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Board of Pharmacy

https://mn.gov/boards/pharmacy/

AT A GLANCE

Board Members and Staff (as of 7/1/2022)

- 9 board members (six pharmacists and three public members) appointed by the Governor
- 23 full time employees

Licenses & Registrations Issued (as of 7/1/2022)

- 19,924 individuals
- 4,123 businesses

Inspections (for FY 2021 and 2022)

• 237 inspections of licensed facilities, including pharmacies, drug manufacturers and wholesalers, and medical gas distributors

Complaint & Discipline (for FY 2021 and 2022)

- 290 new jurisdictional complaints received
- 289 jurisdictional complaints resolved
- 58 disciplinary actions taken

Prescription Monitoring Program (PMP) (for calendar year 2021)

- 6.54 million controlled substance prescriptions reported to PMP
- 25,402 enrolled PMP Users
- 4.09 million database queries

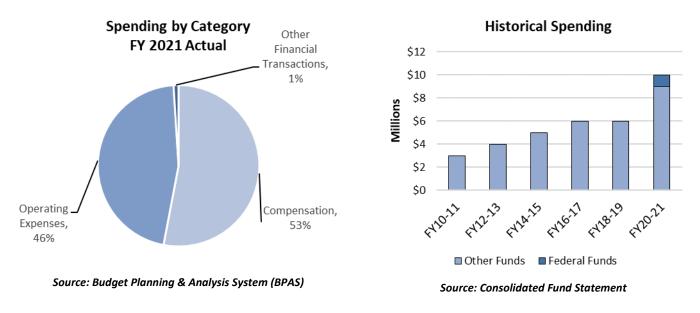
PURPOSE

The Board's 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, regulation of the manufacturing and distribution of pharmaceuticals, inspection of licensed facilities, investigation of complaints, and the issuance of disciplinary orders and agreements for corrective action. Board staff also help educate pharmacists and others about laws, rules and best standards of practice. The Board provides information to the public on its website related to the practice of pharmacy and prescription drugs.

The Board also administers several programs, including: The Minnesota Prescription Monitoring Program, the Opiate Product Fee Registration Program, and the Minnesota Insulins Safety Net Program.

BUDGET



The Board is mostly funded by licensure fees and, with two recent and temporary exceptions for the Opiate Product Registration Fee Program and the Insulin Safety Net Program, has received no general fund or healthcare access fund dollars. Minnesota Statutes section 214.06, subdivision 1(a) requires the Board to collect fees in the amount sufficient to cover direct and indirect expenditures. Funds are 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 expenses such as salaries, rent, costs associated with disciplinary/contested cases and operating expenditures. It also pays statewide indirect costs through an open appropriation.

In addition to Board operations, licensure fees fund activities that support other boards and agencies. Some of these are: the Administrative Services Unit (inter-board), Health Professionals Services Program (inter-board), Prescription Monitoring Program (Pharmacy Board), Office of the Attorney General for legal services, and the Criminal Background Check Program (inter-board).

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. 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 issue licenses and registrations 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 over 2,000 in-state pharmacies, drug wholesalers, drug manufacturers, medical gas distributors and controlled substance researchers. Each facility is inspected by

a Board Surveyor before it can open. Subsequent, unannounced inspections are also periodically conducted.

- **Complaint Investigations.** The Board investigates every jurisdictional complaint it receives. 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. 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. The Surveyor or the AGO Investigator issues a report which is reviewed by the Board's Complaint Review Panel (CRP). CRP may dismiss the complaint if the allegations aren't proven or may refer the matter on for discipline.
- 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 or propose statutory changes. In addition, Board staff very frequently provide 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. Board staff provides direct services to the public. Staff provide information to the public in response to inquiries concerning the legal requirements and standards for pharmacy practice. 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 free copies of disciplinary orders to the public upon request.

Prescription Monitoring Program. The purpose of the Prescription Monitoring Program (PMP) is to promote public health, safety, and welfare by detecting abuse or misuse of controlled substances— drugs that have a high potential for abuse and addiction, such as narcotics and stimulants. The PMP collects information concerning 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 if a patient is 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 such an activity 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.

Type of Measure	Name of Measure	Previous	Current	Dates
Quantity	Percentage of in-state facility inspections completed annually*	11.4%	8%	FY 2021 FY 2022
Quality	Percentage of complaints investigated and resolved within 12 months	67.5%	60.3%	FY 2021 FY 2022
Results	Number of individuals who receive prescriptions from five or more prescribers and have them filled at five or more pharmacies within a three-month period of time	227	135	1/1/2020- 3/31/2020 1/1/2021- 3/31/2021

*The decrease in inspections coincides with the characterization of the COVID-19 outbreak as a pandemic by the World Health Organization, the national emergency declaration issued by the President, and the Executive Orders issued in Minnesota.

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.

Agency Expenditure Overview

(Dollars in Thousands)

	Actual	Actual	Actual	Estimate	Forecast Ba	Base	
	FY20	FY21	FY22	FY23	FY24	FY25	
Expenditures by Fund							
1000 - General	87	202					
1201 - Health Related Boards	3,833	4,194	4,025	4,781	4,403	4,403	
2000 - Restrict Misc Special Revenue	14	107	42	53	48	48	
2001 - Other Misc Special Revenue		414	607	872			
2005 - Opiate Epidemic Response		88	66	226	126	126	
2360 - Health Care Access				152	76	38	
3000 - Federal	321	457	220	90	847	621	
Total	4,256	5,461	4,961	6,174	5,500	5,236	
Biennial Change				1,418		(399)	
Biennial % Change				15		(4)	
Expenditures by Program							
Pharmacy Board	4,256	5,461	4,961	6,174	5,500	5,236	
Total	4,256	5,461	4,961	6,174	5,500	5,236	
Expenditures by Category							
Compensation	2,828	2,930	2,846	3,195	3,141	3,193	
Operating Expenses	1,426	2,472	2,114	2,966	2,346	2,030	
Capital Outlay-Real Property	1,120	2,172	2,111	5	2,310	2,000	
Other Financial Transaction	2	59	0	8	8	8	
Total	4,256	5,461	4,961	6,174	5,500	5,236	
	.,	_,	.,		3,000		
	21.30	21 50	20.76	24.00	24.00	24.00	
Full-Time Equivalents	21.30	21.58	20.76	24.00	24.00	24.00	

Agency Financing by Fund

(Dollars in Thousands)

	Actual	Actual Actual	l Estimate	e Forecast Base		
	FY20	FY21	FY22	FY23	FY24	FY25
1000 - General						
Balance Forward In		285				
Direct Appropriation	370					
Cancellations		83				
Balance Forward Out	283					
Expenditures	87	202				
Biennial Change in Expenditures				(289)		0
Biennial % Change in Expenditures				(100)		
Full-Time Equivalents	0.44	0.06				

1201 - Health Related Boards

Balance Forward In		810		378		
Direct Appropriation	4,307	4,341	4,403	4,403	4,403	4,403
Open Appropriation	15					
Transfers In	6					
Cancellations		958				
Balance Forward Out	494		378			
Expenditures	3,833	4,194	4,025	4,781	4,403	4,403
Biennial Change in Expenditures				778		0
Biennial % Change in Expenditures				10		0
Full-Time Equivalents	20.49	20.47	19.75	22.00	22.00	22.00

2000 - Restrict Misc Special Revenue

Balance Forward In	3	4	8	5		
Receipts	16	109	40	48	48	48
Balance Forward Out	4	6	5			
Expenditures	14	107	42	53	48	48
Biennial Change in Expenditures				(26)		1
Biennial % Change in Expenditures				(21)		1
Full-Time Equivalents	0.04	0.41	0.26			

2001 - Other Misc Special Revenue

Receipts 41	60	7 872	
Expenditures 41	60	7 872	

Pharmacy, Board of

Agency Financing by Fund

(Dollars in Thousands)

	Actual	Actual	Actual	Estimate	Forecast I	Base
	FY20	FY21	FY22	FY23	FY24	FY25
Biennial Change in Expenditures				1,066		(1,479)
Biennial % Change in Expenditures						(100)
Full-Time Equivalents		0.04				

2005 - Opiate Epidemic Response

Balance Forward In		40	100		
Direct Appropriation	126	126	126	126	126
Balance Forward Out	38	100			
Expenditures	88	66	226	126	126
Biennial Change in Expenditures			205		(40)
Biennial % Change in Expenditures					(14)
Full-Time Equivalents	0.29	0.75	1.00	1.00	1.00

2360 - Health Care Access

Balance Forward In		76		
Direct Appropriation 7	76	76	76	38
Cancellations 7	5			
Balance Forward Out	76			
Expenditures		152	76	38
Biennial Change in Expenditures		152		(38)
Biennial % Change in Expenditures				

3000 - Federal

Balance Forward In	1	1			
Receipts	320	457	220	847	621
Transfers Out		1			
Balance Forward Out	1				
Expenditures	321	457	220	847	621
Biennial Change in Expenditures			(46	8)	1,158
Biennial % Change in Expenditures			(6	D)	374
				1.00	1.00

Pharmacy, Board of

Agency Change Summary

(Dollars in Thousands)

	FY23	FY24	FY25	Biennium 2024-25
Direct				
Fund: 1201 - Health Related Boards				
FY2023 Appropriations	4,403	4,403	4,403	8,806
Forecast Base	4,403	4,403	4,403	8,806
Fund: 2005 - Opiate Epidemic Response				
FY2023 Appropriations	126	126	126	252
Forecast Base	126	126	126	252
Fund: 2360 - Health Care Access				
FY2023 Appropriations	76	76	76	152
Base Adjustments				
Current Law Base Change			(38)	(38)
Forecast Base	76	76	38	114
Dedicated				
Fund: 2000 - Restrict Misc Special Revenue				
Planned Spending	53	48	48	96
Forecast Base	53	48	48	96
Fund: 2001 - Other Misc Special Revenue				
Planned Spending	872			
Forecast Base	872			
Fund: 3000 - Federal				
Planned Spending	90	847	621	1,468
Forecast Base	90	847	621	1,468
Revenue Change Summary				
Dedicated				
Fund: 2000 - Restrict Misc Special Revenue				
Forecast Revenues	48	48	48	96
Fund: 2001 - Other Misc Special Revenue				
Forecast Revenues	872			
Fund: 3000 - Federal				
Forecast Revenues	90	847	621	1,468

Agency Change Summary

(Dollars in Thousands)

	FY23	FY24	FY25	Biennium 2024-25
Non-Dedicated				
Fund: 1201 - Health Related Boards				
Forecast Revenues	3,407	3,407	3,407	6,814
Fund: 2005 - Opiate Epidemic Response				
Forecast Revenues	13,550	13,550	13,550	27,100