State Board of Pharmacy

Senate Finance and Financial Institutions Committee

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Legislative Service Commission

May 2, 2007

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for the

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May 2, 2007

State Board of Pharmacy

- Current service levels to be maintained
- Prescription Monitoring Program fully operational

OVERVIEW

Duties and Responsibilities

The State Board of Pharmacy, first created in 1884, is responsible for administering and enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act (Chapter 4729. of the Revised Code), the Controlled Substances Act (Chapter 3719. of the Revised Code), the Pure Food and Drug Act (Chapter 3715. of the Revised Code), and the Criminal Drug Law (Chapter 2925. of the Revised Code). The Board is a nine-member panel composed of eight pharmacists and one person representing the public who is at least 60 years old. Each member serves a four-year term and may be re-appointed one time at the Governor's discretion. In addition to the nine Board members, it carries enough annual funding to employ a staff of around 50 full-time equivalents (FTEs) to perform licensure and enforcement activities. The Board's activities can be divided into licensure and drug law enforcement, as described in more detail below.

Licensure

The licensure activities of the Board include the testing and certification of pharmacists and pharmacy interns entering the profession in Ohio, as well as renewing the licenses of practicing pharmacists annually. In addition, the Board licenses sites where dangerous drugs (primarily those requiring a prescription) are purchased and stored prior to the delivery to a patient. The site licenses are issued by the Board as either a terminal distributor of dangerous drugs (mainly retail type settings) or a wholesale distributor of dangerous drugs. Terminal distributor sites include, but are not limited to, retail pharmacies, hospitals, nursing homes, prisons and jails, emergency medical squads, clinics, and medical gas distributors.

The Board's licensing activity is summarized in the table immediately below.

Number of Licensees/Registrants								
License/Registrant Type	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**
Registered Pharmacists	13,786	13,797	13,597	14,056	14,540	14,682	14,953	15,308
Pharmacy Interns	1,643	1,437	1,434	1,510	1,634	2,076	1,906	2,158
Terminal Distributors	9,423	10,089	10,329	9,958	10,485	11,117	11,453	11,994
Wholesale Distributors	1,048	1,087	1,080	1,119	1,144	1,251	1,305	1,386
Controlled Substance	481	468	462	489	511	525	535	550
Totals	**26,381**	**26,878**	**26,902**	**27,132**	**28,314**	**29,651**	**30,152**	**31,396**

The total number of licenses issued by the Board annually has increased from 26,381 in FY 1999 to 31,396 in FY 2006, an increase of 19.0%. One area of the licensing in which the Board's work has noticeably increased is in relation to terminal distributors of dangerous drugs. In FY 1999, the Board

licensed 9,423 terminal distributors of dangerous drugs, and by FY 2006, that licensed number was up to 11,994, an increase of 2,571, or 27.3%.

Drug Law Enforcement

The Board is the only state agency that has statewide jurisdiction to enforce the criminal drug laws, and as a result, is sometimes responsible for criminal investigations and prosecutions of doctors, nurses, dentists, veterinarians, or other individuals. By enforcing the laws and rules regulating drugs and pharmacists, the Board may deny, suspend, or revoke a license and place a pharmacist or pharmacy intern on probation. Such action may be taken for reasons that include: conviction of a misdemeanor committed in the practice of pharmacy, or any felony; dishonesty or unprofessional conduct in the practice of pharmacy; drug or alcohol addiction that causes a practitioner to be unfit for practice; and any violation of provisions under Chapters 2925., 3719., or 4729. of the Revised Code.

Board Investigations			
Calendar Year	Number of Investigations	Investigations Closed for No Time*	Percent Closed for No Time*
1998	1,198	374	31.2%
1999	1,309	397	30.3%
2000	1,404	424	30.2%
2001	1,692	370	21.9%
2002	1,421	252	17.7%
2003-2004	2,526	308	12.2%
2005-2006	2,083	231	11.1%

*"No Time" is a decision made by a Board field agent.

The Board's investigations are classified as either criminal (involving drug trafficking, forging prescriptions, fraud, etc.) or administrative (involving errors in dispensing, administrative code violations, etc.). With the exception of a matter that involves the dispensing of an incorrect drug, an investigation can be closed due to a lack of time to fully investigate a case. This is usually what happens to cases that take longer than 45 days to investigate. These cases are illustrated in the above table, under the column heading "Investigations Closed for No Time."

From 1998 through 2006, the Board averaged around 1,300 investigations annually and the percentage of those investigations that had to be "closed for no time" was cut by more than half, from 31.2% to 11.1%. From the Board's perspective, this is an indicator that, as additional field staff has been hired in recent years, its ability to fully investigate cases has been greatly enhanced.

Fund 4K9

The State Board of Pharmacy is one of 20-plus independent professional and occupational licensing boards that draw their primary source of funding from the Occupational Licensing and Regulatory Fund (Fund 4K9). The fund, which was established by Am. Sub. H.B. 152 of the 120th General Assembly, is a repository for license fees and other assessments collected by those boards.

Prior to the creation of the fund, appropriations for each of the affected boards were drawn from the GRF. This created a problem, as some boards generated revenues that exceeded their expenditures, while other boards had to be subsidized by the GRF since their expenditures exceeded their generated revenue. Fund 4K9 was designed to eliminate that cash flow problem. The philosophy of the fund is that

each board must generate enough revenues to cover its expenses. It is also quite common for the boards to develop a surplus in the fund to cover unforeseen economic hardships.

Pharmacy Board Fund 4K9 Cash Flow History			
Fiscal Year	**Revenue**	**Expenses**	**Net**
1996	$ 3,131,677	$ 2,762,321	$ 369,356
1997	$ 3,214,543	$ 3,060,104	$ 154,439
1998	$ 4,369,170	$ 3,254,336	$ 1,114,834
1999	$ 4,225,210	$ 3,364,074	$ 861,136
2000	$ 4,282,302	$ 3,815,769	$ 466,533
2001	$ 4,288,827	$ 3,837,911	$ 450,916
2002	$ 4,265,201	$ 4,176,816	$ 88,385
2003	$ 4,458,368	$ 4,490,725	$ (32,357)
2004	$ 4,484,926	$ 4,369,323	$ 115,603
2005	$ 4,510,488	$ 4,513,155	$ (2,667)
2006	$ 4,578,206	$ 4,525,101	$ 53,105
TOTALS	**$45,808,918**	**$42,169,635**	**$3,639,283**

The table above displays the amount of revenue that the State Board of Pharmacy has deposited to the credit of Fund 4K9 from FYs 1996 through 2006, as well as the amount of funding that the Board has drawn from Fund 4K9 over the same period of time. The table also suggests that the Board has historically deposited more revenue to the credit of Fund 4K9 annually than it has drawn from Fund 4K9 to support annual operating expenses. The Board last raised fees in FY 1997. Fees were raised by 50%.

There is some notable background information to the financial material displayed in the above table. Drug fine collections make up around 22%, or roughly $1.1 million, of the total revenue deposited annually by the State Board of Pharmacy to the credit of Fund 4K9 annually. The "Net" amounts in the table's last column do not reflect Board moneys removed from Fund 4K9 by the Office of Budget and Management for administrative purposes. Thus, the "Net" amounts do not exactly equal the Board's cash balance in Fund 4K9. That said, the table is, however, a reasonable indication of the Board's cash flow picture over the last 10 or so fiscal years.

Projected Financing Deficit

Based on its anticipated revenues and expenditures, the Board estimates it will spend approximately $500,000 more than it deposits in revenue to the credit of Fund 4K9 over the course of FYs 2008 and 2009. The Board will be able to in effect finance this "deficit" by tapping into its remaining cash balance in Fund 4K9. This creates a fiscal situation for FY 2010 and beyond that may require a fee increase.

Prescription Monitoring Program (PMP)

Substitute House Bill 377 of the 125th General Assembly, effective May 2005, (1) permits the State Board of Pharmacy to establish and maintain an electronic database to monitor the misuse and diversion of controlled substances and certain dangerous drugs, and (2) if the Board establishes and maintains such a database, requires each pharmacy licensed as a terminal distributor of dangerous drugs that dispenses drugs to patients in the state (as specified in rules adopted by the Board) and each

wholesale distributor of dangerous drugs that delivers drugs to prescribers in the state to submit to the Board for entry into the database certain prescription and purchase information. The bill was silent on how the drug database and its related costs would be funded.

To date, the Board has secured three federal grants totaling $930,000 for the purpose of planning and implementing the prescription monitoring program (PMP) authorized by Am. Sub. H.B. 377. The program, which is currently managed by three staff, became fully operational in October 2006. The Board has applied for another federal grant to be used for the purpose of program enhancements. The federal funding available to the states has been restricted to PMP planning, implementation, and improvements. Moneys have not been available for what might be termed routine operating or maintenance expenses.

Staffing

The table below displays the number of staff the State Board of Pharmacy has employed, or will employ, from FYs 2001 through 2009.

State Board of Pharmacy Staffing Levels by Fiscal Year								
2001	**2002**	**2003**	**2004**	**2005**	**2006**	**2007***	**2008****	**2009****
46	47	47	47	47	47	50	51	51

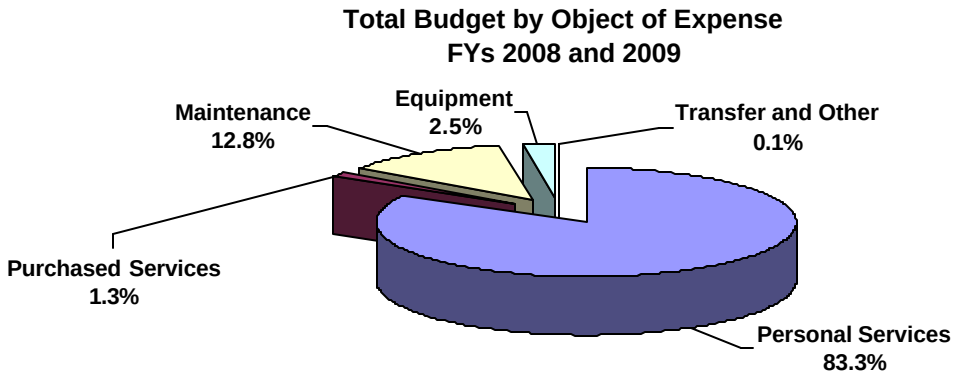
*Of these 50 positions, 49 are currently filled.
**One new staff person will be added to the three-person team currently administering the PMP.

CAVU Licensing System

Most of the state's licensing boards have implemented the CAVU licensing system. CAVU is a provider of licensing, permitting, and enforcement software solutions for eGovernment. The State Board of Pharmacy is the last of Ohio's state agencies to contract with CAVU for online licensing services. The Ohio Department of Administrative Services (DAS) administers the CAVU agreements. As each licensing board comes online, costs of the contracts are administratively removed from Fund 4K9. The costs will be distributed among the boards according to the degree of licensing activity by each entity. According to the State Board of Pharmacy, due to the complex nature of the Board's fee structure, implementation of the CAVU system was delayed until now. At this time, it is unclear how much of the total contracting costs will be allocated to the State Board of Pharmacy; however, the Board estimates that it could be approximately $20,000 annually. Again, these expenses would be taken from the Fund 4K9's total pool of available funds by DAS at the time the contracts are due to be paid. The Board will not be required to budget for these expenses.

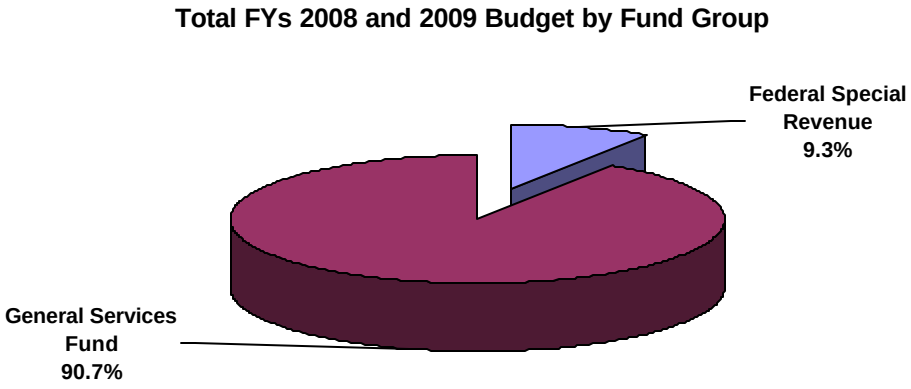
Object of Expense Summary

The pie chart immediately below shows the total recommended appropriations (FYs 2008 and 2009) by major object of expense. This information is shown for all funds, including the GRF.



Fund Group Summary

The pie chart immediately below shows the total recommended appropriations (FYs 2008 and 2009) by fund group. This information is shown for all funds, including the GRF.



ANALYSIS OF EXECUTIVE PROPOSAL

Single Program Series **Regulation**

Purpose: To administer and enforce the laws governing the legal distribution of drugs and the practice of pharmacy.

The following table shows the three line items that are used to fund the State Board of Pharmacy's licensing, registration, and enforcement activities, as well as the Governor's recommended funding levels.

Fund	ALI	Title	FY 2008	FY 2009
General Services Fund (GSF)				
4A5	887-605	Drug Law Enforcement	$75,550	$75,550
4K9	887-609	Operating Expenses	$4,874,572	$5,251,032
		General Services Fund Subtotal	**$4,950,122**	**$5,326,582**
Federal Special Revenue Fund (FED)				
3BC	887-604	Dangerous Drugs Database	$558,531	$491,405
		Federal Special Revenue Fund Subtotal	**$558,531**	**$491,405**
Total Funding: Regulation			**$5,508,653**	**$5,817,987**

License, Registration, and Enforcement

Program Description: The Board's core activities center on the licensing of all persons who distribute dangerous drugs and sites where dangerous drugs are stored and the enforcement of certain drug laws.

Funding Sources: (1) licensing and other fees collected from pharmacists, pharmacy interns, distributors of dangerous drugs, and manufacturers of controlled substances, (2) various fines and bail or property forfeitures, and (3) federal grants to plan, implement, and enhance the Board's Prescription Monitoring Program (PMP).

Line Items: See above table

Implication of Executive Recommendation: From the Board's perspective, the executive-recommended levels of funding for FYs 2008 and 2009 should cover its future cost of maintaining current service and staffing levels.

Temporary and Permanent Law Provisions

It does not appear that the executive-recommended budget contains any permanent or temporary law provisions directly affecting the State Board of Pharmacy's licensing, registration, and enforcement activities.

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General Services Fund Group

4A5 887-605 Drug Law Enforcement

2004	2005	2006	2007 Estimate	2008 House Passed	2009 House Passed
$72,977	$272,755	$115,727	$75,550	**$75,550**	**$75,550**
	273.8%	-57.6%	-34.7%	**0.0%**	**0.0%**

Source: GSF: State Board of Pharmacy's share of certain fines and bail or property forfeitures collected as a result of its drug law enforcement efforts

Legal Basis: ORC 4729.65; Section 209.42 of Am. Sub. H.B. 66 of the 126th G.A.

Purpose: The fund is used by the Board to provide its compliance and enforcement staff with current technology and training for the purpose of increasing their productivity and ability to obtain evidence of pharmacy and drug law violations. By law, the moneys in the fund must be segregated from the Board's other sources of revenue. The Board is restricted to using the revenue in the fund for drug law enforcement purposes only.

4K9 887-609 Operating Expenses

2004	2005	2006	2007 Estimate	2008 House Passed	2009 House Passed
$4,409,451	$4,547,205	$4,525,101	$5,400,537	**$4,874,572**	**$5,251,032**
	3.1%	-0.5%	19.3%	**-9.7%**	**7.7%**

Source: GSF: Moneys appropriated from the Occupational Licensing and Regulatory Board Fund (Fund 4K9), which consists of license fees and other assessments collected by certain independent professional and occupational boards, as well as various fines and forfeited bonds and bails collected by the State Board of Pharmacy and not credited to its Fund 4A5

Legal Basis: ORC 4729.65; Section 209.42 of Am. Sub. H.B. 66 of the 126th G.A. (originally established by Am. Sub. H.B. 152 of the 120th G.A., the main operating appropriations act covering FYs 1994 and 1995)

Purpose: Funds appropriated to the line item are used by the State Board of Pharmacy to administer and enforce laws governing the legal distribution of dangerous drugs and the practice of pharmacy.

Federal Special Revenue Fund Group

3BC 887-604 Dangerous Drugs Database

2004	2005	2006	2007 Estimate	2008 House Passed	2009 House Passed
$0	$0	$318,577	$299,317	**$558,531**	**$491,405**
		N/A	-6.0%	**86.6%**	**-12.0%**

Source: FED: Harold Rogers Prescription Drug Monitoring Program grants distributed from the Edward Byrne Memorial State & Local Law Enforcement Assistance Discretionary Grants Program (CFDA 16.580)

Legal Basis: Originally established by Controlling Board on August 15, 2005

Purpose: Moneys deposited to the credit of the fund consist of federal grants awarded to the State Board of Pharmacy for the purpose of planning, implementing, and enhancing the prescription drug monitoring program authorized by Sub. H.B. 377 of the 125th General Assembly. The program is a system in which controlled substance prescription data are submitted to a centralized database administered by the Board and is designed for the purpose of helping prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level. By law, the Board cannot impose a charge on any terminal distributor, pharmacist, or prescriber for establishment or maintenance of the database.

LSC Budget Spreadsheet by Line Item, FY 2008 - FY 2009

Fund	ALI	ALI Title	Estimated 2007	As Introduced 2008	House Passed 2008	% Change Est. 2007 to House 2008	As Introduced 2009	House Passed 2009	% Change House 2008 to House 2009
PRX		**Pharmacy, State Board of**							
4A5	887-605	Drug Law Enforcement	$75,550	$ 75,550	$ 75,550	0.0%	$ 75,550	$ 75,550	0.0%
4K9	887-609	Operating Expenses	$5,400,537	$ 4,874,572	$ 4,874,572	-9.7%	$ 5,251,032	$ 5,251,032	7.7%
General Services Fund Group Total			**$ 5,476,087**	**$ 4,950,122**	**$ 4,950,122**	**-9.6%**	**$ 5,326,582**	**$ 5,326,582**	**7.6%**
3BC	887-604	Dangerous Drugs Database	$299,317	$ 558,531	$ 558,531	86.6%	$ 491,405	$ 491,405	-12.0%
Federal Special Revenue Fund Group Total			**$ 299,317**	**$ 558,531**	**$ 558,531**	**86.6%**	**$ 491,405**	**$ 491,405**	**-12.0%**
Total All Budget Fund Groups			***$ 5,775,404***	***$ 5,508,653***	***$ 5,508,653***	***-4.6%***	***$ 5,817,987***	***$ 5,817,987***	***5.6%***