

Table of Contents

Pharmacy, Board of

<i>Agency Profile</i>	1
<i>Agency Expenditure Overview</i>	5
<i>Agency Financing by Fund</i>	6
<i>Agency Change Summary</i>	8
<u>Change Item(s)</u>	10
<i>Operating Adjustment</i>	10
<i>PMP Operating Adjustment</i>	12
<i>Pharmacy Surveyor for Compliance Activities</i>	14
<i>Controlled Substance Registration System</i>	17
<i>Fee Increase</i>	19
<i>Opioid Manufacturer and Wholesaler Fee</i>	22
<u>Additional Documents</u>	24
<i>Federal Funds Summary</i>	24

mn.gov/boards/pharmacy/

AT A GLANCE

In FY 2016,

Board Members and Staff

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

Licenses & Registrations Issued

- 21,271 individuals
- 4,143 businesses

Inspections

- 336 inspections of licensed facilities, including pharmacies, drug manufacturers and wholesalers, and medical gas distributors

Complaint & Discipline

- Receipt of 221 new jurisdictional complaints
- Resolution of 176 jurisdictional complaints
- 39 disciplinary actions taken

In calendar year 2017,

Prescription Monitoring Program (PMP)

- 7.42 million controlled substance prescriptions reported to PMP
- 26,157 enrolled PMP Users
- 1.24 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.

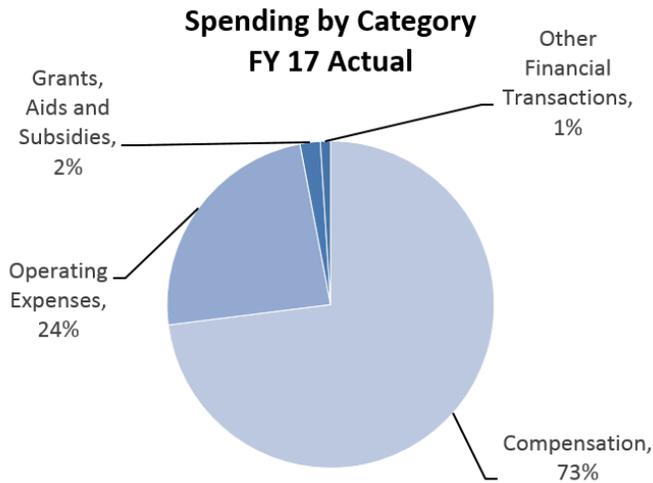
The Board fulfills this mission through examination and licensure of pharmacists, regulation of the practice of pharmacy, inspection of licensed facilities, investigation of complaints, and the issuance of disciplinary orders and agreements for corrective action. Board staff also help educate pharmacists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

The Minnesota Prescription Monitoring Program (PMP), a tool that prescribers and pharmacists can use to help prevent prescription drug abuse, is also administered by the Board.

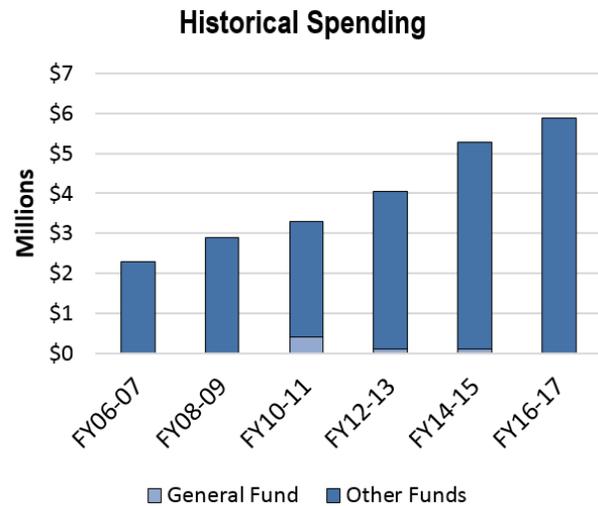
The Board contributes to the following state wide outcomes:

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

BUDGET



Source: Budget Planning & Analysis System (BPAS)



Source: Consolidated Fund Statement

The activities of the board are largely funded by license fees collected from licensees of 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 is funded by licensure fees and receives no general fund dollars. Minnesota Statutes section 214.06, subdivision 1(a) compels 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 2,125 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. 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. 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 of 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.

RESULTS

<i>Type of Measure</i>	<i>Name of Measure</i>	<i>Previous</i>	<i>Current</i>	<i>Dates</i>
Quantity	Percentage of in-state facility inspections completed annually	17.1%	19.3%	FY 2015 FY 2016
Quality	Percentage of complaints investigated and resolved within 12 months	71.7%	77.4%	FY 2015 FY 2016
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	908	452	7/1/2016 – 12/31/2016 7/1/2017 – 12/31/2017

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

(Dollars in Thousands)

	Actual FY16	Actual FY17	Actual FY18	Estimate FY19	Forecast Base		Governor's Recommendation	
					FY20	FY21	FY20	FY21
<u>Expenditures by Fund</u>								
1201 - Health Related Boards	2,729	3,161	3,105	3,383	3,301	3,338	3,624	3,654
2000 - Restrict Misc Special Revenue		1	12	17	16	16	16	16
2365 - Opioid Stewardship							1,643	1,285
3000 - Federal	35	182	131	836	584	434	584	434
Total	2,763	3,344	3,248	4,236	3,901	3,788	5,867	5,389
Biennial Change				1,377		205		3,772
Biennial % Change				23		3		50
Governor's Change from Base								3,567
Governor's % Change from Base								46

Expenditures by Program

Pharmacy Board	2,763	3,344	3,248	4,236	3,901	3,788	5,867	5,389
Total	2,763	3,344	3,248	4,236	3,901	3,788	5,867	5,389

Expenditures by Category

Compensation	2,226	2,440	2,491	2,682	2,736	2,745	3,659	3,686
Operating Expenses	536	813	753	1,534	1,157	1,035	2,200	1,695
Grants, Aids and Subsidies		64		20	8	8	8	8
Other Financial Transaction	2	26	4					
Total	2,763	3,344	3,248	4,236	3,901	3,788	5,867	5,389

Full-Time Equivalent

	18.48	19.30	19.82	21.00	21.00	21.00	30.25	30.25
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(Dollars in Thousands)

	Actual FY16	Actual FY17	Actual FY18	Estimate FY19	Forecast Base		Governor's Recommendation	
					FY20	FY21	FY20	FY21
1201 - Health Related Boards								
Balance Forward In		263		117				
Direct Appropriation	2,962	3,033	3,164	3,243	3,276	3,313	3,599	3,629
Open Appropriation				23	25	25	25	25
Transfers In	30	98	58					
Transfers Out		10	1					
Cancellations		223						
Balance Forward Out	263		117					
Expenditures	2,729	3,161	3,105	3,383	3,301	3,338	3,624	3,654
Biennial Change in Expenditures				598		151		790
Biennial % Change in Expenditures				10		2		12
Governor's Change from Base								639
Governor's % Change from Base								10
Full-Time Equivalents	18.48	19.30	19.49	19.08	19.71	19.83	20.71	20.83

2000 - Restrict Misc Special Revenue

Balance Forward In	1	1		1				
Receipts			13	16	16	16	16	16
Balance Forward Out	1		1					
Expenditures		1	12	17	16	16	16	16
Biennial Change in Expenditures				28		3		3
Biennial % Change in Expenditures						11		11
Governor's Change from Base								0
Governor's % Change from Base								0

2365 - Opioid Stewardship

Direct Appropriation							1,643	1,285
Expenditures							1,643	1,285
Biennial Change in Expenditures				0		0		2,928
Biennial % Change in Expenditures								
Governor's Change from Base								2,928
Governor's % Change from Base								
Full-Time Equivalents							8.25	8.25

3000 - Federal

(Dollars in Thousands)

	Actual	Actual	Actual	Estimate	Forecast Base		Governor's Recommendation	
	FY16	FY17	FY18	FY19	FY20	FY21	FY20	FY21
Balance Forward In	1	1	1	1				
Receipts	35	182	131	835	584	434	584	434
Balance Forward Out	1	1	1					
Expenditures	35	182	131	836	584	434	584	434
Biennial Change in Expenditures				751		51		51
Biennial % Change in Expenditures				346		5		5
Governor's Change from Base								0
Governor's % Change from Base								0
Full-Time Equivalents			0.33	1.92	1.29	1.17	1.29	1.17

(Dollars in Thousands)

	FY19	FY20	FY21	Biennium 2020-21
Direct				
Fund: 1201 - Health Related Boards				
FY2019 Appropriations	3,243	3,243	3,243	6,486
Base Adjustments				
Current Law Base Change		25	62	87
Pension Allocation		8	8	16
Forecast Base	3,243	3,276	3,313	6,589
Change Items				
Operating Adjustment		124	126	250
Pharmacy Surveyor for Compliance Activities		199	190	389
Total Governor's Recommendations	3,243	3,599	3,629	7,228
Fund: 2365 - Opioid Stewardship				
Change Items				
PMP Operating Adjustment		696	699	1,395
Controlled Substance Registration System		663	460	1,123
Opioid Manufacturer and Wholesaler Fee		284	126	410
Total Governor's Recommendations		1,643	1,285	2,928
Open				
Fund: 1201 - Health Related Boards				
FY2019 Appropriations	23	23	23	46
Base Adjustments				
Forecast Open Appropriation Adjustment		2	2	4
Forecast Base	23	25	25	50
Total Governor's Recommendations	23	25	25	50
Dedicated				
Fund: 2000 - Restrict Misc Special Revenue				
Planned Spending	17	16	16	32
Forecast Base	17	16	16	32
Total Governor's Recommendations	17	16	16	32
Fund: 3000 - Federal				
Planned Spending	836	584	434	1,018
Forecast Base	836	584	434	1,018
Total Governor's Recommendations	836	584	434	1,018
Revenue Change Summary				

(Dollars in Thousands)

	FY19	FY20	FY21	Biennium 2020-21
<i>Dedicated</i>				
Fund: 2000 - Restrict Misc Special Revenue				
Forecast Revenues	16	16	16	32
Total Governor's Recommendations	16	16	16	32
Fund: 3000 - Federal				
Forecast Revenues	835	584	434	1,018
Total Governor's Recommendations	835	584	434	1,018
<i>Non-Dedicated</i>				
Fund: 1201 - Health Related Boards				
Forecast Revenues	2,979	3,013	3,013	6,026
Change Items				
Fee Increase		651	651	1,302
Total Governor's Recommendations	2,979	3,664	3,664	7,328
Fund: 2365 - Opioid Stewardship				
Change Items				
Controlled Substance Registration System		7,918	7,918	15,836
Opioid Manufacturer and Wholesaler Fee		18,000	18,000	36,000
Total Governor's Recommendations		25,918	25,918	51,836

Pharmacy, Board of

FY 2020-21 Biennial Budget Change Item

Change Item Title: Operating Adjustment

Fiscal Impact (\$000s)	FY 2020	FY 2021	FY 2022	FY 2023
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Other Funds				
Expenditures	124	126	126	126
Revenues	0	0	0	0
Net Fiscal Impact = (Expenditures – Revenues)	124	126	126	126
FTEs	0	0	0	0

Recommendation:

The Governor recommends additional funding of \$250,000 in the FY 2020-2021 biennium to maintain the current level of service delivery at The Board of Pharmacy.

Rationale/Background:

Each year, the cost of doing business rises—employer-paid health care contributions, FICA and Medicare, along with other salary and compensation-related costs increase. Other operating costs, like rent and lease, fuel and utilities, and IT and legal services also grow. This cost growth puts pressure on agency operating budgets that remain flat from year to year.

The Board is entirely fee supported and receives no General Fund dollars to provide all services. Fees must be collected to cover all direct and indirect expenditures and are deposited as non-dedicated revenue into the State Government Special Revenue Fund (SGSRF). The Minnesota Legislature makes appropriations from the fund to pay for expenses incurred by the Board.

Proposal:

The Governor recommends increasing agency operating budgets to maintain the delivery of current services. For the Board of Pharmacy, this funding will cover known employee compensation growth, rent, legal services, and MN.IT costs. IT cost growth drivers may include dedicated MN.IT staff compensation-related increases, increased volume usage of enterprise IT services, increased software licensing costs, and/or application support and maintenance cost increases.

Small Agency Increase:	FY 2020	FY 2021	FY 2022	FY 2023
Salary Increases	\$44,000	\$61,000	\$61,000	\$61,000
Other Benefits – Board Member Per Diems	\$2,000	\$0	\$0	\$0
Rent Increases	\$12,000	\$12,000	\$12,000	\$12,000
Professional/Technical Contracts – Expert witness	\$5,000	\$5,000	\$5,000	\$5,000
Communications	\$3,000	\$3,000	\$3,000	\$3,000
In-State Travel	\$3,000	\$0	\$0	\$0
Out-State Travel	\$10,000	\$2,000	\$2,000	\$2,000
Employee Development	\$10,000	\$8,000	\$8,000	\$8,000
Administrative Hearings	\$5,000	\$5,000	\$5,000	\$5,000
Repairs	\$2,000	\$2,000	\$2,000	\$2,000

Small Agency Increase:	FY 2020	FY 2021	FY 2022	FY 2023
MN.IT Enterprise Services	\$28,000	\$28,000	\$28,000	\$28,000
Total	\$124,000	\$126,000	\$126,000	\$126,000

Equity and Inclusion:

The Board does not discriminate on the basis of race, ethnicity, gender, sexual orientation, or disability. The positive impact of this change will be to continue to provide services for all people of the State of Minnesota without discrimination. The proposal has no impact, either positive or negative on equity and inclusion.

IT Related Proposals:

A portion of this request includes an increase for database maintenance and to cover annual MN.IT service rates.

Category	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Payroll						
Professional/Technical Contracts						
Infrastructure						
Hardware						
Software						
Training						
Enterprise Services	\$28,000	\$28,000	\$28,000	\$28,000	\$28,000	\$28,000
Staff costs (MNIT or agency)						
Total	\$28,000	\$28,000	\$28,000	\$28,000	\$28,000	\$28,000
MNIT FTEs						
Agency FTEs						

Results:

This proposal is intended to allow agencies to continue to provide current levels of service and information to the public.

Type of Measure	Name of Measure	Previous	Current	Dates
Quantity	Percentage of complaints investigated and resolved within 12 months	77%	85%	FY 2014 FY 2016

Statutory Change(s):

No statutory change will be required.

Pharmacy, Board of

FY 2020-21 Biennial Budget Change Item

Change Item Title: Prescription Monitoring Program Operating Adjustment

Fiscal Impact (\$000s)	FY 2020	FY 2021	FY 2022	FY 2023
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Opioid Stewardship Fund				
Expenditures	696	699	699	699
Revenues	0	0	0	0
Net Fiscal Impact = (Expenditures – Revenues)	696	699	699	699
FTEs	2	2	2	2

Recommendation:

The Governor recommends additional funding of \$1.395 million from the Opioid Stewardship Fund in the FY 2020-2021 biennium to maintain the current level of service delivery at The Board of Pharmacy for the Prescription Monitoring Program (PMP).

This proposal is part of a package of proposals recommended by the Governor to address rising rates of opioid use. The package of proposals is funded by new fees on opioid manufacturers, wholesalers, and entities that handle controlled substances.

Rationale/Background:

Each year, the cost of doing business rises—employer-paid health care contributions, FICA and Medicare, along with other salary and compensation-related costs increase. Other operating costs, like rent and lease, fuel and utilities, and IT and legal services also grow. This cost growth puts pressure on agency operating budgets that remain flat from year to year.

The workload for the Board’s PMP staff has increased since the program’s inception in 2010. Part of the increased workload involves the processing of an increased number of search warrants, the need to do more analysis of data to assess the program, and the need to do additional work involving the accuracy and integrity of prescription data submitted to the program.

The Board previously held a contract with Health Information Designs, LLC (HID) for the PMP platform and service and support necessary to collect and store data, and to make it available to permissible users. The Board will be migrating to a new platform developed by APPRISS, which is called AWARxE. The AWARxE platform is far more robust than the existing platform.

Proposal:

The Governor recommends increasing agency operating budgets to maintain the delivery of current services. For the Board of Pharmacy, this funding will cover known employee compensation growth, rent increases, IT costs including enterprise rates and PMP system migration. IT cost growth drivers may include dedicated MN.IT staff compensation-related increases, increased volume usage of enterprise IT services, increased software licensing costs, and/or application support and maintenance cost increases.

Equity and Inclusion:

The Board does not discriminate on the basis of race, ethnicity, gender, sexual orientation, or disability. The positive impact of this change will be to continue to provide services for all people of the State of Minnesota without discrimination. There will be no direct impact on equity and inclusion.

IT Related Proposals:

This proposal contains costs related to the migration of the PMP system.

Results:

This proposal is intended to allow agencies to continue to provide current levels of service and information to the public.

<i>Type of Measure</i>	<i>Name of Measure</i>	<i>Previous</i>	<i>Current</i>	<i>Dates</i>
Quantity	Percentage of search warrants processed within one business day	95%	75%	FY 2017 FY 2018
Quantity	Percentage of data uploaders reporting daily as required.	87%	94%	FY 2012 FY 2016

Statutory Change(s):

No changes in statutes are required.

Pharmacy, Board of

FY 2020-21 Biennial Budget Change Item

Change Item Title: Pharmacy Surveyor for Compliance Activities

Fiscal Impact (\$000s)	FY 2020	FY 2021	FY 2022	FY 2023
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Other Funds				
Expenditures	199	190	190	190
Revenues	0	0	0	0
Net Fiscal Impact = (Expenditures – Revenues)	199	190	190	190
FTEs	1	1	1	1

Recommendation:

The Governor recommends funding for a pharmacy surveyor at the Board of Pharmacy. The Board will hire another Pharmacy Surveyor in order to increase the number of in-state facility inspections that are completed and to better handle the increased number of complaints it has been receiving.

Rationale/Background:

The Board's workload has increased over the past decade due to an increase in the facilities licensed by the Board by 1,296 between 2008 and 2018 (a 43% increase). The number of individuals licensed by the Board increased by 5,609 during the same period of time (a 34% increase). Due to several factors, the number of complaints that the Board needs to process has tripled since FY 2008, totaling between 200 and 250 complaints per year (about one complaint per business day). The complexity of the complaints has also increased, with many complaints involving out-of-state compounding pharmacies, which have to be reviewed by the Board's Pharmacy Surveyors.

The Board currently employs seven Pharmacy Surveyors. However, two of those Surveyors are assigned to duties not related to facility inspections, complaint investigations, or review of out-of-state facility inspection reports. One of the Surveyors shares time as the Complaint Coordinator, ensuring that complaints are properly entered into our system, assigned to a Surveyor for investigation, and brought before the Board's Complaint Review Panel for resolution. The second Surveyor shares time as the Variance and Policy Review Coordinator, making sure that variance requests are properly entered into the system and reviewed by the Surveyors and acting as chair of the Board's Variance and Policy Review Committee. All of the Surveyors spend time responding to requests for technical assistance from licensees.

Proposal:

This proposal would allow the Board to hire an additional Pharmacy Surveyor so that the in-state facilities that the Board licenses can be inspected more frequently and complaints can be investigated and resolved more quickly. This proposal would allow the Board to hire an eighth Surveyor. As seen in the Results table below, the number of in-state facilities inspected decreased between FY 2016 and FY 2018 for three reasons: 1) several Pharmacy Surveyors retired and time to train new Surveyors to the point that they can complete inspections on their own; 2) Surveyors have had to spend a lot of time reviewing the inspection reports submitted by out-of-state facilities that are seeking Minnesota licenses; and 3) Surveyors have had to focus on complaint investigations. The percentage of complaints that are investigated and resolved has increased over the past several years.

The cost for the salaries and benefits of the current seven Pharmacy Surveyors is approximately \$1.25 million. The cost for the salary and benefits of an eighth Surveyor is projected to be \$187,000. An additional \$12,000 will be

used in FY2020 to pay for equipment and fixtures. An additional \$3,000 will be needed in FY 2021 to pay for IT services such as desktop and mobile device support and office software. The figure of \$187,000 is based on the salaries and benefits paid to current Pharmacy Surveyors and assumes a 2.8% increase in salaries and benefits for the next biennium. The \$3,000 cost for IT services was based on information provided by MN.IT.

The hiring process will be implemented and completed by the beginning of fiscal year 2020.

Small Agency Increase:	FY 2020	FY 2021	FY 2022	FY 2023
Salary Increases (Pharmacy Surveyor)	\$187,000	\$187,000	\$187,000	\$187,000
Equipment and Fixtures	\$9,000			
IT central services	\$3,000	\$3,000	\$3,000	\$3,000
Total	\$199,000	\$190,000	\$190,000	\$190,000

Equity and Inclusion:

The Board does not discriminate on the basis of race, ethnicity, gender, sexual orientation, or disability. The positive impact of this change will be to continue to provide services for all people of State of Minnesota without discrimination.

IT Related Proposals:

Some funds will be expended for routine IT services, such as a computers and office software.

Category	FY 2020	FY 2021	FY 2022	FY 2023
Payroll				
Professional/Technical Contracts				
Infrastructure				
Hardware				
Software				
Training				
Enterprise Services	3,000	3,000	3,000	3,000
Staff costs (MNIT or agency)				
Total	3,000	3,000	3,000	3,000
MNIT FTEs	0		0	0
Agency FTEs	0	0	0	0

Results:

By hiring an additional Pharmacy Surveyor, the Board should see improvements in the number of in-state facilities inspected annually. The goal is to inspect every in-state facility at least once every 24 months. Currently, the Board is unable to inspect at this rate. The completion of the training of the newer Surveyors, plus the addition of an eighth Surveyor, should help the Board meet this goal. Additionally, an increase in the percentage of complaints that are investigated and resolved within 12 months is expected with an additional Pharmacy Surveyor. Improvements have already been made in this area and will continue.

<i>Type of Measure</i>	<i>Name of Measure</i>	<i>Previous</i>	<i>Current</i>	<i>Dates</i>
Quantity	Number of in-state facility inspections completed annually	467	351	FY 2016 FY 2018
Quantity	Percentage of complaints investigated and resolved within 12 months	77%	85%	FY 2014 FY 2016

Statutory Change(s):

No changes in statutes are required.

Pharmacy, Board of

FY 2020-21 Biennial Budget Change Item

Change Item Title: Controlled Substances Registration System

Fiscal Impact (\$000s)	FY 2020	FY 2021	FY 2022	FY 2023
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Opioid Stewardship Fund				
Expenditures	663	460	460	460
Revenues	7,918	7,918	7,918	7,918
Net Fiscal Impact = (Expenditures – Revenues)	(7,255)	(7,458)	(7,458)	(7,458)
FTEs	4.25	4.25	4.25	4.25

Recommendation:

The Governor recommends the establishment of a controlled substances registration system by the Board of Pharmacy. This proposal is part of a package of proposals recommended by the Governor to address rising rates of opioid use. This proposal represents one revenue source to support expenditures across many state agencies, including the Board of Pharmacy.

Rationale/Background:

At least 26 other states have established a controlled substances registration system that is equivalent to the federal controlled substance registration system administered by the United States Drug Enforcement Administration (DEA).

Through investigations, the Board of Pharmacy would have the authority to administratively remove a pharmacy's controlled substance registration if it is found to be in violation of state and federal laws. For example, if the Board received a complaint alleging that a pharmacy had begun purchasing a large number of opioids and if, after an investigation, the Board determined that the pharmacy was operating knowingly filling inappropriate prescriptions, the Board could administratively remove the pharmacy's controlled substance registration. This could be done more quickly than taking action against the license of the pharmacy, which requires lengthy due-process procedures. Establishing a controlled substance registration system would also help to identify prescribers of controlled substances who, under current law, are supposed to register for and maintain a Prescription Monitoring Program account.

Drug wholesalers, pharmacies, and prescribers all bear some of the responsibility for the opioid epidemic. Drug wholesalers have been fined by the Drug Enforcement Administration for not reporting suspiciously large sales of opioids to pharmacies and other purchasers who were inappropriately dispensing opioids. Similarly, the DEA has levied civil penalties against some of the large, national pharmacy chains – based on allegations that the pharmacists working for those chains did not appropriately verify the validity of controlled substance prescriptions. Prescribers, acting in accordance with pain treatment guidelines that are now considered flawed, inappropriately prescribed opioids.

Proposal:

The Board would establish a controlled substance registration system. The following businesses or entities would be required to obtain a controlled substance registration if they were involved in the manufacture, sale, prescribing, or handling of any controlled substances: drug manufacturers, drug wholesalers, pharmacies, prescribers, and controlled substance researchers. The registration would have to be renewed annually. All fee

revenue would be deposited in the Opioid Stewardship Fund. The funds would be used to administer the registration system, upgrade the PMP, and to fund several activities across state government.

Fiscal Impact:

Controlled Substances Registration Fee Expenditures				
	FY20	FY21	FY22	FY23
Salary	387	387	387	387
IT	125	25	25	25
Other Operating Costs	151	48	48	48
Total	663	460	460	460

This proposal would require an additional 4.25 staff, including 0.25 manager, a pharmacy surveyor, a program lead, and two processing agents. The program would require modifications to the Board’s current registration system. There are a number of other operating costs, including costs for space, communications with impacted providers, and other supplies.

Controlled Substances Registration Fee Revenue Calculation			
Registration Type	Number	Proposed Fee (annual)	Revenue
Pharmacy - Chain	882	\$2,500	\$2,205,000
Pharmacy - Independent	307	\$500	\$153,500
Pharmacy - Hospital (> 50 beds)	85	\$2,500	\$212,500
Pharmacy - Hospital (< 50 beds)	59	\$500	\$29,500
Researcher	214	\$125	\$26,750
Manufacturer - large	10	\$75,000	\$750,000
Manufacturer - medium	28	\$5,000	\$140,000
Manufacturer - small	49	\$500	\$24,500
Wholesaler - large	3	\$75,000	\$225,000
Wholesaler- smaller	13	\$2,500	\$32,500
Practitioners	32,946	\$125	\$4,118,250
Total	34,596	TOTAL	\$7,917,500

IT Related Proposals:

There will be costs to pay for additional services from our licensing software vendor; purchase of computers, monitors, phones, etc. for new staff; one-time MN.IT costs related to reviewing the work done by the vendor; and costs associated with obtaining more server space.

Results:

The primary purpose of this proposal is to create a permanent and stable source of revenue to fund various state programs that are part of the effort to combat opioid abuse, including the Prescription Monitoring Program. The ultimate goal is to reduce opioid abuse and to reduce the number of deaths that are being caused by opioid overdoses.

Statutory Change(s):

Statutory changes will be required to sections 152.01, 152.10, 152.11, 152.12, 151.125 and 151.126.

Pharmacy, Board of

FY 2020-21 Biennial Budget Change Item

Change Item Title: Fee Increase

Fiscal Impact (\$000s)	FY 2020	FY 2021	FY 2022	FY 2023
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Other Funds				
Expenditures	0	0	0	0
Revenues	651	651	651	651
Net Fiscal Impact = (Expenditures – Revenues)	(651)	(651)	(651)	(651)
FTEs	0	0	0	0

Recommendation:

The Governor recommends a fee increase for the Board of Pharmacy to maintain its core functions.

Rationale/Background:

The Board’s workload has dramatically increased over the past decade. The number of facilities licensed by the Board increased by 1,296 between 2008 and 2018 (a 43% increase). The number of individuals licensed by the Board increased by 5,609 during the same period of time (a 34% increase). Due to several factors, the number of complaints that the Board needs to process has tripled since FY2008. The Board’s last fee increases occurred in FY 2015.

Proposal:

This proposal to increase fees is intended to ensure that the Board will have funds to carry out its mission to protect the public by covering personnel costs and other operating expenses. This increase would allow the Board to continue its services of completing facility inspections, responding to complaints, imposing disciplinary actions, and issuing licenses and registrations.

Application fees	Current Fee	Proposed New Fee
pharmacist licensed by examination	145	175
pharmacist licensed by reciprocity	240	275
pharmacy intern	37.50	50
pharmacy technician	37.50	50
pharmacy	225	260
drug wholesaler, legend only or legend & nonlegend	235	260
drug wholesaler, nonlegend drugs, veterinary legend drugs, or both	210	260
drug wholesaler, medical gases	175	260
drug wholesaler, also licensed as a pharmacy in Minnesota	150	260
drug manufacturer, legend only or legend & nonlegend	235	260
drug manufacturer, nonlegend or veterinary legend drugs	210	260
drug manufacturer, medical gases	185	260
drug manufacturer, also licensed as a pharmacy in Minnesota	150	260
medical gas distributor	110	260

Application fees	Current Fee	Proposed New Fee
controlled substance researcher	75	100
pharmacy professional corporation	125	150
Original license fee		
pharmacist original licensure fee	145	175
Annual renewal fees		
pharmacist	145	175
pharmacy technician	37.50	50
pharmacy	225	260
drug wholesaler, legend drugs only	235	260
drug wholesaler, legend and nonlegend drugs	235	260
drug wholesaler, nonlegend drugs, veterinary legend drugs, or both	210	260
drug wholesaler, medical gases	185	260
drug wholesaler, also licensed as a pharmacy in Minnesota	150	260
drug manufacturer, legend drugs only	235	260
drug manufacturer, legend and nonlegend drugs	235	260
drug manufacturer, nonlegend, veterinary legend drugs, or both	210	260
drug manufacturer, medical gases	185	260
drug manufacturer, also licensed as a pharmacy in Minnesota	150	260
medical gas distributor	110	260
controlled substance researcher	75	100
pharmacy professional corporation	75	100
Miscellaneous fees		
intern affidavit	20	30
duplicate small license	20	30
duplicate large certificate	30	30

Calculations

Fee Name	New Fee	2020 # Paying	2020 Estimate	2021 # Paying	2021 Estimate
Intern Affidavit Fee	\$30.00	30	\$900.00	30	\$900.00
New Tech Fee	\$50.00	1,836	\$91,800.00	1,836	\$91,800.00
MNFCTR Lic	\$260.00	18	\$4,680.00	18	\$4,680.00
MNFCTR Gas	\$260.00	70	\$18,200.00	70	\$18,200.00
MNFCTR Non-RX	\$260.00	600	\$156,000.00	600	\$156,000.00
WHLSLR Lic	\$260.00	235	\$61,100.00	235	\$61,100.00
WHLSLR Gas	\$260.00	95	\$24,700.00	95	\$24,700.00
Phar Renewal	\$175.00	9,329	\$1,632,575.00	9,329	\$1,632,575.00
Pharmacists: Late Fee	\$87.50	80	\$7,000.00	80	\$7,000.00
Pharmacists: Arrears		0	\$0.00	0	\$0.00
Pharmacists: Exam Fee	\$175.00	375	\$65,625.00	375	\$65,625.00
Pharmacists: Original Fee	\$175.00	340	\$59,500.00	340	\$59,500.00
Pharmacists: Reciprocity Fee	\$275.00	135	\$37,125.00	135	\$37,125.00
Pharmacists: Intern Regist Fee	\$50.00	450	\$22,500.00	450	\$22,500.00
Pharmacy: License Fee	\$260.00	2,125	\$552,500.00	2,125	\$552,500.00
Pharmacy: Late Fee	\$130.00	35	\$4,550.00	35	\$4,550.00
Pharmacy: Arrears		0	\$0.00	0	\$0.00

Fee Name	New Fee	2020 # Paying	2020 Estimate	2021 # Paying	2021 Estimate
Wholesaler Lic Fee	\$260.00	165	\$42,900.00	165	\$42,900.00
Wholesaler Late Fee		0	\$0.00	0	\$0.00
Wholesaler in Arrears		0	\$0.00	0	\$0.00
Manufacture License	\$260.00	45	\$11,700.00	45	\$11,700.00
Manufacture Late Fee		0	\$0.00	0	\$0.00
Manufacture in Arrears		0	\$0.00	0	\$0.00
Corporation Fee - Ren \$75/New \$125		0	\$0.00	0	\$0.00
Drug Researcher Fees	\$100.00	15	\$1,500.00	15	\$1,500.00
Researcher Late Fee		0	\$0.00	0	\$0.00
Med Gas Dist Lic Fee	\$260.00	115	\$29,900.00	115	\$29,900.00
Medical Gas Late Fee	\$130.00	3	\$390.00	3	\$390.00
Duplicate License	\$30.00	55	\$1,650.00	55	\$1,650.00
Duplicate Certificate	\$30.00	2	\$60.00	2	\$60.00
Proceedings Costs		0	\$0.00	0	\$0.00
Pharmacy Service Charge		0	\$0.00	0	\$0.00
Phar Tec Fee	\$50.00	9,000	\$450,000.00	9,000	\$450,000.00
Phar Tech Late Fee	\$25.00	400	\$10,000.00	400	\$10,000.00
New PHCY Lic	\$260.00	250	\$65,000.00	250	\$65,000.00
WHLSLR Non-RX	\$260.00	1,200	\$312,000.00	1,200	\$312,000.00
Total Fee Revenue			\$3,663,855.00		\$3,663,855.00
Previous Projected Fee Revenue			\$3,013,037.50		\$3,013,037.50
Extra Revenue with fee increase			\$650,817.50		\$650,817.50

Results:

By retaining current staff, the Board should see improvements in the percentage of in-state facilities inspected annually. The Board also anticipates that license applications will be processed more quickly. The percentage of complaints that have been investigated and resolved within 12 months increased from 77% to 85% between FY 2014 and 2016.

Type of Measure	Name of Measure	Previous	Current	Dates
Quantity	Number of in-state facility inspections completed annually	467	351	FY 2016 FY 2018
Quality	Percentage of complaints investigated and resolved within 12 months	77%	85%	FY 2014 FY 2016

Equity and Inclusion:

The Board does not discriminate on the basis of race, ethnicity, gender, sexual orientation, or disability. The positive impact of this change will be to continue to provide services for all people of State of Minnesota without discrimination.

Statutory Change(s):

The Board's fee are listed in Minn. Stats. §151.065, which will need to be amended.

Pharmacy, Board of

FY 2020-21 Biennial Budget Change Item

Change Item Title: Opioid Wholesaler and Manufacturer Registration Fees

Fiscal Impact (\$000s)	FY 2020	FY 2021	FY 2022	FY 2023
General Fund				
Expenditures	0	0	0	0
Revenues	0	0	0	0
Other Funds				
Expenditures	284	126	126	126
Revenues	18,000	18,000	18,000	18,000
Net Fiscal Impact = (Expenditures – Revenues)	(17,716)	(17,784)	(17,784)	(17,784)
FTEs	2	2	2	2

Recommendation:

The Governor recommends the establishment of fees on opioid wholesalers and manufacturers. This proposal is part of a package proposals recommended by the Governor to address rising rates of opioid use. This proposal represents one revenue source to support expenditures across many state agencies, including the Board of Pharmacy.

Rationale/Background:

The opioid crisis has had a devastating impact on communities across Minnesota and opioid overdose deaths continue to rise in Minnesota. In 2016, there were:

- 395 total opioid overdose deaths—an 18% increase since 2015
- 194 overdose deaths that involved prescription opioids
- 150 overdose deaths that involved heroin

In 2017, the number of overdose deaths rose to 773 and this crisis has not been limited to any one area of the state.

The Governor and legislature have taken steps to address the issue. Key initiatives include, the Minnesota State Substance Abuse Strategy, the Opioid Prescribing Improvement and Monitoring Work Group, the Integrated Care for High Risk Pregnant Women Initiative grant funds to expand care for pregnant women and substance exposed infants, funding to increase access to Naloxone, and efforts to make disposing of unused prescription opioids easier. Minnesota has also received a number of federal grants to support Minnesota's response to the opioid epidemic. While these efforts are an important start, the scope and impact of this crisis requires even more robust, urgent, and sustained action. This proposal seeks to build upon and expand these existing efforts and ensure there are on-going and sustainable resources available to address opioid abuse.

Proposal:

This proposal would establish an annual registration fee for both opioid manufacturers and wholesale drug distributors who distribute opioids in the state of Minnesota. The total of all manufacturer fees would be \$11 million. This amount would be prorated across manufacturers based on the number of units sold, delivered, or distributed across the state. The total of all wholesaler fees would be \$7 million, which would be prorated in the same manner. This proposal would also fund two FTEs and \$150,000 in IT database development costs.

Fiscal Impact:

Manufacturer and Wholesales Registration Fee Expenditures				
	FY20	FY21	FY22	FY23
Salary	120	120	120	120
IT	150	3	3	3
Other Operating Costs	14	3	3	3
Total	284	126	126	126

Results:

This funding stream will support state efforts to impact the following indicators:

- Reduce opioid overdose related deaths;
- Increase the number of people who receive opioid use disorder treatment and recovery services
- Reduce percentage of people reporting past 12-month pain reliever misuse
- Increased the number of buprenorphine waived physicians

Statutory Change(s):

New statute for fees and fund.

(Dollars in Thousands)

Federal Agency and CFDA #	Federal Award Name and Brief Purpose	New Grant	FY2018 Actuals	FY2019 Budget	FY2020 Base	FY2021 Base	Required State Match or MOE?	FTEs
US Department of Justice, Office of Justice Programs - 16.754	2016-Harold Rogers Prescription Drug Monitoring Program Purpose: To enhance the MN Prescription Monitoring Program (PMP).	-	\$61	\$312	\$199	\$199	no	.05
US Department of Justice, Office of Justice Programs - 16.754	2018-Harold Rogers Prescription Drug Monitoring Program Purpose: To further, enhance of the MN Prescription Monitoring Program.	New	\$0	\$300	\$300	\$150	no	.38
MN Department of Health - 93.136	Injury Prevention and Control Research and State and County Based Programs Purpose: Increase registration and use of PMP through integrating account registration into the health professional's licensing process. Funds to be, in part, awarded to health licensing boards.	-	\$50	\$74	\$0	\$0	no	
MN Department of Human Services - 93.243	Substance Abuse and Mental Health Service Project of Regular and National Significance Purpose: Plan and carryout the delivery of four regional information/educations sessions for health care providers with permissible use of PMP data.	-	\$20	\$150	\$85	\$85	no	.86
	Budget Activity Total		\$131	\$836	\$584	\$434		1.29
	Program Total		\$131	\$836	\$584	\$434		1.29
	Federal Fund – Agency Total		\$131	\$836	\$584	\$434		1.29

Narrative

The Board of Pharmacy receives an annual allocation from the MN Legislature to conduct the day-to-day operations of the MN Prescription Monitoring Program (PMP). The federal funds are primarily used to enhance system features to ensure health care professionals have the most robust tool to assist them in providing quality patient care while ensuring patient safety.

2016 Harold Rogers Prescription Drug Monitoring Program:

Funds were awarded to enhance the functioning of the data collection and analysis system, enhance educational and training programs, facilitate information sharing among states, enhance the capacity to provide unsolicited reports to health care professionals regarding their patients and travel as required by the grant conditions.

2018 Harold Rogers Prescription Drug Monitoring Program:

Funds were awarded to educate end users about the database and the updated functionalities; to ensure continued and accurate use of the system; create and distribute an educational tool; deploy analytics, visualization, and clinical intervention tools for system end users; expand the system's report generation

capabilities; travel to mandatory meetings as required by the grant conditions; and fund .38 FTE for grant management.

The creation and distribution of educational tools and resources is expected to cease within 12 months of the implementation of the updated system functionalities. There is a long-term commitment to continue to provide the enhanced version of the system including the analytics, visualization and additional clinical tools, and to expand the report generation capabilities of the system. With the additional report generation capabilities, it is anticipated that at minimum the .38 FTE position will need to be retained.

Injury Prevention and Control Research and State and County Based Programs:

Funds were provided by the MN Department of Health specifically to support the development of a solution to integrate the PMP registration process into the health licensing board's initial licensee application process and to measure the effectiveness of their solutions. It is anticipated that this funding once expended will not have an impact on the day-to-day operations of the program.

Substance Abuse and Mental Health Service Project of Regular and National Significance:

The MN Department of Human Services provided funds to plan and carryout the delivery of four regional information/education sessions. To continue to provide educational opportunities related to opioid abuse, misuse, and overdose as well as the use of the PMP system, it is anticipated that the .86 FTE position will need to be retained.