

STATE OF MARYLAND

BOARD OF PHARMACY



Fiscal Year 2009
ANNUAL REPORT

July 1, 2008
Through
June 30, 2009

VISION

Setting a standard for pharmaceutical services, which ensures safety and quality health care for the citizens of Maryland.

MISSION STATEMENT

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy, through licensing pharmacists, registering pharmacy technicians and issuing permits to pharmacies, and distributors; setting standards for the practice of pharmacy through regulations and legislation; receiving and resolving complaints and educating consumers. The Maryland Board of Pharmacy sets standards that ensure safety and quality health care for the citizens of Maryland.

VALUES AND GUIDING PRINCIPLES

Integrity - The Board selected integrity as its over-arching value. It is defined through the following guiding principles:

Trust - Treating all parties served in ways that will demonstrate that the Board of Pharmacy is honest, impartial, professionally competent, consistent and ethical; that all of the Board's actions and judgments are legal and appropriately serves customers and stakeholders.

The Board respects and appropriately maintains the confidentiality of the individuals and groups that it represents and regulates.

Quality Service - The Board offers accurate, timely and appropriate services to customers and stakeholders by being responsive, accessible, respectful, attentive, consistent and tactful in accordance with its unified vision.

Responsibilities - The Board carries out disciplinary and licensing activities in an impartial, comprehensive and appropriate manner.

The Board addresses issues in accordance with established written guidelines, policies, and procedures.

Decisions are made after gathering and analyzing all pertinent information available from all parties involved.



FY 2009 BOARD COMMISSIONERS

President

Donald Taylor

Chain Drug Store Representative

Secretary

David Chason

Acute Care Hospital Representative

Treasurer

Michael Souranis

Independent Representative

Cynthia Anderson

Home Infusion/ Home Care

Richard W. Matens

Consumer Representative

Lynette Bradley-Baker

At Large Representative

Harry Finke, Jr.

Independent Representative

Lenna Israbian-Jamgochian

Acute Care Hospital Representative

Alland Leandre

Consumer Representative

Mayer Handelman

Long Term Care Representative

Rodney H. Taylor

At Large Representative

Reid Zimmer

Acute Care Hospital

FY 2009 BOARD STAFF

EXECUTIVE

Executive Director
LaVerne G. Naesea

Executive Assistant
LaToya Simmons

ADMINISTRATION AND PUBLIC SUPPORT UNIT

APS Manager
Patricia Gaither

Public Information and
Education Officer/Emergency
Preparedness Coordinator
Summar J. Goodman

Administrative Assistant
LaToya Simmons

Secretary/Receptionist
Anasha Page

LEGISLATION/ REGULATIONS UNIT

Legislation/Regulations
Manager
Anna D. Jeffers

LICENSING UNIT

Licensing Manager
Shirley Costley

Licensing Specialist
Doris James

Licensing Renewal Clerk
Keisha Wise

Licensing Analyst
Fannie Yorkman

Licensing Secretary
Laurie Cohen

MANAGEMENT AND INFORMATION SYSTEMS

MIS Manager
Tamarra Banks

Database Officer
Michelle Hsu

Computer Specialist
Matthew Smith

PHARMACIST COMPLIANCE UNIT

Compliance Manager
Dorcas Taylor

Compliance Investigator
Colin Eversley

Compliance Specialist
Vanessa Thomas-Gray

Lead Pharmacy Inspector
Joseph Taylor

Pharmacy Inspector
Nancy Richard

Pharmacy Inspector
Jeannelle McKnight

Pharmacy Inspector
Vacant

Pharmacist Inspector
Emory Lin

BOARD COUNSEL

Linda Bethman
Francesca Gibbs

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REMARKS FROM THE BOARD CHAIRMAN

Donald Taylor



2009 was both a year of implementation and a year of updates. The year began with a flurry of activity. With the Board's new pharmacy inspectors hired and trained, the Board's Disciplinary Unit began performing its own annual and opening pharmacy inspections. The Board's new inspectors are striving to meet the Board's legislative mandate of inspecting every Maryland pharmacy yearly while trying to perform efficiency and still keep the actual inspection time short to minimize disruptions to the pharmacy being inspected.

With the passing of the recent update to the existing influenza law allowing pharmacists to also administer herpes zoster and pneumococcal pneumonia vaccines, the Board has been kept busy processing new pharmacist applications as they completed the new training required to become certified in the administration of the approved vaccines.

In May I had the honor, on behalf of the Board, of congratulating the new pharmacy graduates from the University of Maryland School of Pharmacy, wishing them well in their careers and administering the Pharmacist's Oath.

The Board hosted a well-attended CE program for Maryland pharmacists in August, welcomed the Shanghai FDA delegation in December to explain how the Board regulates pharmacies and pharmacists in Maryland and participated in the annual Baltimore Flower Mart in May – winning a prize for the best decorated booth.

Many diverse updates were ongoing throughout the year. Following the passage of the Pharmacy Technician legislation, the Board developed procedures to approve pharmacy technician training programs, applications for pharmacy technicians and procedures for registering pharmacy technicians and printing registrations. The Board was very proactive during the legislative session in Annapolis, preparing many position papers and testifying before different legislative committees.

The Board was once again an active member of the Maryland Professional Volunteer Corp. The Board participated in the State's annual CDC drill and evaluation of Maryland's emergency preparedness plan. The pharmacy contingent received very high marks and was congratulated for their participation. As the threat of the H1N1 influenza began to grow in the public's awareness, the Board worked closely with the DHMH to develop plans that would enable the State to preposition antivirals such as Tamiflu and Relenza throughout the State, as well as order and distribute supplies of the vaccine when it became available. Those plans were to ensure that Maryland hospitals, FQHCs, local health departments and pharmacies would have sufficient supplies to treat the citizens of Maryland.



MESSAGE FROM THE EXECUTIVE DIRECTOR

LaVerne G. Naesea



MESSAGE FROM THE EXECUTIVE DIRECTOR LaVerne G. Naesea

I am pleased to present the *Fiscal Year 2009 Annual Report* that provides an overview of the Maryland Board of Pharmacy's (the Board) operations between July 1, 2008 and June 30, 2009. The Board faced several challenges during FY 2009 that affected the processing of a considerably increased number of applications; particularly from wholesale distributors and pharmacy technicians.

Implementing new regulations for pharmacy technicians and wholesale distributors required complicated shifts in business rules including, review of required criminal background reports for applicants for pharmacy technicians and distributor personnel; and surety bonding and physical inspections for all distributor facilities. Start-up delays resulted in the Board extending the acceptance and approval of both the wholesale distributor and pharmacy technician applications. Board staff members were also required to field hundreds of clarification inquiries through the Board's overtaxed telephone system.

The Board's contract to integrate its database systems presented different types of challenges during the year. The planned upgraded database system would have automated many manually performed staff functions, while significantly reducing the potential for human error. However, the vendor was unsuccessful in meeting contract provisions timely and within agreed upon costs, so the contract was terminated. Processing the increased volume and complicatedness of new and renewal applications was further delayed because staff members were required to continue manual tasks that had been projected to be automated under the failed contract.

A further test of Board and staff resilience occurred towards the end of FY 2009 when two of its stellar Unit Managers tendered their resignations. The Licensing Unit Manager Shirley Costley, retired after more than 30 years of state service, and the Pharmacist Compliance Manager for the Compliance Unit, Dorcas (Ann) Taylor moved on to a position with the FDA. Both managers played considerable roles in adjusting operations to meet new Board requirements.

The welcomed addition of new Board Commissioner and consumer representative, Richard Matens, helped to offset the loss of the key managers. Mr. Matens, Assistant Health Commissioner, Division of Chronic Disease Prevention, for the Baltimore City Health Department, began service on the Public Relations sub-committee immediately following his Board appointment in June 2008. The Public Relations Committee hosted nearly 200 licensees at a successful continuing education session on patient safety in October 2008. The Board engaged in several other forms of information sharing with constituents, licensees and others in the Fall, including: meeting with the intended Deans of two probable

new pharmacy schools: the College of Notre Dame School of Pharmacy and the University of Maryland, Eastern Shore. In June, I also represented the Board at Notre Dame's first white coat ceremony for its first class to begin in September 2009. Kudos to Notre Dame!

The Compliance Unit's oversight responsibilities significantly expanded during the start of FY 2009. The unit was reorganized to perform investigations, monitoring of Board Public Orders and inspections of pharmacies and distributors. Plans were launched in July for four newly recruited Board inspectors to assume responsibilities for annual inspections of pharmacies and opening inspections of new pharmacies. In December, they also began inspecting wholesale distributor facilities. The inspectors used a revised community inspection form, a new hospital inspection form and a new wholesale distributor inspection form, each developed by the Disciplinary committee, to facility operations in Maryland. To support the revamped Compliance Unit, the Board was also hired a Pharmacist Inspection Supervisor and to convert the unit's contractual Secretary, to permanent in September 2008 (FY 2009).



ADMINISTRATION AND PUBLIC SUPPORT UNIT

OVERVIEW

The Administration and Public Support Unit (APS) is responsible for managing the fiscal, personnel contracting and public information and education functions at the Board. The Board derives its revenue through payments for license, permits and other applicable fees. Expenditures are made based on submission of an annual budget request that must be approved by the Secretary for the Department of Health and Mental Hygiene, the Governor's office and subsequently by the State Legislature. Included in the Budget Request are requests for personnel and funding for new program areas.

FY 2009 REVENUE

Total revenue collection of \$2,241,441 was 25% higher than in fiscal year 2008, largely due to the new pharmacy technician registration program.

Carryover from Fiscal Year 08	962,723
Collections FY 2009	2,241,441
Pharmacist Examination	37,000
Pharmacist Renewals	593,117
Reciprocity	32,380
Reinstatement	28,942
Pharmacy New/Renewals	458,080
Distributor New/Renewals	850,400
Pharmacy Technicians	202,878
Other	38,644
TOTAL REVENUE	3,204,164

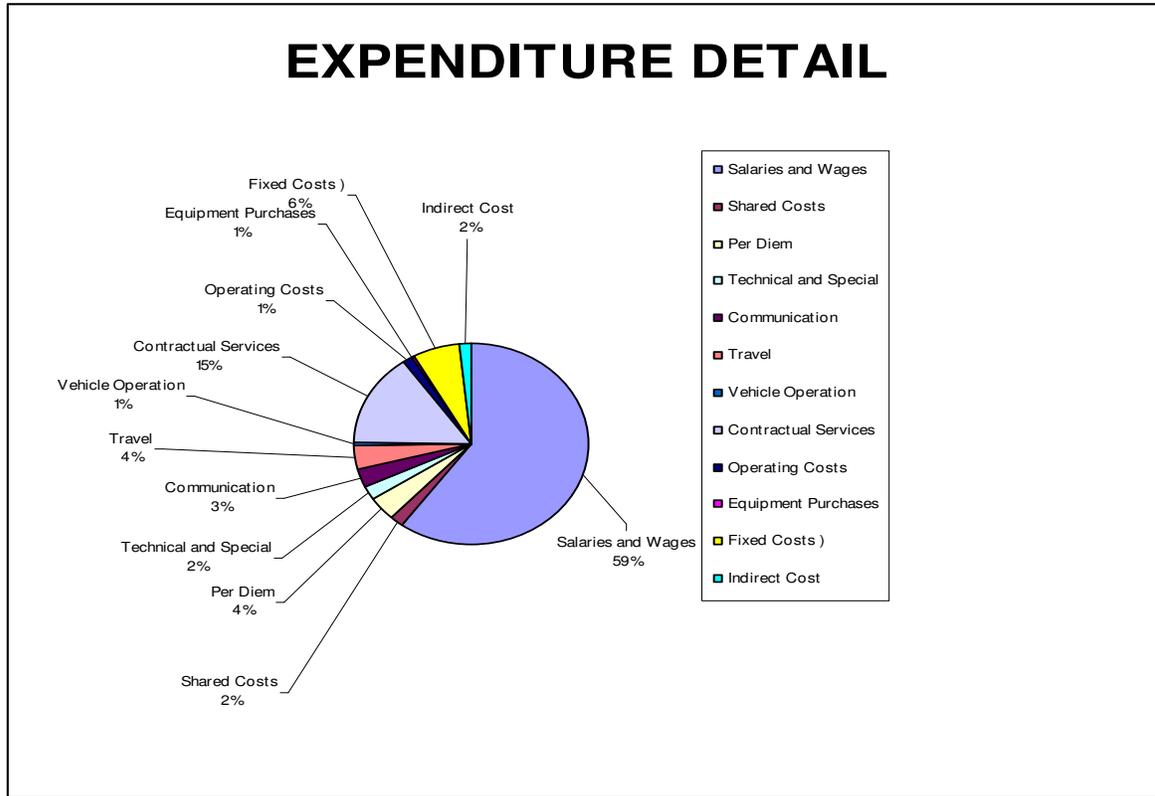
FY 2009

EXPENDITURES

Board expenditures for FY 2009 were \$2,277,551 28% more than FY 2008. Expenditure increases were related to filling of pin positions vacant in FY 2008, the New Wholesale Distributor Program and increased activity related to the Pharmacy Technician program.

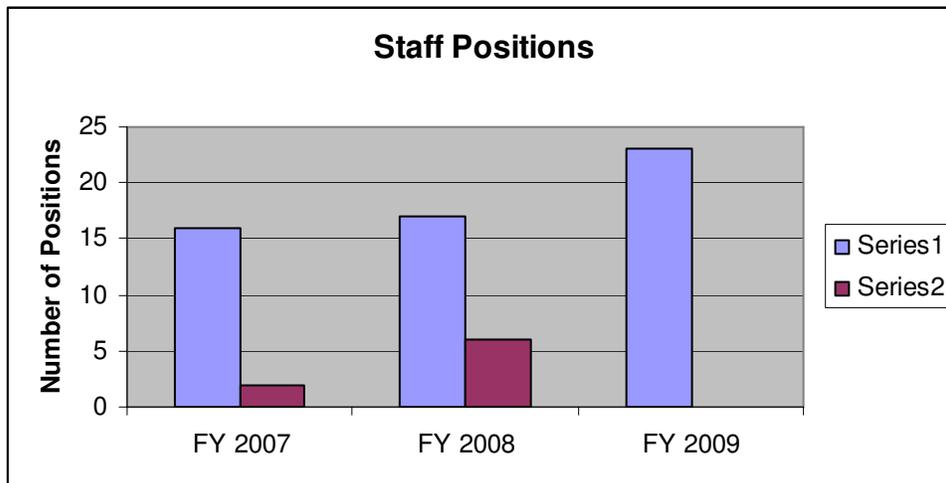
EXPENDITURE DETAIL	
Salaries and Wages	1,364,370
Shared Costs	45,711
Per Diem	87,968
Technical and Special	53,701
Communication	64,088
Travel	88,436
Vehicle Operation	12,617
Contractual Services	342,298
Operating Costs	20,928
Equipment purchases	14,100
Fixed Costs)	143,236
Indirect Cost	40,098
Total Expenditures	\$2,277,551

EXPENDITURE DETAIL



PERSONNEL

The six (6) new contractual positions awarded to the Board in fiscal year 2008 to handle the responsibilities of the Pharmacy Inspection Program assumed from the Division of Drug Control were converted to permanent (PIN) positions in fiscal year 2009. The inspection positions are: one Pharmacist Inspector, one Lead Inspector, three Pharmacy Inspectors and one Compliance Office Secretary I. By the end of FY 2009 the Board had 23 permanent (PIN) positions. Ninety six (96) percent of the positions were filled at all times during fiscal year 2009. The Board also had a contractual Help Desk position on staff in fiscal year 2009.



CONTRACTUAL AGREEMENTS

In fiscal year 2009 the Board closed its Database and Disaster Recovery contractual agreement with Towson University. The Board will seek another vendor with the more skilled in bringing efficiency to the Board's data collection and sharing operations. A continuation contract with the University of Maryland to evaluate the outcomes of Drug Therapy Management agreement to measure the success of the Drug Therapy Management project will expire December 31, 2009. The Board continues its long-standing Pharmacist Rehabilitation Services contract to support impaired practitioners under Board orders and practitioners who voluntarily (and anonymously) entered into treatment.. The Board also continued its contract with the Maryland State Archives to provide service web hosting and web statistics.

PUBLIC INFORMATION AND EDUCATION

The Board's Public Information and Education component of the APS Unit is responsible for providing information and education about the Board to the Public and Pharmacist Community. Training and educational activities have included coordinating emergency preparedness activities. In carrying out this responsibility the Public Information and Education Officer is responsible for year-round recruitment and training of volunteer pharmacists. Additionally, the Board's quarterly newsletter, annual reports and several brochures are other informational tools produced and disseminated to ensure that practitioners and consumers are informed of changes in legal requirements and board procedures and recommended safety measures.

The Public Information and Education component coordinates responses to all requests made to the Board under the Public Information Act. The Public Information Act allows certain Board information to be release regarding licensees and Board activities. The Public Information and Education Officer is responsible for ensuring that the information that is released does not violate state and federal confidentiality rules. This role is extended to coordinating responses to pharmacy related inquiries made to the Governor and Secretary for the Department of Health and Mental Hygiene. The Board is frequently asked to prepare written responses (controlled correspondence) on their behalf to constituents.

Two other, as important responsibilities for this component of the APS Unit include monitoring pharmacy-related news and coordinating media responses; and planning and staffing events to ensure the Board of Pharmacy's presence around the state. Both of these functions are necessary to encourage patient safety, keep the communities informed of how the Board works to protect Maryland's consumers, and ensure continuous communications between the Board, its licensees, other governmental agencies, and the public.

FY 2009 HIGHLIGHTS OF ACTIVITIES

- August 2008- Maryland State Fair Exhibit
- August 2008- American Society of Consultant Pharmacists(ASCP) Mid-Atlantic Conference, Rocky Gap, Maryland
- October 2008 – Pharmacist Continuing Education Brunch, Baltimore, MD,
- May 2009 - Flower Mart Exhibit in partnership with Maryland Pharmacy Coalition and University of Maryland School of Pharmacy

- June 2009 - Maryland Pharmacists Association (MPhA) Exhibit, Ocean City, Maryland

NEXT YEAR AT A GLANCE

The Board projects \$2,033,042 in revenue for FY 2010. These projections were 9½ % lower because the Board will not receive collections for the wholesaler distributor renewals in fiscal year 2010. Fiscal year 2009 collections for the New Wholesaler Distributor covered a two year period. The Pharmacy Technician program which originated in fiscal year 2008 extended its deadline to February 2009 for all pharmacy technicians to register under the Mew Pharmacy Technician program. The Board experiences increased spending related to the Board's assumption of responsibility for performing annual inspections of pharmacies (this responsibility was previously performed by the Labs Administration's Division of Drug Control). The Board hired six additional staff persons, purchased vehicles and spent additional monies for travel, equipment and mailing expenses. The Board is seeking to increase fees to cover the increase in expenditures. Fees are expected to increase in early fiscal year 2010.

The Board expects to heighten visibility throughout the state via its public information and education program and emergency preparedness activities. The Board of Pharmacy will also support the National Association of Boards of Pharmacy in hosting its Annual Meeting in Baltimore, Maryland in mid-Spring 2009.



LICENSING UNIT

Overview

The Licensing Unit is responsible for all activities related to the issuance of new and renewal Maryland practice licenses, permits and registrations to qualified pharmacists, pharmacy technicians and pharmacy owners and pharmaceutical distributors, respectively. In addition, the Licensing Unit processes applications for the Prescription Drug Repository Program and for qualified pharmacists to administer Influenza Vaccinations. The Licensing Unit consists of five members including, a Programs Manager, Licensing Specialist, Licensing Analyst, Renewal Specialist and a Secretary. Information processed by the Licensing Unit includes:

- New and renewal applications for pharmacists, pharmacy technicians, resident and non-resident pharmacies, in-state and out-of state wholesale distributors, reciprocity and reinstatement pharmacy, prescription drug repositories and the administration of vaccines by pharmacists
- Pharmacy technician training program submissions
- Criminal background checks related to pharmacy technician and wholesale distributor applications
- Verifications or Licenses, permits
- Inspection reports
- Licensing Committee and Board meeting deliberations

New Developments

All Wholesale Prescription Drug or Device Distributors that applied to operate in Maryland in FY 2009 were required to demonstrate that they met the provisions of the new Distribution Permitting and Prescription Drug Integrity Act and revised COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors regulations. To allow time to ensure that the requirements could be met, the Board extended the deadline for renewal applications to August 31, 2010.

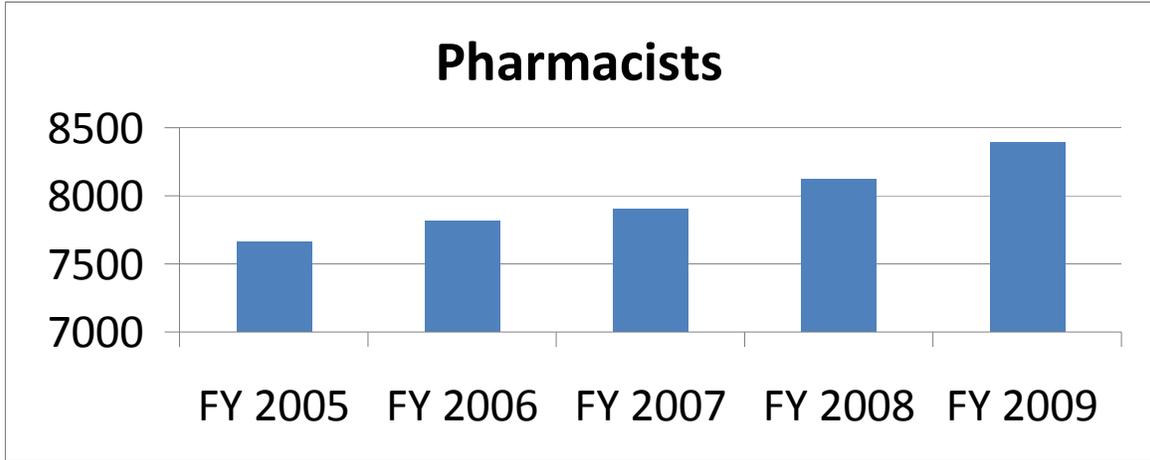
The registration deadline for pharmacy technicians was extended to allow staff to accurately process the overwhelming number of applications received and to allow the technicians to either enroll in a Board approved training program or obtain certification through one of the nationally accredited pharmacy technician certification programs. All non-registered pharmacy personnel working in the pharmacy area after the February 28 deadline date were required to be enrolled in a Board approved training program; allowing them to continue to work until the training program was completed and they became Board registered. Permit holders had the responsibility to retain documentation of trainees who are enrolled in a training program.

Despite the high number of pharmacy technician applications submitted, some candidates were not able to submit applications in FY 2009 because only three pharmacy technician training programs were approved by the end of the fiscal year.

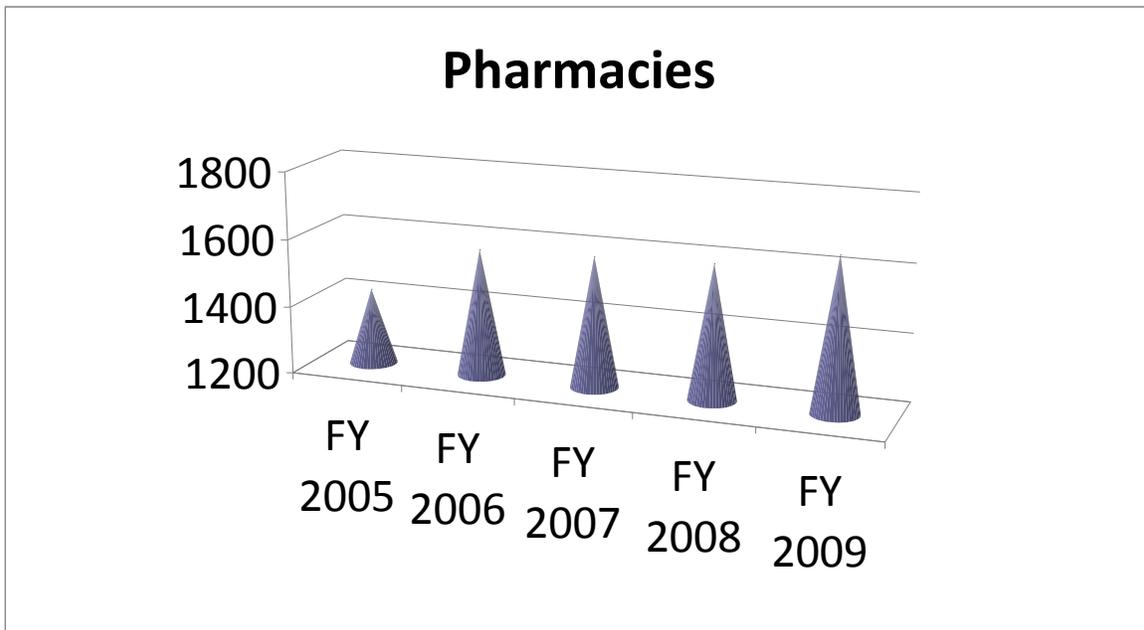
A list of Board approved pharmacy technician training programs is available on the Board's web site at <http://dhmh.maryland.gov/pharmacyboard/>

Statistics

New Maryland pharmacists are licensed by examination or reciprocity and are required to renew every two years during their birth month. The number of pharmacists licensed in Maryland has continued to increase each year. The total number of pharmacists licensed at the end of FY 2009 was 8,393; 271 more than last fiscal year.

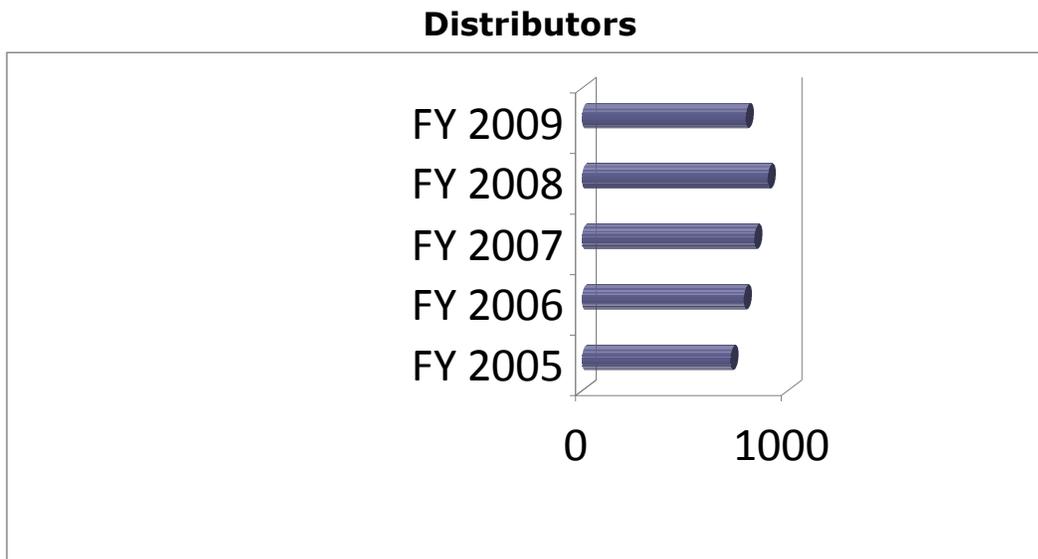


All Pharmacy permits expire December 31st of each year. The total number of licensed pharmacies at the end of FY 2009 was 1,613. Of that number 1,133 are in state, including 104 waiver pharmacies.



Pharmaceutical Distributors also expire December 31st of each year. The total number of licensed Distributor permit holders at the end of FY 2009 was 797. Of that number, 159 are in state. The number of distributors applying for licensure in Maryland increased from FY 2005

through FY 2008. This increase is suspected to be related to the more restrictive laws that have been imposed on distributors in other states since FY 2003. In response the Board successfully encouraged the legislature to revise the Maryland statute so that greater scrutiny of Maryland distributor applicants and applications may be undertaken.



Accomplishments

Over 5,600 pharmacy technicians were registered during the fiscal year. Also, approximately 600 out of state wholesale distributors and 200 in state distributors registered with the Board. The Board's two newest programs were successfully implemented despite the very complicated new regulatory changes.

Next Year At A Glance

The Board of Pharmacy anticipates that the upcoming establishment renewal season will be challenging with the implementation of the new Wholesale Distribution Permitting and Prescription Drug Integrity Act. The Act requires more detailed information to be submitted with applications, including submission of certain personnel to criminal background checks, evidence of company surety bonds, and physical inspections of the distributor sites. The Board, Licensing Committee and Unit staff members anticipate complicated and extended reviews to take place with the first round of applications under the new law. There may be a significant influx of new applications for the Pharmacy Technician program in FY 2009, since so few applied and were approved in FY 2008. The Board plans to begin listing approved pharmacy technician training programs on its web site in FY 2010. Finally, the Licensing Unit will also work closely with the Boards' Regulations/Legislation Manager in the upcoming year to revise applications that will implement the regulations to expand Administration of Vaccination rules to allow pharmacists to administer two additional vaccinations: herpes zoster and pneumococcal pneumonia.

PHARMACY COMPLIANCE UNIT

The Compliance Unit protects the public health of Maryland's citizens by ensuring compliance with state laws and regulations regarding the practice of pharmacy. Unit staff consists of a pharmacy compliance officer, coordinator, secretary, investigator and inspectors. They perform the following functions:

- receive, investigate and respond to questions and complaints
- monitor licensees and permit holders who are under order by the Board
- report disciplinary action to national databases
- inspect pharmacies and wholesale distributors

Complaints

The compliance unit receives complaints from a variety of sources and is charged with addressing each complaint. An individual may obtain a complaint form from the Board of Pharmacy website at www.dhmh.maryland.gov/pharmacyboard and may file a complaint by fax, phone, mail, in person, or e-mail. All information related to the complaint is compiled and presented to the Board's disciplinary committee for review and action. The disciplinary committee makes recommendations regarding Board actions to the full Board. If the issue is outside of the Board's scope or jurisdiction, the complaint will be referred to the appropriate authority.

Figure 1 **Complaints Processed July 1, 2008-June 30, 2009**

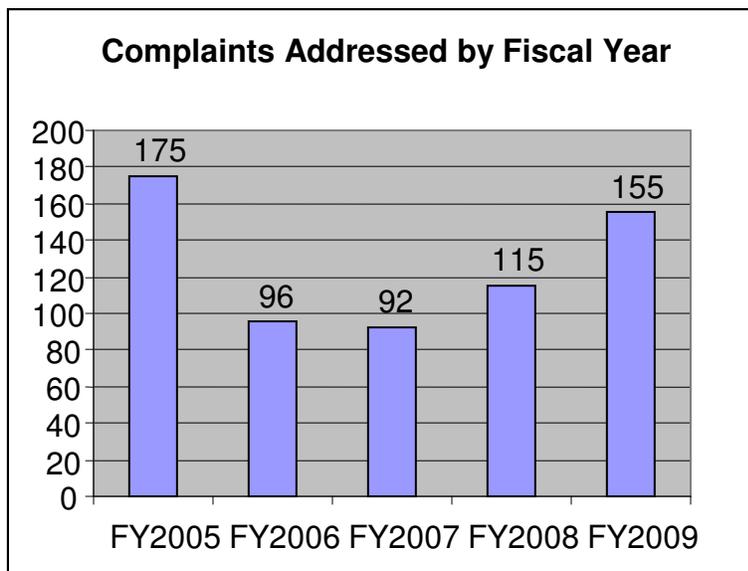


Figure 1 above compares the number of complaints processed by fiscal year. This fiscal year, although not the highest, shows a significant increase over the previous year.

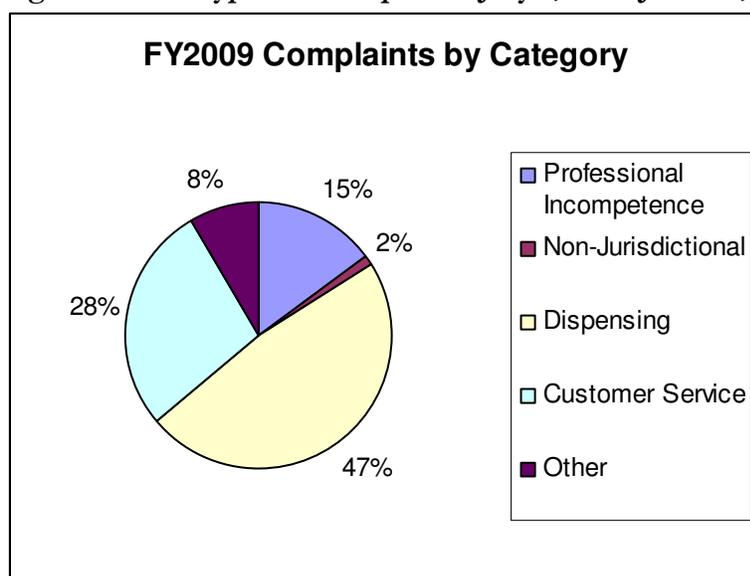
Figure 2 **Complaints against Licensees, Registrants and Permit Holders**

July 1, 2008-June 30, 2009

Pharmacists	Pharmacy Technicians	Pharmacies or Wholesale Distributor
130	9	16

This is the first year that the Maryland Board of Pharmacy began registering technicians. As a result, technician compliance is also part of the Board's purview. The table in *Figure 2* above reveals 5.8% of the complaints filed in this fiscal year were against pharmacy technicians.

Figure 3 Types of Complaints July 1, 2008-June 30, 2009



The types of complaints received are broadly categorized (*see Figure 3*). The majority relate to dispensing errors, with the number two complaint type falling in the customer service realm (communication, wait time, responsiveness, etc.).

Disciplinary Cases

All complaints are investigated by Board staff members. Approximately 61% of all complaints result in the Board taking formal or informal disciplinary action. Examples of informal actions include letters of education, letters of admonishment and/or letters that require the licensee to obtain continuing education credits on a particular topic. Examples of formal actions include, a license or permit being placed on probation or suspended. The remaining 39% of complaints are closed by the Board following a review of the information presented. *Figure 4* shows the number of formal and informal actions taken for Fiscal Year 2009, compared to the previous 4 years.

Figure 4 Disciplinary Actions-Fiscal Year Comparison

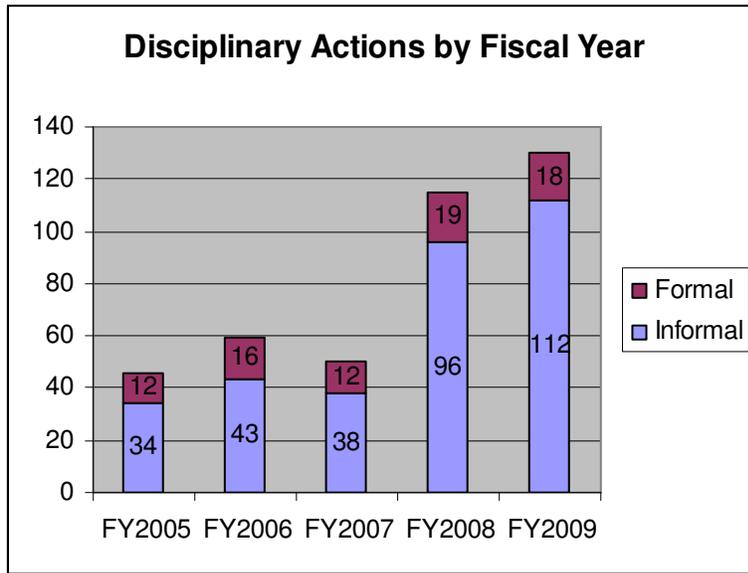
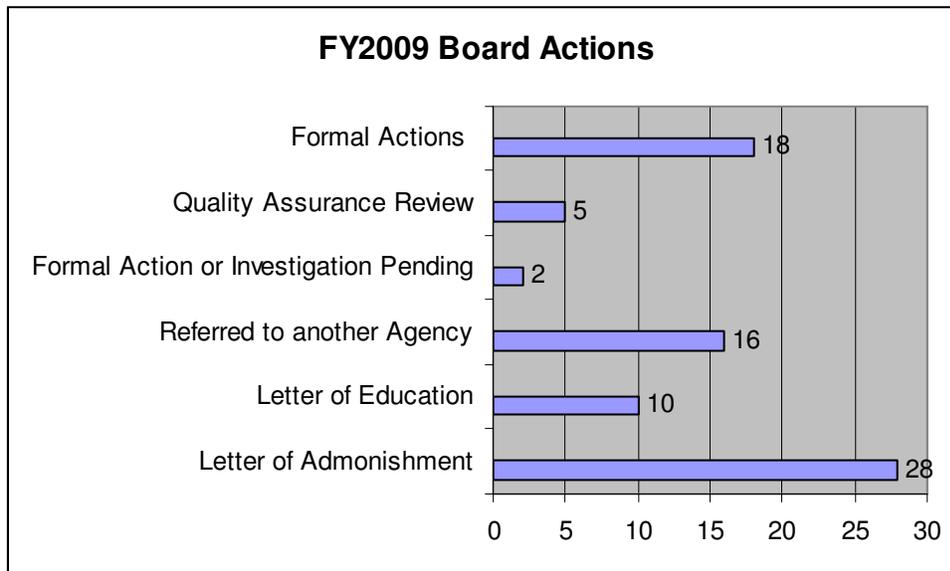


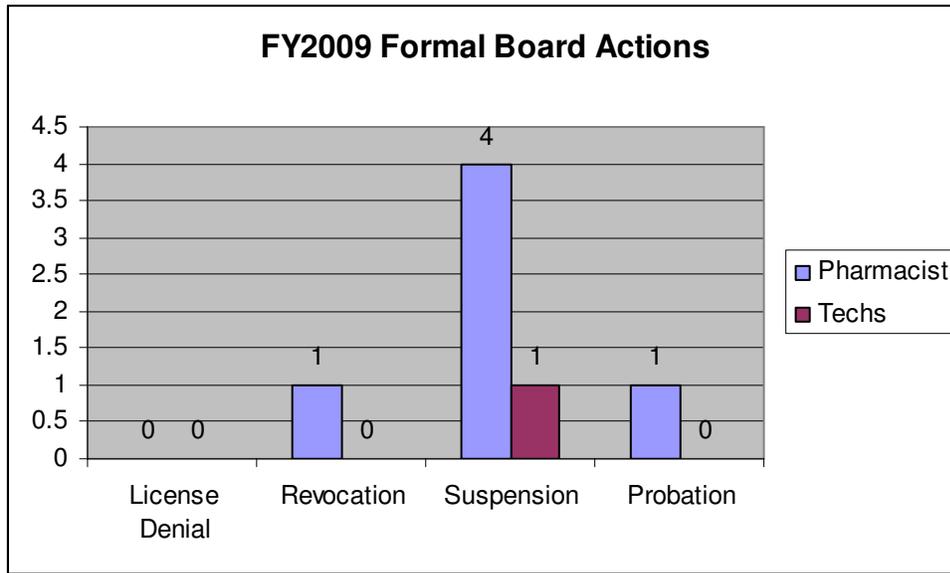
Figure 5 represents a description categorically of the various types of formal and informal actions taken in the most recent fiscal year.

Figure 5 Board Actions July 1, 2008-June 30, 2009



Once disciplined under a public order, the licensee, registrant or permit holder's information is reported to the National Practitioner Data Bank and or the Healthcare Integrity and Protection Data Bank. Figure 6 below reflects the formal actions taken against pharmacists and pharmacy technicians in Fiscal Year 2009. Some formal actions against licensees or permit holders included fines which are excluded from figure 6. Most formal actions, including fines are published in the Board of Pharmacy newsletter along with the license holder, permit holder or applicant name. Only two cases remained open before June 30th and were continued into the next fiscal year.

Figure 6 Formal Board Actions Taken July 1, 2008-June 30, 2009



Inspections

The compliance unit continues to work closely with the Division of Drug Control (DDC) in performing inspections. The Board of Pharmacy conducts opening and annual inspections of in-state pharmacies, while DDC performs all closing inspections. The Board has a goal of inspecting all in-state pharmacy annually. This year marked the launch of the Board's inspection program. The chart in *Figure 7* reflects the total number of annual and opening inspections performed in FY 2009.

Figure 7

Annual inspections	735
Opening inspections	55
Total inspections	790

The Board was also required to inspect all new and renewing wholesale distributors under the new *Wholesale Distribution Permitting and Prescription Drug Integrity Act*. During 2009, the first year of the Act, the Board of Pharmacy inspected all approved wholesale distributor facilities located in Maryland as well as some in neighboring states (Pennsylvania, Delaware and Virginia). Several out-of-state facilities required inspections, so the Board contracted with the National Association of Boards of Pharmacy (NABP), a Board-approved national wholesale distributor accreditation agency, to inspect approximately 20 facilities on the Board's behalf.

Pharmacists and Substance Abuse

The prevalence of chemical dependency among health care professionals has been estimated over the years and continues to plague society. Among its many options in addressing disciplinary actions, the Maryland Board of Pharmacy may opt to mandate substance abuse treatment. If treatment is so ordered, the staff is responsible to monitor the individual to ensure compliance with the terms of the order. The Board provides direct monitoring of these licensees which include but are not limited to:

- Random drug tests
- Substance abuse treatment or psychotherapy
- Participation in local NA/AA programs

Once disciplined, the licensee or permit holder's information is reported to the National Practitioner Data Bank and or the Healthcare Integrity and Protection Data Bank. In FY 2009, the Board monitored 13 pharmacists who were under orders that involved substance abuse. The Board will also monitor registered pharmacy technicians who are issued public orders for actions involving substance abuse. There were no public orders related to substance abuse issued to the registered technicians during FY 2009.

The Maryland Board also contracts with the PEAC rehabilitation committee to provide assessments, treatment referral, and monitoring of pharmacists and pharmacy technicians that voluntarily request substance abuse assistance. Individual assistance provided by the rehabilitation committee is confidential, with monthly aggregate reports provided to the Board. Each client served by the rehabilitation committee is required to sign a contract indicating that it understand that the Board of Pharmacy will be notified if they violate the terms of their contracts.

In FY 2009 the pharmacist rehabilitation committee, PEAC, monitored 22 pharmacists and pharmacy technicians, combined.

Next Year At A Glance

For FY10 the Compliance Unit plans to:

- provide additional training to staff
- examine customer service
- have more uniform review of customer reports
- continue to have a full cadre of compliance staff and pharmacy inspectors



LEGISLATIVE/REGULATIONS UNIT

Overview

The Legislative and Regulations Unit (the “Unit”) plays an active role in supporting the Board by evaluating, developing and drafting Board-directed legislative and regulatory proposals that protect the public and promote quality health care in the pharmaceutical profession. The Unit is also responsible for supporting the Board and its various committees in the areas of legislative review, health policy research, regulatory evaluation and a variety of special assignments. The committees staffed by this Unit are Pharmacy Practice and Legislative. Special sub-committee and task forces staffed during Fiscal Year 2009 included the Long Term Care Workgroup and the Home Infusion Task Force which were convened to explore and recommend regulatory revisions.

Throughout the year the Unit responds to phone calls and email inquiries from the public, applicants, licensees, permit holders, Maryland agencies, pharmaceutical companies, legislators, other state agencies, other state boards, attorneys throughout the country and students. The Unit makes every effort to respond in detail, addressing all the issues, in the order in which the inquiries were received. Questions posed to the Unit that require Board interpretation or involve controversial issues are presented at the monthly Practice Committee Meeting. Depending on the Practice Committee's recommendations, some of the responses are brought to the public Board Meetings for approval. During Fiscal Year 2009 the Unit responded to 2,076 phone calls and provided written responses to 650 email inquiries. The Unit responded to approximately 57 % more phone calls and approximately 70% more emails during Fiscal Year 2009 than in Fiscal Year 2008.

Legislative Initiatives

During the Maryland Legislative Session, the Unit reviews and tracks legislation, prepares written position papers, determines fiscal impacts of bills, testifies before legislative committees and meets with legislators, stakeholders and subcommittees regularly to insure that the Board’s legislative initiatives are successful in Annapolis. The Unit is most visible during the session as it strives to effectively communicate Board policies to health professional boards, local and national health associations and the regulated industry.

The Unit identified 35 bills (of approximately 2,654 bills) to present to the Board of Pharmacy’s Legislative Committee for consideration. The Unit tracked, drafted position papers and/or letters to legislative committees for 16 of the 35 bills. Below is provided a chart of the 16 bills (companion bills are counted as one bill) and the results.

Bill #	Bill Name	Result
HB 83	Health Occupations - Pharmacies - Display of SMARxT Disposal Campaign Poster	WITHDRAWN
SB 229	Public Health - Ephedrine, Pseudoephedrine, or Phenylpropanolamine Purchases - Statewide Electronic Logbook	UNFAVORABLE REPORT
SB 242	Dispensation of Prescription Medication – Provision of Information Relating to Incorrectly Filled Prescriptions	PASSED

SB 309	State Board of Pharmacy - Pharmacy Permit - Term and Renewal	PASSED
HB 252	State Board of Pharmacy - Pharmacy Permit - Term and Renewal	PASSED
HB 344	Consumer Protection – Sale or Distribution of Personal Information – Limitations	WITHDRAWN
HB 368	Baltimore City Health Department – Overdose Prevention Pilot Program	WITHDRAWN
SB 386	Baltimore City Health Department – Overdose Prevention Pilot Program	WITHDRAWN
HB 635	Criminal Procedure - Occupational Licenses or Certificates - Criminal Conviction	PASSED
SB 700	Pharmacists – Administration of Vaccinations – Expanded Authority	PASSED
SB 791	Group Model Health Maintenance Organizations - Drug Therapy Management	PASSED
HB 725	Group Model Health Maintenance Organizations - Drug Therapy Management	PASSED
HB 756	Cultural and Linguistic Health Care Provider Competency Program	PASSED
SB 881	Maryland Health Security Act of 2009	FAILED
HB 1186	Maryland Health Security Act of 2009	FAILED
HB 1195	Prescription Drugs - Wholesale Drug Distribution - Surety Bond Requirements	PASSED
HB 1275	Health Occupations Boards – Revisions	FAILED
SB 956	Health Occupations Boards – Revisions	FAILED
HB 1389	State Government - Access to Public Records - Electronic Documents	WITHDRAWN
HB 1431	Professional Boards - Transfer of Funds - Repayment	UNFAVORABLE REPORT
SB 1052	Health Occupation Boards – Exemption from Hiring Freeze	WITHDRAWN

Summaries of major bills from the 2009 Legislative Session are provided below.

SB 242 - Dispensation of Prescription Medication – Provision of Information Relating to Incorrectly Filled Prescriptions

This legislation requires all Maryland pharmacy permit holders, non-resident pharmacy permit holders, and any licensees that are issued a dispensing permit in Maryland to post a conspicuously positioned and readable sign at the point where prescription drugs are dispensed to consumers that informs consumers how to report an incorrectly filled prescription, or provide written notification with the consumer’s prescription that informs consumers how to report an incorrectly filled prescription.

SB 309 - State Board of Pharmacy - Pharmacy Permit - Term and Renewal

This legislation provides for alternating renewal years for pharmacies and wholesale distributors so that the Board may have sufficient staff resources and time to review and process renewal applications. In alternating the years for submission of distributor and pharmacy permits, the Board of Pharmacy would be relieved from the need for excessive staff overtime, recruitment of temporary staff and extending the approval period required to review and process each type of application. This helps decrease Board expenditures for costs related to these functions. There would be no additional costs or fiscal impact to the Board or licensees. Pharmacy owners would be required to pay \$1,000 every other year beginning in December 2009, rather than \$500.00 every year.

SB 700 - Pharmacists – Administration of Vaccinations – Expanded Authority

This legislation expands the types of vaccinations that may be administered by pharmacists to any vaccination that has been determined by the Board of Pharmacy, with the agreement of the Board of Physicians and the Board of Nursing to be in the best health interests of the community. At the present time pharmacists may administer influenza, pneumococcal pneumonia or herpes zoster.

HB 1195 - Prescription Drugs - Wholesale Drug Distribution - Surety Bond Requirements

This legislation alters the surety bond requirement under the Wholesale Distribution Permitting and Prescription Drug Integrity Act (the “Act”) by establishing a two tiered amount for the required surety bond depending on the annual gross receipts of the applicant. Currently, all applicants are required to obtain a \$100,000 surety bond in order to operate in Maryland. A \$100,000 surety bond would still be required if the annual gross receipts of the applicant for the previous tax year are \$10,000,000 or more. However, if the annual gross receipts of the applicant for the previous tax year are less than \$10,000,000, a \$50,000 surety bond would be required. All applicants would continue to pay the same application fee. This legislation is an Emergency Bill so that eligible applicants may take advantage of this change as soon as the Governor signs the bill.

Regulatory Initiatives

The Unit assists in revising the Board’s regulations. Below is provided a chart of the regulatory revisions and accomplishments.

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .34, revisions effective since July 1, 2008:

COMAR Citation	Title	Effective Date
10.27.04	Board of Nursing regulations that were jointly promulgated with the Board of Pharmacy	February 9, 2009
10.34.19	Sterile Pharmaceutical Compounding	December 31, 2008
10.34.19	Sterile Pharmaceutical Compounding	February 23, 2009
10.34.22	Licensing of Wholesale Prescription Drug or Device Distributors	June 18, 2009 Emergency Status

Pursuant to the **Regulatory Review and Evaluation Act**, the Board submitted a Work Plan for review of the following regulatory chapters on October 1, 2008.

- 10.34.03 Inpatient Institutional Pharmacies
- 10.34.05 Pharmacy Security
- 10.34.06 Reporting Pharmacist's Mailing Address and Location of Employment
- 10.34.07 Pharmacy Equipment
- 10.34.12 Removal of Expired Prescription Drugs
- 10.34.13 Reinstatement of Expired Licenses for Pharmacists
- 10.34.15 Licensure by Reciprocity
- 10.34.17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties
- 10.34.18 Continuing Education for Pharmacists
- 10.34.23 Pharmaceutical Services to Residents in Long-Term Care Facilities

Throughout the remainder of Fiscal Year 2009, the Practice and Licensing Committees recommended revisions for the above chapters, except for 10.34.03 and 10.34.23. A separate subcommittee was formed for 10.34.03 and a workgroup was formed for 10.34.23. The Final Reports under the Regulatory Review and Evaluation Act were submitted to the Office of Regulations Coordination during June 2009.

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .34 and other COMAR chapters, currently in the revision or promulgation process:

COMAR Citation	Title	Proposal status
10.13.01	Dispensing of Prescription Drugs by a Licensee	Revisions under consideration pursuant to the Regulatory Review and Evaluation Act Report dated February 28, 2008. Board of Pharmacy in correspondence with Board of Physicians concerning revisions.
10.34.09	Fees	Proposed to increase fees for pharmacists, pharmacy permit holders, and distributors, in part to address additional workload created by the registration of technicians and distributors, a new inspection program and expansion of other programs. Proposal submitted June 12, 2009
10.34.17	Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties	Proposed revisions include 1) what constitutes a pharmaceutical specialty; 2) evaluation criteria for the Board to consider when approving an application for a waiver permit; and 3) the restrictions placed on a waiver pharmacy. Reproposal submitted June 24, 2009.
10.34.20	Format of Prescription Transmission	Revisions under consideration in Practice Committee. To be released for informal comment in July 2009.
10.34.23	Pharmaceutical Services to Residents in	Published August 6, 2004 and withdrawn December 23, 2005 by operation of law.

	Long-Term Care Facilities	Proposal revisions under consideration in Long Term Care Workgroup.
10.34.25	Delivery of Prescriptions	Informal comments under consideration in Practice Committee.
10.34.28	Automated Medication Systems	Regulatory revisions under consideration pursuant to HB 1387/SB 767 Health Occupations - Board of Pharmacy - Remote Automated Medication Systems, 2008. Informal comments under consideration in Practice Committee.
10.34.32	Pharmacist Administration of Influenza Vaccination	Regulatory revisions under consideration pursuant to SB 717 Pharmacists – Administration of Vaccinations – Expanded Authority, 2008. Re-proposal to be submitted for publication.

Summaries of regulatory changes that became effective in FY 2009 are provided below.

10.34.19 - Sterile Pharmaceutical Compounding

This action revised the existing regulations to reflect the U.S. Pharmacopeia (USP) 797 General Chapter Pharmaceutical Compounding Sterile Preparations and U.S. Pharmacopeia (USP) General Chapter 795 Pharmaceutical Compounding—Non-Sterile Preparations. Revisions include a definition for closed system vial transfer device; a rewording for clarity and consistency; and the inclusion of language that requires pharmacists whose practice includes compounding of radiopharmaceuticals to comply with COMAR 10.34.19, except where U.S. Pharmacopeia (USP) General Chapter Pharmaceutical Compounding—Sterile Preparations addresses radiopharmaceuticals, USP 821 Radioactivity and USP 823 Radiopharmaceuticals for Positron Emission Tomography—Compounding would apply.

10.34.22 - Licensing of Wholesale Prescription Drug or Device Distributors

This action revised the regulations to comply with Emergency Bill, HB 1195 (2009) Prescription Drugs – Wholesale Drug distribution – Surety Bond Requirements, which alters the surety bond requirement for applicants for a wholesale distributor permit to \$50,000 for those applicants with annual gross receipts under \$10,000,000 from sales of prescription drugs and devices in Maryland. The surety bond remains \$100,000 for those applicants with annual gross receipts of \$10,000,000 or more from sales of prescription drugs and devices in Maryland.

Legislative Reports

The Unit is also responsible for drafting and obtaining Board approval for legislative reports including the following:

- Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act
- Annual Report on the Operation of the Prescription Drug Repository Program
- Report on the reasonableness of the fees to cover the expenditures under Pharmacy Technician Registration
- Other legislative reports as required.

Accomplishments

Law Book

The 2008 Edition of the Maryland Pharmacy Laws book was revised during the summer of 2009 and distributed to all pharmacy permit holders in November of 2008. It has been offered for sale to pharmacists and the public on the Board's website since that time.

Completion of Wholesale Distributor SB 759 Workgroup Tasks

A major accomplishment for the Unit during FY 2008 and FY 2009 has been the staffing of the Wholesale Distributor SB 759 Workgroup. The Workgroup was convened pursuant to the Wholesale Distributor Permitting and Prescription Drug Integrity Act, passed during the 2007 Maryland Legislative Session. The initial task of the Workgroup was to review and recommend regulations to implement the Act. The Board reviewed the recommendations of the Workgroup and promulgated the regulations effective on April 7, 2008.

Additionally the Workgroup was mandated to (1) survey the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain; (2) determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and (3) based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain.

The Workgroup conducted a survey on the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain in the summer of 2008, and made its recommendations to the Board.

Based on recommendations from the Workgroup, the target dates established by the Board for implementation of electronic track and trace pedigree technology are as follows:

- January 1, 2016: Manufacturers (generic and brand) must pedigree:
 - 50 percent of their products by 2016; and
 - 50 percent by 2017;
- July 1, 2017: Wholesalers and repackagers must accept and pass pedigrees.
- July 1, 2018: Pharmacies and pharmacy warehouses must accept pedigrees.

The Unit completed the tasks of the Wholesale Distributor SB 759 Workgroup during the fall of 2008 and submitted a report to the Legislature by January 1, 2009.

New Year at a Glance (Projections for FY 2010)

The Unit will be busy in the beginning of Fiscal Year 2010, preparing five legislative reports due January 1, 2010. Those reports include:

- Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act
- Annual Report on the Operation of the Prescription Drug Repository Program

- Report on the reasonableness of the fees to cover the expenditures under Pharmacy Technician Registration
- Maryland Board of Pharmacy Drug Therapy Management Report on the Study to Access the Outcomes Achieved by Drug Therapy Management Agreements to the General Assembly
- Maryland Board of Pharmacy Annual Report to the Senate Education, Health and Environmental Affairs and House Health and Government Operations Committees on the Effect if Remote Automated Medication Systems on Patient Safety in Nursing Homes in Maryland

The Unit will to coordinate, review, format, and process the regulatory chapters reviewed under the Regulatory Review and Evaluation Act throughout Fiscal Year 2010.

At the end of FY 2010, the Unit will begin the process of revising the Maryland Pharmacy Laws Book. The expectation is that the review and proofing process will be completed in the late summer of 2010 with a shipment date in the fall. As with the other Maryland Pharmacy Laws books, it will be distributed to all pharmacy permit holders and will be offered for sale to pharmacists and the public on the Board's website.



MANAGEMENT AND INFORMATION SERVICES UNIT

FY2009 brought many challenges, for the newly launched programs that required continued development and support from MIS, as well as for the existing systems such as web, email, and online servers, wireless Internet and maintaining an internal secure web site for conducting Board committee business for 5-6 meetings per month. To accomplish many tasks MIS focused on completing the new in-house database system because the mainframe system caused many delays and possessed limitation for adding new fields and manipulating data.

During the year, MIS worked with the Department installing a new VLAN that would add more security to all the agencies in the Metro Building, participated in an Computer System Audit, purchased and installed new laptops for wireless/paperless meetings and continuing to maintain older mainframe equipment that parts are slowly becoming more difficult to replace or fix. Despite the everyday challenges, progress did occur during the year.

Implementation of the new in-house, integrated database system ended with the Board's decision not to continue using Towson University's RESI, the vendor selected in 2006 for the database design due to additional months and money added to the contract and extensions resulting in a system that was only 80% completed by February 2009. The Board will consider other options to create a comprehensive updated database system.

In December, an automated inspection system developed by the MIS and Compliance Units for the purpose of inspecting the Board 1,200 in state pharmacies and 186 distributors located in Maryland. Board inspectors equipped with laptop computers inspect these facilities across the State which has the ability to provide electronic tracking and reporting of inspection outcomes. Previously, all inspections were performed on carbon based multi-page forms, which were hard to read, track outcomes, not to mention they took up a lot of space in the Board's office.

After the Board was approved for its submission of a Disaster Recovery Plan (DRP) which detailed exact steps for performing critical business functions after various types and degrees of emergency situations. The next step included a cooperative effort with Maryland Public Television to develop an automated process for transferring Board data. A process was developed for maintaining information off-site which includes physically locating to another location in the event the Board is unable to access the Metro Executive Building or its equipment.

The Board's Public Relations Committee (PR) had been working on revamping the Boards public web site, and in April 2009, the MIS developed the prototype based on the PR Committee's recommendations. The new design was intended to display the Board's new logo, and be more user friendly for finding information. The web site will need to be submitted to the Department for final approval.

At the end of the fiscal year, the MIS Help Desk Support position for all the new systems ended. The Board hopes to retain this position full time in the next fiscal year.

New Year at a Glance (Projections for FY 2010)

- 1) Completing design and implementation of the new in-house, integrated database system;
- 2) Update outdated office equipment in conjunction with updated database systems;
- 3) Updating the existing DRP alternate site with all the changes from the previous year;
- 4) Launching the Boards public web site that includes more online services; and
- 5) Obtain permanent staff for Help Desk Support for all the new systems.

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