

State Board of Pharmacy

House Higher Education Subcommittee

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February 24, 2005

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LSC Redbook for the State Board of Pharmacy

House Higher Education Subcommittee

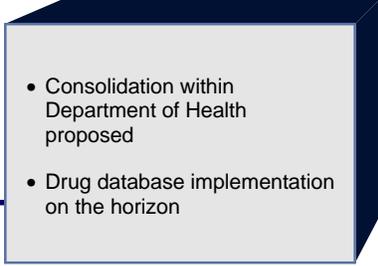
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February 24, 2005

State Board of Pharmacy

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- Consolidation within Department of Health proposed
 - Drug database implementation on the horizon

OVERVIEW

Duties and Responsibilities

The State Board of Pharmacy 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 47 full-time equivalents (FTEs) to perform licensure and enforcement activities. Of the 47 FTEs, 24 (9 pharmacists and 15 former law enforcement officers) are investigative field agents. The Board's activities can be divided into licensure and drug law enforcement, as described in more detail below.

Fund 4K9

The State Board of Pharmacy is one of 20-plus independent professional and occupational licensing 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 board's generated revenues exceeded their expenditures, while other boards had to be subsidized by the GRF since their expenditures exceed their generated revenue. Fund 4K9 was designed to eliminated that cash flow problem. The philosophy of the fund is that each board must generate enough revenues to cover their expenses. It is also quite common for the boards to develop a surplus in the fund to cover unforeseen economic hardships.

Independent Professional and Occupational Licensing Boards

Currently, there are 27 independent professional and occupational licensing boards. The primary goal of the boards is to set standards for licensure and registration for the members of various professions and occupations to ensure that only qualified applicants receive licenses, thus protecting the public. The boards enforce these professional standards through examination, inspection, investigation, and continuing education. Three boards have been created since FY 2004: the Chemical Dependency

Professional Licensing Board, the State Board of Career Colleges and Schools, and the Ohio Manufactured Homes Association.

Consolidation of Regulatory Boards (Section 315.03)

The Executive Budget recommends that the 27 independent professional and occupational licensing boards be consolidated with the Departments of Health, Commerce, and Public Safety not later than July 1, 2006. Funding is included for each of the affected boards for FY 2006, but no appropriations are included for FY 2007. The consolidation will be planned during FY 2006 by a transition team consisting of the Office of Budget and Management (OBM), and the departments of Administrative Services, Commerce, Health, and Public Safety. Current staff will be retained through FY 2006 and a hiring freeze and early retirement incentive will be offered to regulatory board staff. Board and commission members for each board will be retained and continue to serve in the manner in which they were appointed. Enabling legislation will be introduced in FY 2006.

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, medical gas distributors, and so forth.

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.

Operating expenses

The Board's annual operating expenses are supported almost entirely by moneys appropriated from Fund 4K9, the occupational licensing and regulatory board fund that receives fees and other assessments collected by 20-plus independent professional and occupational licensing boards and in turn finances the annual operating expenses of the those boards.

Dangerous Drugs Database

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 is silent on how the drug database and its related costs would be funded

According to the Board, although cost prohibitive in the current fiscal climate, in order to fully perform the duties and responsibilities permitted by the bill, the Board might need as many as 8.5 new FTE staff positions. Those 8.5 FTEs would include four full-time pharmacists, four full-time clerical staff, and one part-time technology (IT) programmer/database administrator, whose time would be split between management of the database and other office duties. Once fully operational, the Board estimates the cost of maintaining such a comprehensive drug database system could be up to \$1.08 million annually, which includes ongoing payroll and related operating expenses.

The Board has already been awarded an \$180,000 federal grant for this purpose by the U.S. Drug Enforcement Agency; the grant must be used by July 1, 2005. Conversations with the Board suggest that this essentially one-time federal grant money would be used for start-up expenses, including computer hardware and software necessary to support the drug database. The Board has also applied for an additional \$350,000 federal grant to further assist in the implementation of the drug database.

The Board estimates it will need to hire, at a minimum, a database administrator to establish and oversee operation of this new information gathering duty and related electronic database. Under the executive-recommended budget, however, the Board would be subject to a hiring freeze as part of its planned consolidation within the Department of Health. As of this writing, the effect of such a freeze on the Board's plan to implement the drug database is uncertain.

Also of note is the fact that all of the states bordering Ohio and several other nearby states have some form of drug database in operation. The Board has indicated that, from its perspective, the practical effect of the absence of such a drug database in Ohio has been to increase the number of drug fraud cases in Ohio because individuals are crossing into the state to fill prescriptions and to conduct illegal business.

Staffing Levels

The table below displays the number of staff employed, or that will be employed, by the State Board of Pharmacy from FYs 2002 through 2007.

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

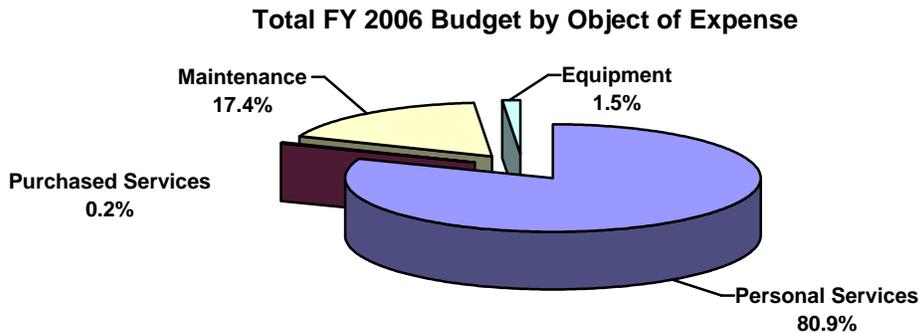
*The staffing levels displayed in the above table for FY 2006 are estimates.

**As the Executive proposes consolidating the Board within the Department of Health not later than July 1, 2006, it has recommended no FY 2007 appropriations. This table assumes that the Board's FY 2007 staffing levels will look more or less like those projected for FY 2006.

Under the Executive's consolidation strategy, current staff will be retained through FY 2006, a hiring freeze will be implemented, an early retirement incentive offered to regulatory board staff, a task force will be appointed to plan the transition, and enabling legislation will be introduced in FY 2006. As of this writing, the Board is uncertain as to how its functions and staffing will be affected by the proposed consolidation.

Object of Expense Summary

The pie chart immediately below shows the total recommended appropriations (FY 2006) by major object of expense. As the Executive proposes a transition team to plan for the consolidation of the Board within the Department of Health effective July 1, 2006, no FY 2007 appropriations have been recommended for the Board's operations.



FACTS AND FIGURES

Number of Licensees/Registrants							
License/Registrant Type	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004
Registered Pharmacists	13,296	13,786	13,797	13,597	14,056	14,540	14,682
Pharmacy Interns	1,430	1,643	1,437	1,434	1,510	1,634	2,076
Terminal Distributors	9,423	9,423	10,089	10,329	9,958	10,485	11,117
Wholesale Distributors	1,048	1,048	1,087	1,080	1,119	1,144	1,251
Controlled Substance Wholesalers	481	481	468	462	489	511	525
Totals	25,678	26,381	26,878	26,902	27,132	28,314	29,651

The total number of licenses issued by the Board annually has increased from 25,678 in FY 1998 to 29,651 in FY 2004, an increase of 15.5%. 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 1998, the Board licensed 9,423 distributors of dangerous drugs, and by FY 2004, that licensed number was up to 11,117, an increase of 1,694, or 18.0%.

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%

*"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, and so forth, or administrative, involving errors in dispensing, administrative code violations, and so forth. 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.

From 1998 through 2004, the Board averaged around 1,400 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 12.2%. 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.

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*	\$ 4,954,465	\$ 4,914,594	\$ 39,871
TOTALS	\$41,674,689	\$38,045,973	\$3,628,716

*The amount for FY 2005 is an estimate.

The Board's annual operating expenses are supported almost entirely by moneys appropriated from Fund 4K9, the occupational licensing and regulatory board fund that receives fees and other assessments collected by 20-plus of the state's independent professional and occupational licensing boards and in turn finances the annual operating expenses of those boards. The table above displays the amount of revenue that the State Board of Pharmacy has deposited, or will deposit, to the credit of Fund 4K9 from FY 1996 through FY 2005, 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%. The idea was that by raising fees a significant amount, the Board would build up a cash reserve that it could then use to cover increased costs, thereby allowing the Board to handle the expenditures for the next several fiscal years.

There is some notable background information to the financial material displayed in the above table. First, the FY 2005 cash flow is an estimate. Second, drug fine collections make up around 25%, or roughly \$1.2 million, of the total revenue deposited annually by the State Board of Pharmacy to the credit of Fund 4K9 annually. Third, 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 several fiscal years.

ANALYSIS OF EXECUTIVE PROPOSAL

Program Series 1

License, Registration, and Enforcement

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

The following table shows the two 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 2006	FY 2007
General Services Fund				
4A5	887-605	Drug Law Enforcement	\$75,550	\$0
4K9	887-609	Operating Expenses	\$4,950,537	\$0
General Services Fund Subtotal			\$5,026,087	\$0
Total Funding: Licensing/Registration/Enforcement			\$5,026,087	\$0

This analysis focuses on the Board's services and activities that can be grouped as follows:

■ **Licensure and Drug Law Enforcement**

Licensure and Drug Law 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 Source: (1) licensing and other fees collected from pharmacists, pharmacy interns, distributors of dangerous drugs, and manufacturers of controlled substances, and (2) various fines and bail or property forfeitures

Line Items: See above table

Implication of Executive Recommendation: From the Board's perspective, the amount of funding recommended for FY 2006 should cover its future cost of maintaining current service and staffing levels. No appropriations were recommended for FY 2007. This reflects the Governor's intention to consolidate 16 health-related regulatory boards, including the State Board of Pharmacy, within the Department of Health not later than July 1, 2006. Under the Executive's consolidation strategy, current staff will be retained through FY 2006, a hiring freeze will be implemented, an early retirement incentive offered to regulatory board staff, a task force will be appointed to plan the transition, and enabling legislation will be introduced in FY 2006. As of this writing, the Board is uncertain as to how its functions and staffing will be affected by the proposed consolidation.

Temporary Law Provision

Consolidation of Regulatory Boards (Section 315.03). The Executive budget contains a temporary law provision that: (1) expresses the intent to consolidate 16 health-related regulatory board, including the State Board of Pharmacy within the Department of Health not later than July 1, 2006, (2) creates a transition team to develop a plan to ensure the smooth and timely transition of those boards into the

Department, and (3) expresses the intent to introduce a bill in FY 2006 that will include the necessary statutory changes to effect the consolidation and include revised appropriations for FY 2007.

REQUESTS NOT FUNDED

The table below shows the difference between the non-GRF funding levels that the State Board Pharmacy requested in each of FYs 2006 and 2007 to pay for its licensure, registration, and enforcement activities and the funding amounts that the Executive recommended.

Licensure/Registration/Enforcement						
Fund/Line Item	FY 2006 Requested	FY 2006 Recommended	Difference	FY 2007 Requested	FY 2007 Recommended	Difference
4A5/887-605	\$75,550	\$75,550	\$0	\$75,550	\$0	\$75,550
4K9/887-609	\$4,914,594	\$4,950,537	\$35,943	\$4,914,594	\$0	\$4,914,594
Totals	\$4,990,144	\$5,026,087	\$0	\$5,122,347	\$0	\$4,990,144

The amount of funding that the Board requested in each of FYs 2006 and 2007 reflected its calculation of the future cost of maintaining current service and staffing levels. The Board's request for FY 2006 is fully funded, however, no FY 2007 funding is recommended. This reflects the Governor's intention to consolidate 16 health-related regulatory boards, including the State Board of Pharmacy, within the Department of Health not later than July 1, 2006. As of this writing, the Board is uncertain as to how its functions and staffing will be affected by the proposed consolidation.

Also of note with regard to the above table is the fact that, for FY 2006, the Executive recommended \$35,943 more than the Board requested in Fund 4K9 funding. This appears to be a result of the Office of Budget and Management's recalculation of payroll and non-personnel cost projections, including various Department of Administrative Services' (DAS) charges.

General Services Fund Group

4A5 887-605 Drug Law Enforcement

2002	2003	2004	2005 Estimate	2006 Executive Proposal	2007 Executive Proposal
\$23,151	\$72,709	\$72,977	\$75,550	\$75,550	\$0
	214.1%	0.4%	3.5%	0.0%	-100.0%

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

Legal Basis: Section 82 of Am. Sub. H.B. 95 of the 125th G.A.; ORC 4729.65

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. The Executive budget proposes to consolidate various health-related regulatory boards, including the State Board of Pharmacy, within the Department of Health not later than July 1, 2006.

4K9 887-609 Operating Expenses

2002	2003	2004	2005 Estimate	2006 Executive Proposal	2007 Executive Proposal
\$4,183,947	\$4,472,980	\$4,409,451	\$4,914,594	\$4,950,537	\$0
	6.9%	-1.4%	11.5%	0.7%	-100.0%

Source: GSF: Moneys appropriated from the Occupational Licensing and Regulatory Board Fund (Fund 4K9), which consists of license fees and other assessments collected by 20-plus 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: Section 82 of Am. Sub. H.B. 95 of the 125th G.A.; ORC 4729.65 (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 Board to administer and enforce laws governing the legal distribution of dangerous drugs and the practice of pharmacy. This line item replaces former GRF line items 881-100, Personal Services, 881-200, Maintenance, and 881-300, Equipment, which supported the Board's operations. The Executive budget proposes to consolidate various health-related regulatory boards, including the State Board of Pharmacy, within the Department of Health not later than July 1, 2006.

LSC Budget Spreadsheet by Line Item, FY 2006 - FY 2007

<i>Fund</i>	<i>ALI</i>	<i>ALI Title</i>	<i>2004</i>	<i>Estimated 2005</i>	<i>Executive 2006</i>	<i>% Change 2005 to 2006</i>	<i>Executive 2007</i>	<i>% Change 2006 to 2007</i>
<i>PRX Pharmacy, State Board of</i>								
4A5	887-605	Drug Law Enforcement	\$ 72,977	\$75,550	\$ 75,550	0.0%	\$ 0	-100.0%
4K9	887-609	Operating Expenses	\$ 4,409,451	\$4,914,594	\$ 4,950,537	0.7%	\$ 0	-100.0%
General Services Fund Group Total			\$ 4,482,428	\$ 4,990,144	\$ 5,026,087	0.7%	\$ 0	-100.0%
Total All Budget Fund Groups			\$ 4,482,428	\$ 4,990,144	\$ 5,026,087	0.7%	\$ 0	-100.0%