

Regulatory Analysis Form		This space for use by IRRC	
(1) Agency Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy		<p style="text-align: center;">RECEIVED 2005 FEB -2 PM 1:56 COMMISSION</p>	
(2) I.D. Number (Governor's Office Use) 16A-5414			
(3) Short Title Biennial Renewal Fees			
(4) PA Code Cite 49 Pa. Code, § 27.91		(5) Agency Contacts & Telephone Numbers Primary Contact: Carole L. Clarke, Counsel State Board of Pharmacy (717) 783-7200 Secondary Contact: Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200	
(6) Type of Rulemaking (check one) <input checked="" type="checkbox"/> Proposed Rulemaking <input type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Policy Statement		(7) Is a 120-Day Emergency Certification Attached? <input checked="" type="checkbox"/> No Yes: By the Attorney General Yes: By the Governor	
(8) Briefly explain the regulation in clear and nontechnical language. The proposed regulation will amend the Board's biennial renewal fees for pharmacists and pharmacies. The Bureau of Finance and Operations of the Department of State predicts that if the biennial renewal fees remain the same, by fiscal year 2005-2006 the Board's expenses will exceed its revenues. Section 8.2(b) of the Pharmacy Act (62 P.S. §390-8.2(b)) requires the Board to increase fees by regulation in an amount adequate to meet the minimum enforcement efforts required by the act. The proposed regulation raises the pharmacist license biennial renewal fee from \$120 to \$150 and the pharmacy permit biennial renewal fee from \$75 to \$100.			
(9) State the statutory authority for the regulation and any relevant state or federal court decisions. The proposed regulation is authorized by section 8.2(a) and (b) of the Pharmacy Act.			

Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. Sections 8.2(a) and (b) of the Pharmacy Act, 63 P.S. §390-8.2(a), (b), require the Board fees be fixed by regulation and that fees be increased if not sufficient to meet expenditures.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The new fees allow the Board to comply with the legislative mandate of its enabling statute that the Board sustain its operating and enforcement costs through fees imposed on its licensees.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Nonregulation of pharmacists and pharmacies increases the risk of substandard pharmacy care, which may adversely affect public health.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The general public and regulated practitioners will benefit from fee increases which assure that the Board will have sufficient revenue to carry out its operating and enforcement activities and ensure the Commonwealth will have an adequate supply of competent practitioners.

Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

On a biennial basis approximately 17,762 pharmacists and 3,160 pharmacies will pay an additional \$30.00 and \$25.00 respectively. This represents a biennial cost to the regulated community of \$532,860.00 for pharmacists and \$79,000.00 for pharmacies.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Approximately 17,762 pharmacists and 3,160 pharmacies apply for licenses and permits biennially.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

In developing and drafting the regulation, the Board considered the fees as both required by law and the least restrictive means of covering the costs of services required to be performed by the Board.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

No legal, accounting or consulting costs are anticipated as a result of the regulation. Biennial renewal fees will cost an additional \$532,860.00 for pharmacists and \$79,000.00 for pharmacies.

Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

Local governments would not be affected by this regulation.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

Because the Board must charge fees that reflect its actual costs in providing services to licensees and applicants, implementing the regulation will produce no identifiable costs or savings to state government.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$ N/A	\$ N/A	\$ N/A	\$ N/A	\$ N/A	\$ N/A
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community	\$0	\$0	\$532,860	\$79,000	\$532,860	\$79,000
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

Cost estimates to the regulated community were derived by multiplying the proposed fee increase by the number of licensees. The biennial renewal fee increase for pharmacists will not start until the October 1, 2006 renewal so the current fiscal year and fiscal year +1 costs are zero. Beginning with the pharmacist license renewal in fiscal year +2 the costs will increase by the amount listed. In fiscal year +3 with the pharmacy permit renewal the costs will increase by the amount listed.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Pharmacy Board	\$1,213,162.22	\$1,389,369.42	\$1,588,828.54	\$1,655,000.00

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The regulation provides for the licensure population to pay for the costs of Board administration in biennial fees which, by law, must meet or exceed expenditures. The proposed fees have been set at the lowest amount possible to sustain the Board.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

No nonregulatory approaches were considered as Section 8.2(b) of the Pharmacy Act, 63 P.S. §390-8.2(b), requires a regulatory approach.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

See paragraph 22 above.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

There are no federal standards that apply.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The fees are comparable to those in surrounding states. The fees should cause no competitive disadvantage.

<u>State</u>	<u>Pharmacist</u>	<u>Renewal Period</u>	<u>Pharmacy</u>	<u>Renewal Period</u>
New York	\$200.00	3 years	\$260.00	3 years
New Jersey	\$140.00	2 years	\$170.00	1 year
Delaware	\$33.00	2 years	\$60.00	2 years
Ohio	\$97.50	1 year	\$150.00	1 year
West Virginia	\$120.00	2 years	\$100.00	1 year
Maryland	\$150.00	2 years	\$250.00	1 year

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The regulation changes Section 27.91, Schedule of fees, 49 Pa. Code §27.91, in the existing regulations.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board provides an opportunity for public input into its activities, including its rulemaking proposals, at its regularly scheduled monthly meetings. The dates times and places of the Board's meetings are available at the Department of Stats Website, www.state.pa.us.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The Board has not identified particular needs for which special provisions need to be developed or anticipated in connection with biennial renewal fees.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The proposed regulation will be effective upon final publication in the Pennsylvania Bulletin. The new fees will take effect for the pharmacist license and pharmacy permit holders with the biennial period commencing October 1, 2006.

(31) Provide the schedule for continual review of the regulation.

The Board will review the effectiveness of this regulation as part of its annual review of its fiscal operations.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)

RECEIVED
2005 FEB -2 PM 1:56

LEGISLATIVE COUNCIL
REVIEW COMMISSION

2456

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

Ann M. Elliott
BY: _____
(DEPUTY ATTORNEY GENERAL)

FEB 21 2004

DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Pharmacy

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5414

DATE OF ADOPTION:

Michael J. Romano
BY: _____
Michael J. Romano, R.Ph.

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

Taryn C. ...
BY: _____

12.7.04

DATE OF APPROVAL

Asst.
(Deputy General Counsel
(Chief Counsel,
Independent Agency,
Strike inapplicable
title)

- Check if applicable Copy not approved. Objections attached.
- Check if applicable. No Attorney General approval or objection within 30 day after submission.

PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA. CODE, CHAPTER 27
Biennial Renewal Fees

The State Board of Pharmacy (Board) proposes to amend 49 Pa. Code §27.91 (relating to fees) to read as set forth in Annex A. The proposed regulation would increase the biennial license renewal fee for pharmacists from \$120.00 to \$150.00 and the pharmacy permit biennial renewal fee from \$75.00 to \$100.00.

Effective Date

The amendment will be effective upon final publication in the Pennsylvania Bulletin. The new fees will take effect for the pharmacist biennial period commencing October 1, 2006.

Statutory Authority

The amendment is authorized under section 8.2(a) of the Pharmacy Act (act) (63 P.S. § 390-8.2(a)). In addition, section 8.2(b), requires the Board to increase fees by regulation in an amount adequate to meet the minimum enforcement efforts required by the act.

Background and Need for Amendment

The Board is required by law to support its operations from revenue it generates from fees, fines and civil penalties. In accordance with section 8.2 of the act (63 P.S. §390-8.2), if the Board anticipates that its revenue will not meet its expenditures, the Board must increase its revenue. The Board raises virtually all of its operating revenue through fees. The biennial license renewal fees are the most substantial revenue generating fees of all the fees charged by the Board. The Board's current biennial license renewal fees were established by regulation in 1998.

At its February 17, 2004, Board meeting and again at its April 20, 2004, Board meeting, the Bureau of Finance and Operations (BFO) presented a summary of the Board's revenues and expenses for fiscal years 2001-2002 and 2002-2003 and projected revenues and expenses for fiscal years 2003-2004 through 2010-2011. The summary, presented in table format below, demonstrated that the Board must raise fees to meet or exceed projected expenditures to comply with section 8.2(b) of the act.

2001-2002 beginning balance	1,047,957.15
FY 01-02 revenue	456,056.98
Prior year returned funds	153,857.90
FY 01-02 expenses	1,207,000.00
Remaining balance	450,872.03

2002-2003 beginning balance	450,872.03
FY 02-03 revenue	2,093,691.14
FY 02-03 expenses	1,270,000.00
Remaining balance	1,274,563.17
2003-2004 beginning balance	1,274,563.17
FY 03-04 projected revenue	478,000.00
FY 03-04 projected expenses	1,495,000.00
Prior year expenses	169,515.61
Remaining balance	88,047.56
2004-2005 beginning balance	88,047.56
FY 04-05 projected revenue	2,094,000.00
FY 04-05 projected expenses	1,540,000.00
Remaining balance	642,047.56
2005-2006 beginning balance	642,047.56
FY 05-06 projected revenue	500,000.00
FY 05-06 projected expenses	1,586,000.00
Remaining balance	(443,952.44)
2006-2007 beginning balance	(443,952.44)
FY 06-07 projected revenue	2,094,000.00
FY 06-07 projected expenses	1,634,000.00
Remaining balance	16,047.56
2007-2008 beginning balance	16,047.56
FY 07-08 projected revenue	500,000.00
FY 07-08 projected expenses	1,683,000.00
Remaining balance	(1,166,952.44)
2008-2009 beginning balance	(1,166,952.44)
FY 08-09 projected revenue	2,094,000.00
FY 08-09 projected expenses	1,733,000.00
Remaining balance	(805,952.44)
2009-2010 beginning balance	(805,952.44)
FY 09-10 projected revenue	500,000.00
FY 09-10 projected expenses	1,733,000.00
Remaining balance	(2,038,952.44)

2010-2011 beginning balance	(2,038,952.44)
FY 10-11 projected revenue	2,094,000.00
FY 10-11 projected expenses	1,785,000.00
Remaining balance	(1,729,952.44)

As the foregoing indicates, at the close of FY 2005-2006, the Board's expenses will exceed its revenues by \$443,952.44. While the pharmacist renewal will bring the Board's account back to a positive balance in FY 2006-2007, BFO estimates that in FY 2007-2008, the deficit will increase to \$1,166,952.44 if fees are not increased. BFO anticipates that the proposed new fees will enable the Board to recapture the FY 2005-2006 deficit and meet its estimated expenditures for the 2006-2007 biennial cycle. The Board would operate at a slight deficit in the FY 2007-2008 pharmacy permit biennial renewal period, but that would be recaptured in the FY 2008-2009 pharmacist license biennial renewal period and the projections out to FY 2010-2011 show the Board carrying a positive balance forward.

The increases in the Board's biennial expenses occurred primarily in law enforcement costs and legal office costs. Law enforcement (the Bureau of Enforcement and Investigation) expenditures increased from approximately \$507,412 in FY 2002-2003 to approximately \$713,280 in FY 2003-2004. The legal office (division of the Bureau of Professional and Occupational Affairs) expenditures increased from approximately \$288,247 in FY 2002-2003 to approximately \$362,304 in FY 2003-2004.

The legal office saw an increase the number of cases closed in calendar years 1998 through 2003. Beginning in 1998 the number of disciplinary sanctions imposed increased markedly. From 1994 through 1997 the number of disciplinary sanctions imposed never reached 100, 95 sanctions being the highest in 1995. However from 1998 through 2003 the number of sanctions imposed never dipped below 125. Furthermore, the Board has undertaken several regulatory initiatives. Two large regulation packages, Technology and Automation and the regulations required under to Act 102 of 2002, have been proposed, as well as other regulation packages the Board has undertaken to revise and update its regulations.

The Board carefully reviewed several options in fee increases to ensure the lowest fee increase possible while keeping the Board out of a long run deficit. In addition to increasing fees the Board is looking at ways to streamline procedures to cut costs, but the fee increases are still necessary to maintain a positive balance in the Board account in the long run. Finally, in developing the proposal, the Board reviewed fees of other states. It found that the proposed fees are comparable to the renewal fees charged in surrounding states and should cause no competitive disadvantage to the Commonwealth.

Description of Proposed Amendments

Based upon the above expense and revenue estimates provided to the Board, the Board proposes to \$27.91 (relating to fees) to increase the fee for biennial renewal of licenses for pharmacists from \$120.00 to \$150.00 and increase the biennial fee for pharmacy permits from \$75.00 to \$100.00. By this increase, the Board will recoup the FY 2005-2006 projected deficit in FY 2006-2007. A smaller deficit in FY 2007-2008 is projected, however by FY 2008-2009 the Board's account should continue to carry a positive balance.

Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the regulation the Board considered the regulations as both required by law and the least restrictive means of covering the costs of services required to be performed by the Board.

Fiscal Impact

The proposed amendments will increase the biennial renewal fee for pharmacists and pharmacies. A pharmacist will pay an additional \$30.00 for biennial renewal. A pharmacy will pay an additional \$25.00 for biennial renewal. The proposed regulation should have no other fiscal impact on the private sector, the general public or political subdivisions.

Paperwork Requirements

The proposed regulation will require the Board to alter some of its forms to reflect the new biennial renewal fees; however, the proposed regulations should not create additional paperwork for the private sector.

Sunset Date

The act requires that the Board monitor its revenue and expenses on a fiscal year and biennial basis. Therefore, no sunset date has been assigned.

Regulatory Review

Under Section 5(a) of the Regulatory Review Act (71 P.S. §745.5(a)), the Board submitted a copy of this proposed regulation on February 2, 2005 to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. In addition to submitting the proposed regulation, the Board has provided IRRC and the committees with a copy of a detailed Regulatory Analysis Form prepared by the Board. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act (71 P.S. §745.5(g)), if IRRC has comments, recommendations or objections regarding any portion of the proposed rulemaking, it will notify the Board within 30 days after the close of the public comment period. The notification shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the General Assembly, and the Governor prior to publication of the regulations.

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Melanie Zimmerman, Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649, within 30 days following publication of this proposed rulemaking in the Pennsylvania Bulletin.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. Professional and Occupational Affairs

CHAPTER 27. STATE BOARD OF PHARMACY

FEES

§ 27.91. Schedule of fees.

An applicant for a license, certificate, permit or service shall pay the following fees at the time of application:

* * *

Registered pharmacist biennial renewal..... [~~\$120~~] \$150

* * *

Biennial renewal of pharmacy permit..... [~~\$75~~] \$100

* * *

FEE REPORT FORM

Agency: State - BPOA

Date: 04/21/04

Contact: Basil Merenda

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Pharmacist Biennial Renewal Fee: \$150.00

Pharmacy Biennial Renewal Fee: \$100.00

Estimated Biennial Revenue:

Pharmacist - \$2,664,300.00 (17,762 renewals x \$150.00)

Pharmacy - \$316,000.00 (3,160 renewals x \$100.00)

Total Estimated Biennial Revenue: \$2,980,300.00

Fee Description:

The fee will be charged biennially to every applicant for license renewal.

Fee Objective:

The fee should defray a substantial portion of the State Board of Pharmacy's administrative overhead, specifically the difference between the Board's total biennial expenditures and its total biennial revenues from non-renewal sources.

Fee-Related Activities and Costs:

Estimated balance at end of 05/06 cycle:	(443,952.44)
FOR BIENNIAL CYCLE 7/01/06-6/30/07	
Estimated non-renewal revenue:	150,000.00
Estimated renewal revenue @ above rates:	2,980,300.00
Total revenue available:	2,686,347.56
Estimated expenditures:	1,634,000.00
Estimated ending balance on 6/30/07:	<u>1,052,347.56</u>
FOR BIENNIAL CYCLE 7/01/07-6/30/08	
Estimated non-renewal revenue:	150,000.00
Estimated renewal revenue @ above rates:	361,250.00
Estimated expenditures:	1,683,000.00
Estimated ending balance on 6/30/08:	<u>(119,402.44)</u>

Analysis, Comment, and Recommendation:

It is recommended that the above renewal fee's be established to cover projected funding shortfalls between the Board's total biennial expenditures and its total biennial revenues from non-renewal sources.



RECEIVED

2005 FEB -2 PM 1:56

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY

Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7156

February 2, 2005

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Pharmacy
16A-5414: Biennial Renewal Fees

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to Biennial Renewal Fees.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Michael J. Romano, R. Ph., Chairperson
State Board of Pharmacy

MJR/CLC:apm

Enclosure

c: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Albert Masland, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Gerald S. Smith, Senior Counsel in Charge
Department of State
Carole L. Clarke, Counsel
State Board of Pharmacy
State Board of Pharmacy

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

I.D. NUMBER: 16A-5414
SUBJECT: State Board of Pharmacy - Biennial Renewal Fees
AGENCY: DEPARTMENT OF STATE

TYPE OF REGULATION

- Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

RECEIVED
 2005 FEB -2 PM 1:56
 INDEPENDENT REGULATORY
 REVIEW COMMISSION

2456

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
2/2/05	<i>Sandra J. Harper</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
2/2/05	<i>Mary Walmer</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
2/2/05	<i>Kristy J.</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
2/2/05	<i>Lee Brown</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)