	2,481	3,216	2,926	2,926	3,040	3,081
Expenditures by Category								
Compensation	1,285	1,499	1,861	2,235	2,172	2,170	2,276	2,308
Operating Expenses	452	608	608	979	753	755	763	772
Other Financial Transactions	14	189	11	2	1	1	1	1
Total	1,751	2,296	2,481	3,216	2,926	2,926	3,040	3,081
		l						
Full-Time Equivalents	13.1	14.5	16.9	16.9	16.9	16.9	17.9	17.9

(Dollars in Thousands)

1201 - Health Related Boards

	Actu		Actual	Estimate	Forecas	Basa	Goveri Recomme	
	FY12	FY 13	FY 14	FY15	FY16	FY17	FY16	FY17
Balance Forward In		641		167				
Direct Appropriation	2,341	2,376	2,555	2,772	2,733	2,733	2,847	2,888
Open Appropriation	0	0	0	0	59	59	59	59
Receipts							379	379
Cancellations		782						
Expenditures	1,704	2,235	2,388	2,939	2,792	2,792	2,906	2,947
Balance Forward Out	637		167					
Biennial Change in Expenditures				1,388		257		526
Biennial % Change in Expenditures				35		5		10
Gov's Exp Change from Base								269
Gov's Exp % Change from Base								5
FTEs	13.1	14.5	16.9	16.9	16.9	16.9	17.9	17.9

2000 - Restricted Misc Special Rev

	Actu	al	Actual	Actual Estimate		Forecast Base		nor's endation
	FY12	FY 13	FY 14	FY15	FY16	FY17	FY16	FY17
Balance Forward In	18	1	19	1				
Receipts		18		1	1	1	1	1
Expenditures	17	0	18	2	1	1	1	1
Balance Forward Out	1	19	1					
Biennial Change in Expenditures				3		(18)		(18)
Biennial % Change in Expenditures				17		(90)		(90)
Gov's Exp Change from Base								0
Gov's Exp % Change from Base								0

3000 - Federal

	Actual		Actual Actual Estimate		Forecas	Baso	Governor's Recommendation	
	FY12	FY 13	FY 14	FY15	FY16	FY17	FY16	FY17
Balance Forward In			16					
Receipts	31	77	60	275	133	133	133	133
Expenditures	31	61	76	275	133	133	133	133
Balance Forward Out		16						
Biennial Change in Expenditures				259		(84)		(84)
Biennial % Change in Expenditures				283		(24)		(24)
Gov's Exp Change from Base								0

Agency Financing by Fund

(Dollars in Thousands)

0

3000 - Federal

Gov's Exp % Change from Base

FY16-17 Biennial Budget Change Item

Change Item: Operating Adjustment

Fiscal Impact (\$000s)	FY 2016	FY 2017	FY 2018	FY 2019
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Health Related Boards Fund				
Expenditures	114	155	155	155
Revenues	0	0	0	0
Net Fiscal Impact =	114	155	155	155
(Expenditures – Revenues)				
FTEs	1	1	1	1

Recommendation:

The Governor recommends additional funding for compensation and operations related costs associated with the delivery of Board of Pharmacy services. This amount represents a 4.8% increase in the board's base appropriation in the FY16-17 biennium. The net fiscal impact of this recommendation to the Health Related Boards Fund (1201) is offset by a recommended fee increase that is described in a separate change item.

Rationale/Background:

The Board of Pharmacy needs an increased appropriation to cover:

- The cost of hiring a complaint coordinator to better manage the increasing number of complaints the Board is receiving;
- Increased costs of in-state travel for inspections and complaint investigations;
- Rent increases; and
- Potential salary increases for existing employees.

The board's workload has increased dramatically over the past decade. The number of facilities licensed by the board increased by 924 between FY04 and FY14 (a 31% increase). The number of individuals licensed by the board increased by 6,299 during the same period (a 49% increase). Due to a number of factors, the board has seen the number of complaints that need to be processed triple since FY08. The board has also been tasked by the Legislature to administer the Prescription Monitoring Program and to more stringently monitor nonresidential businesses that ship drugs into Minnesota. In response, the board has had to nearly double its staff since 2005.

The Board's appropriation has been increased in the past to account for some increases in staff size and to cover inflationary increases for rent, supplies, equipment, and salaries and benefits. However, the appropriation needs to be increased again to avoid laying off some recently hired staff members.

Proposal:

The Governor recommends increasing the Board of Pharmacy's appropriation by \$114,000 in FY16 and \$155,000 in FY17. This funding intended to ensure that the board will have sufficient authority to expend the funds necessary to carry out its mission to protect the public. If this fee increase is not granted, the board will have to reduce its staff. That will result in fewer facility inspections being completed, longer response times for complaints, delayed disciplinary actions, and delayed issuance of licenses and registrations. Collectively, those changes may have an adverse impact on public health and safety.

Results:

The board anticipates that retaining current staff will result in improvements in the percentage of in-state facilities inspected annually. The board also anticipates that license applications will be processed more quickly. Unfortunately, the percentage of complaints investigated and resolved within 12 months dropped sharply in FY13 due to a significant increase in the total number of complaints received as well as the number of complaints serious enough to warrant discipline. By hiring a complaints coordinator, the board expects the percentage of complaints that are investigated and resolved within 12 months to improve going forward.

Type of Measure	Name of Measure	Previous	Current	Dates
Quantity	Percentage of in-state facility inspections completed annually	27.7%	28.8%	FY 2011 FY 2013
Quantity	Percentage of complaints investigated and resolved within 12 months	89.4%	67.5%	FY 2012 FY 2013

Statutory Change(s): None required.

FY16-17 Biennial Budget Change Item

Change Item: Fee Increase

Fiscal Impact (\$000s)	FY 2016	FY 2017	FY 2018	FY 2019
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Health Related Boards Fund				
Expenditures	0	0	0	0
Revenues	\$379	\$379	\$379	\$379
Net Fiscal Impact =	(\$379)	(\$379)	(\$379)	(\$379)
(Expenditures – Revenues)				
FTEs	0	0	0	0

Recommendation:

The Governor recommends that fees assessed by the Board of Pharmacy be increased as shown in the "Proposal" section of this change item. These increases are expected to generate an additional \$379,000 per year in fee revenue that is needed to support existing board operations and cover the cost of a proposed operating adjustment. \$379,000 represents 16% of the total amount of fee revenue collected by the board in FY14.

Rationale/Background:

The Board of Pharmacy's workload has increased dramatically over the past decade. The number of facilities licensed by the board increased by 924 between FY04 and FY14 (a 31% increase). The number of individuals licensed by the board increased by 6,299 during the same period (a 49% increase). Due to a number of factors, the board has seen the number of complaints that need to be processed triple since FY08. The board has also been tasked by the Legislature to administer the Prescription Monitoring Program and to more stringently monitor nonresidential businesses that ship drugs into Minnesota. In response, the board has had to nearly double its staff since 2005. Despite this increase in workload and staff, the Board has increased fees only once since 2002.

The recommended fee increase is necessary to cover the cost of an increased appropriation recommended in the board's other change item. An increased appropriation is needed to cover the cost of administrating the Prescription Monitoring Program and address year-over-year growth in the board's operational expenses (driven primarily by compensation growth, rent increases and increased utilization of the attorney general's office). An increased appropriation is also needed to cover the cost of hiring a complaints coordinator to better manage the higher volume of complaints.

Proposal:

The table below shows proposed adjustments to fees assessed by the Board of Pharmacy. These adjustments are intended to ensure that the board has the funds necessary to carry out its mission to protect the public. If the recommended fee increase is not granted, the board will have to reduce its staff resulting in fewer facility inspections being completed, longer response times for complaints, delayed disciplinary actions, and delayed issuance of licenses and registrations. Collectively, those changes may have an adverse impact on public health and safety.

Application fees	Current	Proposed
pharmacist licensed by examination	130	145
pharmacist licensed by reciprocity	225	240
pharmacy intern	30	37.50
pharmacy technician	30	37.50
pharmacy	190	225
drug wholesaler, legend drugs only	200	235
drug wholesaler, legend and non-legend drugs	200	235
drug wholesaler, non-legend drugs, veterinary legend drugs, or both	175	210
drug wholesaler, medical gases	150	175
drug wholesaler, also licensed as a pharmacy in Minnesota	125	150
drug manufacturer, legend drugs only	200	235

Application fees	Current	Proposed
drug manufacturer, legend and non-legend drugs	200	235
drug manufacturer, non-legend or veterinary legend drugs	175	210
drug manufacturer, medical gases	150	185
drug manufacturer, also licensed as a pharmacy in Minnesota	125	150
medical gas distributor	75	110
controlled substance researcher	50	75
pharmacy professional corporation	100	125
Original license fee		
pharmacist original licensure fee	130	145
Annual renewal fees		
pharmacist	130	145
pharmacy technician	30	37.50
pharmacy	190	225
drug wholesaler, legend drugs only	200	235
drug wholesaler, legend and non-legend drugs	200	235
drug wholesaler, non-legend drugs, veterinary legend drugs, or both	175	210
drug wholesaler, medical gases	150	185
drug wholesaler, also licensed as a pharmacy in Minnesota	125	150
drug manufacturer, legend drugs only	200	235
drug manufacturer, legend and non-legend drugs	200	235
drug manufacturer, non-legend, veterinary legend drugs, or both	175	210
drug manufacturer, medical gases	150	185
drug manufacturer, also licensed as a pharmacy in Minnesota	125	150
medical gas distributor	75	110
controlled substance researcher	50	75
pharmacy professional corporation	45	75
Miscellaneous fees		
intern affidavit	15	20
duplicate small license	15	20
duplicate large certificate	25	30

Results:

The board anticipates that retaining current staff will result in improvements in the percentage of in-state facilities inspected annually. The board also anticipates that license applications will be processed more quickly. Unfortunately, the percentage of complaints investigated and resolved within 12 months dropped sharply in FY13 due to a significant increase in the total number of complaints received as well as the number of complaints serious enough to warrant discipline. By hiring a complaints coordinator, the board expects the percentage of complaints that are investigated and resolved within 12 months to improve going forward.

Type of Measure	Name of Measure	Previous	Current	Dates
Quantity	Percentage of in-state facility inspections completed annually	27.7%	28.8%	FY 2011 FY 2013
Quantity	Percentage of complaints investigated and resolved within 12 months	89.4%	67.5%	FY 2012 FY 2013

Statutory Change(s):

The Board of Pharmacy's fees are found in MN Stats. §151.065.