

STATE OF MARYLAND
BOARD OF PHARMACY
ANNUAL REPORT

July 1, 2005 – June 30, 2006



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Board Chairman Remarks by Mark Levi



Fiscal Year 2006 was extremely active ending with the Board of Pharmacy moving its offices to a new location. The space expansion was necessary in anticipation of additional staff related to the Board's newest responsibility of regulating pharmacy technicians. Offices are now located on the first floor in the same building on Patterson Avenue in Baltimore City, Maryland.

The Board and staff were very excited about the watershed legislation to register pharmacy technicians. Maryland has joined the majority of states that now register pharmacy technicians and require technicians to have a certain level of education and experience. This legislation enabled the Board of Pharmacy to have some control over what had been referred to as "unlicensed pharmacy personnel". We all look forward to the registration process after the regulations are promulgated in FY in 2007.

The Board developed two draft pre-inspection forms for community and hospital pharmacies. The forms are intended to facilitate a more efficient inspection process and minimize disruptions to the normal flow of business. These forms will be implemented in 2007.

Sterile Compounding regulations have been amended for promulgation in FY 2007 after amendments to the USP 797 federal standards are completed. The Board's regulations will reflect much of what is required by the USP 797 standards. Pharmacy inspectors will be trained on the new federal standards so that the state regulations can be enforced.

Although the legislative initiative to regulate pharmacy wholesalers failed in FY 2006, the Board looks forward to passage of a streamlined version of the failed bill that will strengthen state oversight of wholesale distributors in 2007. The Board of Pharmacy anticipates a safer drug distribution system in future years.

The Influenza Immunization regulations passed this year and I am happy to report that 119 pharmacists were certified to administer flu shots in FY 2006. The Administration of Influenza Vaccine certification along with Drug Therapy Management contracts have allow many pharmacists an expanded to role in caring for Maryland patients.

The Board of Pharmacy supported the Drug Repository bill introduced by Delegate David Rudolph. When implemented, the statute will enable the recycling of unused medication under certain circumstances. We look forward to implementation of this law and associated regulations.

In closing, I would like to thank Donald Yee and John Balch for their service to the Board of Pharmacy. Both had invaluable experience that supported the Board's numerous initiatives over the past eight (8) years. Cynthia Anderson replaced Don Yee as a hospital representative and Harry Fink replaced John Balch as a community pharmacist. Alland Leandre was also appointed as a consumer member to fill the position that had been vacant for over a year. The Board of Pharmacy now has a full complement of commissioners who have one common goal of making sure that Maryland consumers are served by the profession of pharmacy in the best possible manner.

Fiscal Year 2006 has been a very active year and it appears that in FY 2007, the Maryland Board of Pharmacy will work to implement a better process for inspecting pharmacies and wholesalers. Thanks are given to all of those who have supported the Board in fulfilling its mission to protect Maryland pharmacy patients and ensure quality health care services. I would encourage attendance to the Board's public meetings, which are generally on the third Wednesday of the month.

Mark Levi

Vision

Setting a standard for pharmaceutical services, which ensure 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 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.

Executive Director's Remarks by LaVerne Naesea



The Maryland Board of Pharmacy's 2006 Annual Report is presented in order to provide Maryland Citizens, State Government officials, and other interested entities on the local, state and national levels with an overview of the Board's operations and programs initiatives between July 1, 2005 and June 30, 2006.

The Maryland Board of Pharmacy continued to make headway in meeting its mission. It assumed several new responsibilities in FY 2006 including, registering and monitoring pharmacists who administer Influenza Vaccines, reviewing and approving Drug Therapy Management Agreements jointly with the MD Board of Physicians, and initiating the new Prescription Drug Repository Program. The Board also received statutory authority to register Pharmacy Technicians and began in FY 2006 to hire staff and promulgate regulations for the program's implementation in 2007.

The Board held its second five-year strategic planning retreat in November 2005, at which Board and staff members examined existing goals and determined strategies to address trends and operations that have impacted consumer health care needs and pharmacy practice in Maryland. The Fall 2006 Retreat helped to ensure that the Board could adequately absorb its new responsibilities. Key focus areas were developed for the subsequent twelve months. Specifically, between January 2006 and December 2006 the Board determined that it would focus on revising the inspection process for permit holders; revising the wholesale distribution evaluation process; obtaining stable employment and staffing patterns; ensuring safe usage of medications by consumers; ensuring consistency of disciplinary actions taken; better integrating technology into board operations; and improving relationships with state and governmental agencies.

The retreat was also welcomed because eight (8) new board members and four of the Board's six key management staff members had changed over the past five years. Additionally, the number of Board staff positions had grown by 50% and the Board experienced an 89% employee retention rate from January through July 2006. There was also an increase of 12% in the number of pharmacists licensed in Maryland, a 9% increase in the number of pharmacy permits issued and an increase of 23% in the number of wholesale distributors.

In follow-up to the retreat, the Board appointed a sub-committee in FY 2006 to amend the wholesale distribution regulations and to consider possible language for statutory amendments. It also revised all of its consumer information brochures, which were subsequently disseminated at the 2006 Flower Mart, Maryland State Fair and other public forums, and the Disciplinary committee reviewed its processes for determining recommendations for disciplinary actions involving pharmacists and permit holders who

may have violated Maryland pharmacy practice laws. The Board also entered into a contract with a vendor to completely revamp and integrate its licensing, disciplinary and cash/mail information technology systems (MIS) and initiated routine meetings with key legislative and state governmental representatives.

The framework provided through the Board’s Strategic Planning Retreat furnished a clear roadmap for the Board’s continued success in FY 2006. This report represents only the highlights of an extremely active and stellar year for the Maryland Board of Pharmacy in meeting its vision to set standards that ensure safety and quality health care for the citizens of Maryland.

LaVerne Naesea

Goals

The following key focus areas were established for the next five years:

- Permit Holder Practice and Review
- Public Information and Awareness
- Continued Integration of Technology
- Staff Development and Reorganization
- Upgrading Compliance Processes
- Strengthening Government Relations

The following goals were established for implementation during this fiscal year:

Goal 1	To revise the inspection process for permit holder
Goal 2	To revise wholesale distribution evaluation process
Goal 3	To obtain stable employment and staffing patterns
Goal 4	To ensure safe usage of medications
Goal 5	To ensure consistency of disciplinary actions
Goal 6	To better integrate technology into board operations
Goal 7	To improve relationship with state and governmental agencies

The framework provided by the above focus areas and first year goals furnish a clear roadmap for continued success over the next five fiscal years.

The retreat culminated during an open public session at which Board members voted on the above strategic direction beginning July 1, 2006 and ending June 30, 2011. The Board also voted to plan additional retreats over the next five years to evaluate accomplishments and reassess goals. The Strategic Plan Report will be published within the coming months.

FY 2006 Board Commissioners

John H. Balch
Board President
Independent Representative

Mark Levi
Board President-Elect
At Large Representative

Donald Taylor
Board Secretary
Chain Drug Store Representative

Jeanne G. Furman
Board Treasurer
Acute Care Hospital Representative

Joseph A. DeMino
Chain Drug Store Representative

Mayer Handelman
Long Term Care Representative

Donald K. Yee
Home Infusion Representative

Margie Anne Bonnett
Consumer Representative

Alland Leandre
Consumer Position

Rodney H. Taylor
At-large Representative

David Chason
Hospital Pharmacy Representative

Michael N. Souranis
Independent Representative

Linda Bethman
Board Council
Office of the Attorney General

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.

Administration and Public Support Report

FY 2006 Summary

Revenue	
Pharmacist Examination	\$41,220
Pharmacist Renewals	\$543,307
Reciprocity	\$20,743
Pharmacist Reinstatement	\$18,321
Establishments	\$898,825
Other	\$32,502
TOTAL REVENUE	\$1,554,918

Expenditures	
Salaries and Wages	\$725,406
Per Diem	\$40,041
Technical and Special	\$114,296
Operating Costs	\$278,266
Purchases	\$14,822
Fixed Costs	\$64,602.17
Indirect Cost	\$68,004
TOTAL EXPENDITURES	\$1,305,437

Administration and Staffing

In fiscal 2006 of the Board two new contractual employees increased the Board's staff. The Board requested the Maryland Legislature to approve additional staff to support the Licensing and Certification Units in. This is necessitated because of the new Pharmacy Technician program to be assumed in FY 2006/2007 and the increase in workload related to existing programs. Two new contractual positions were assigned to the Licensing to carry out new responsibilities associated Pharmacy Technician programs. Of the now seventeen positions at the Board, 76% were filled at all times during fiscal year. About 50% the Board staff members have tenures of 5 plus years.

Personnel Statistics

PIN positions (Permanent)	13
Total Contractual Positions	4
Total Positions	17

* Two of the four Contractual positions were awarded in FY 2006.

Fiscal Year 2006 at a Glance

The Board with the adoption of the Pharmacy Technician bill can expect significant increases in revenues. With the rise in pharmaceutical issues and heightening of emergency preparedness, the Board expects to participate in additional public relations and emergency preparedness activities. Training for Board staff and pharmacists

volunteers will intensify. Board and staff members will. The Board of Pharmacy along with the School of Pharmacy will host the NABP District I and District II meeting in the Fall of 2006.

Public Information and Education/ Emergency Preparedness Coordinator Report

The following charts describe the activities and initiatives led by the Public Information and Education Unit which are geared toward educating and increasing consumers’ knowledge about pharmaceutical services and medications, promoting awareness for the prevention of medication errors, and maintaining on-going activities to protect the public.

Consumer Events /Education		
	DATE	DESCRIPTION
Annual Report	January 2007	Compiling information and designing the Board’s Annual Report.
Consumer Brochures	April 2006	The Board’s brochure “What You Should Know About Pharmacy in Maryland” was updated.
2006 Flower Mart Mount Vernon Baltimore, MD	May 5, 2006	The Board’s was awarded 3 rd place in the booth decorating contest for the Wellness Village. The Board, along with the Maryland Pharmacy Coalition handed out health brochures and promotional items at the event. Students from the University of MD. School of Pharmacy tested consumer’s blood pressure and performed surveys to assess consumers risk for diabetes. The Board greeted over 900 consumers at the booth from 9 a.m. until 5 p.m.
Maryland State Fair Maryland State Fairgrounds	August 28, 2005	The Board disseminated health brochures and promotional items at the Department of Mental Health and Hygiene booth.
Public Information Requests	Ongoing	The Board filled 204 public information requests.
Banner	October 2006	A banner was designed in an effort to better promote the Board. Thee new Board of Pharmacy Banner was unveiled in late October. It is displayed in the Board’s office and will be used to promote the Board at outside events.

Pharmacist Events/ Education		
	DATE	DESCRIPTION
Board of Pharmacy Newsletter	Fall 2005 Winter 2005 Spring 2006 Summer 2006	The Board's newsletter is considered an official method of notification to pharmacists and pharmacies. The newsletter was redesigned in-house and the new look debuted with the Spring 2006 issue. The unit produces newsletters on a quarterly basis.
Website	Ongoing	Information pertinent to the pharmacy community was posted on the Board of Pharmacy's website.
Maryland Health Professional Volunteer Corps Newsletter	Quarterly	Articles on the Board's Emergency Preparedness program are submitted quarterly.

Board of Pharmacy Events		
	DATE	DESCRIPTION
NABP District I and II Meeting	October 2005 until October 2006	Began planning for the National Association of Boards of Pharmacy's District I and II Meeting scheduled for October 12-14, 2006 at the Renaissance Harborplace Hotel.
Volunteer Recognition Breakfast	October 19, 2005	The Board recognized the 13 Maryland pharmacists who volunteered in Louisiana to assist Hurricane Katrina victims.
Board of Pharmacy Retreat	November 16, 2005	Board members and staff met at the Belmont Conference Center to revisit the organizations strategic goals.
Board of Pharmacy Recognition Ceremony	November 16, 2005	Board members and staff joined together to recognize Board past Board members at a dinner ceremony at the Belmont.
Teamwork Day	December 4, 2005	The Board staff participated in team building activity and had breakfast in honor of Teamwork Day.
Maryland Pharmacists Association	June 11, 2006	The unit had a booth and answered pharmacists questions at the Maryland Pharmacists Association in Ocean City.

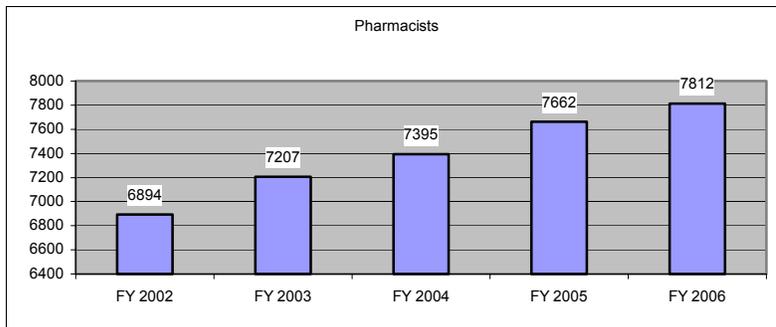
Emergency Preparedness		
	DATE	DESCRIPTION
Deployment - Hurricane Katrina	September 5, September 11 and September 17, 2005	A total of 13 volunteers deployed to Jefferson Parish, Louisiana to assist in residents in the aftermath of Hurricane Katrina.

End of Deployment	September 21, 2005	All volunteers had returned home.
Hurricane Katrina Statistics	September 5-17, 2005	According to DHMH, more than 6,200 Louisiana patients received treatment from Maryland health occupation board volunteers between September 5 and September 21.

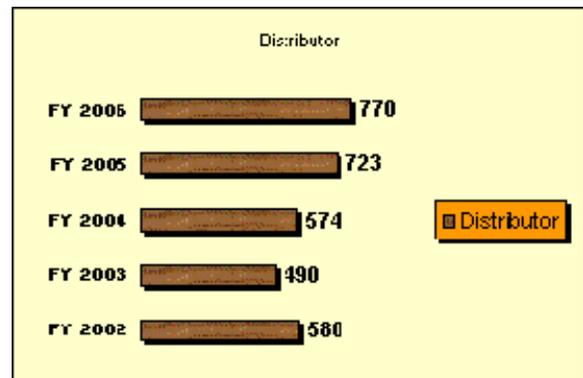
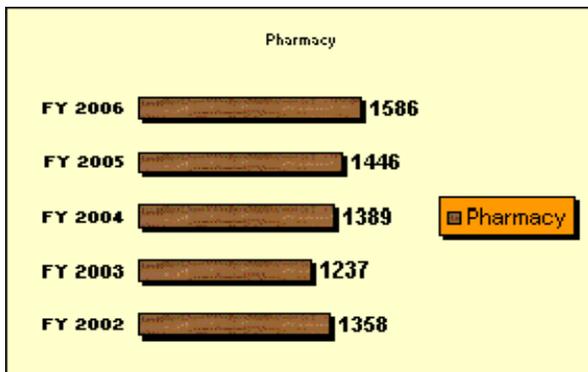
Licensing Unit Report

The Licensing unit is responsible for issuing Maryland practice licenses to qualified pharmacists, registering pharmacy technicians and issuing Maryland operating permits to qualified pharmacy owners and pharmaceutical distributors. The Unit's main goal is to protect the public by ensuring that pharmacists licensed by the Board meet credentialing requirements that are then evaluated through an accurate and timely licensure process. This will ensure high quality pharmacy services to the citizens of Maryland.

Pharmacists are licensed through examination or reciprocity and are required to renew every two years during their birth month. The number of pharmacists licensed in Maryland has increased over the past five years. There were 372 new licenses issued this fiscal year. The total number of pharmacists licensed at the end of FY 2006 was 7812.



There was also an increase in licensure of new Establishments this fiscal year with the addition of 130 new Pharmacy permits and 146 new Distributors permits.



Two new programs were assumed by the Licensing Unit during FY 2005, Administration of Influenza Vaccination and Drug Therapy Management. The first application for the Administration of Influenza Vaccination was received in April 2006. Eighteen (18) pharmacists applied for certification to administer the vaccine between April 4 and June 30, the end of FY 2006.

The Joint Committee began meeting and approved the first Drug Therapy Management Agreement and Protocol for Thrombosis, February 24, 2006. Six pharmacists and 3 physicians were approved to be included in the physician-pharmacist agreement. Two more Drug Therapy Management physician-pharmacist agreements and protocols were approved in August 2006. Both of these, Tobacco Use and Dependence; and Metabolic Syndrome, include two approved pharmacists and eight approved physicians. All three approved Drug Therapy Management agreements and protocols were submitted by various units of University of Maryland Medical Center.

In addition to the two new programs assumed by the Unit in FY 2006, the Licensing Unit assumed responsibility for the Registration of Pharmacy Technicians. Although the Board will not begin registering Pharmacy Technicians until FY 2007, much work has been done to assure that the program, when up and running, will run smoothly and efficiently. Regulations are in the final stages and policy, procedures and applications are being developed for the new program. It is estimated that the Board will register 2,000 to 5,000 pharmacy technicians within the first six months. Additional staff will be hired to operate this program. Routinely updated information will be available on the Board's website regarding the Board's progress in implementing the new program.

Pharmacy Compliance Unit Report

OVERVIEW OF THE PHARMACY COMPLIANCE UNIT AND ITS FUNCTION

The Pharmacist/Pharmacy Compliance Unit (PCU) is comprised of a Pharmacist Compliance Officer and two non-pharmacists, a Compliance Specialist and a Compliance Investigator. Due to low salary and high demand for qualified pharmacists in the market place, the Board of Pharmacy was unable to recruit a pharmacist for the Pharmacist Compliance Officer position for the year 2006. Recruitment and employment of a qualified pharmacist for the Pharmacist Compliance Officer position will be a key goal for the Board for 2007.

The Pharmacy Compliance Unit has many responsibilities, which include, but are not limited to, the following:

- ensuring that pharmacists, pharmacies and distributors continue to meet state laws and regulations;
- responding to consumer complaints;
- providing advice and assistance to legislators, inspectors, regulations coordinators, and federal, state and non-public agencies regarding compliance with pharmacy rules;

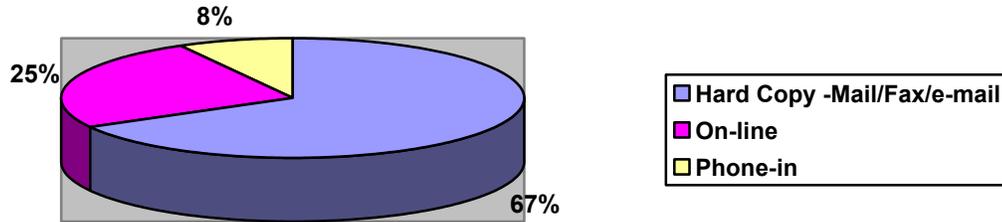
- assisting the Board in taking action against pharmacists and establishments that do not meet the minimum practice standards (or who violate specific rules designed to protect the public); and
- monitoring pharmacists who have been placed under Board orders for various violations.

The Pharmacist Compliance Unit, in conjunction with other Board Units, strives to protect Maryland consumers, and promote quality health care in the field of pharmacy by monitoring and enforcing compliance with Maryland Pharmacy Laws. For example, the Licensing Unit and PCU work together to identify and investigate pharmacies or pharmacists who fail to renew their license, as well as license/permit applicants who have been identified as having been subjects of disciplinary or criminal actions in other states. A major goal of the Compliance Unit is to implement and manage an efficient, fair and consistent compliant process that enhances the quality of care provided through licensed health care professionals and the regulated industry.

Written Complaints and Disciplinary Cases

In addition to verbal complaints (discussed on page 4), the PCU receives written complaints from consumers and other entities and is charged with addressing or investigating each complaint. A complaint form is used by the Board of Pharmacy to recognize and act upon consumer complaints. The consumer and other entities are offered three ways of completing a complaint form – entering information on a hard copy complaint form, providing the information over the phone to a compliance Investigator, or entering the information on-line at <http://www.mdbop.org/forms/complaint.htm>. The hard copy complaint form is mailed, faxed or emailed by the consumer to the Board. Sixty-seven percent of complaints filed in FY 2006 were through submission of hard copy forms (see Figure 1). Sometimes the complaint is not in the Board of Pharmacy's jurisdiction. In these cases, the consumer is provided alternative telephone numbers for other consumer protection agencies or programs based upon their concern.

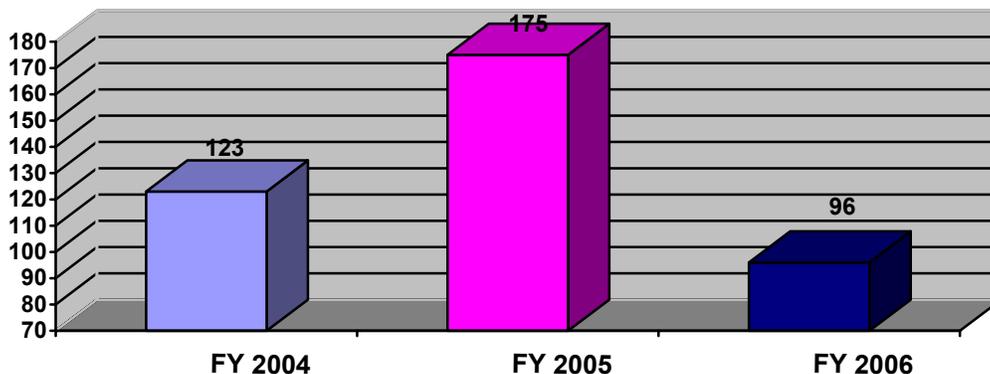
FIGURE 1. METHODS USED FOR SUBMISSION OF FORMAL COMPLAINTS FY 2006 BY CONSUMERS/ENTITIES



Once the complaint form is received, the compliance investigator initially reviews the complaint to determine if further investigation is required and enters all pertinent information into a database. In addition the compliance investigator notifies the consumer of receipt of the complaint, as well as requesting the pharmacy or pharmacist to respond to the written complaint. All information is aggregated, analyzed, and presented to the Board's Disciplinary Committee which makes recommendations such as informal actions (e.g. letters of education or admonishment) or more formal actions (e.g. such as charges or emergency suspension) to the full Board. The Board then votes on the final actions that will be taken. If the Board votes to issue formal charges, the Compliance Unit provides information gathered through interviewing witnesses and investigational findings to the Attorney General Office prosecutors.

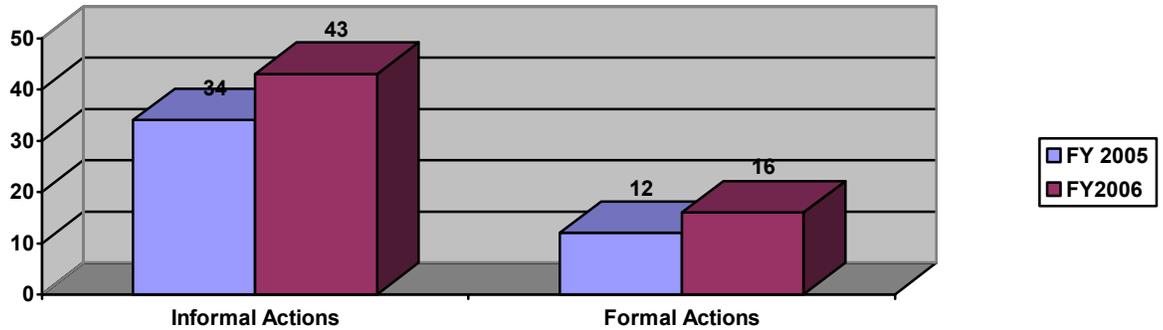
The total number of written complaints (i.e. hard copy, online, e-mail, etc.) processed over the past three years is shown in Figure 2.

**FIGURE 2. NUMBER OF WRITTEN COMPLAINTS PROCESSED BY THE PCU
FY 2004, FY 2005, AND FY 2006**



Informal actions are not subject to public review; where as formal actions are subject to public review. A comparison of the number of Board issued informal actions (e.g. letters of education, letters of admonishment) and formal actions (e.g. reinstatements, probation, revocation of license, fines, etc.) received for FY 2005 versus FY 2006 is shown in Figure 3.

FIGURE 3. NUMBER OF INFORMAL AND FORMAL ACTIONS FY 2005 VERSUS 2006



There were 96 written complaints received by the Pharmacy Compliance Unit FY 2006. The complaint categories are listed in Figure 4. The majority of complaints were classified as dispensing errors. Regulations under Chapter 10, Pharmacist Code of Conduct of the Code of Maryland Regulations (C.O.M.A.R.) are relevant to many of the issues addressed by the Compliance Unit. The types of actions taken as a result of the written complaints are listed in Figure 5 on page 4. Twenty three (23.9%) of the complaint cases were found by the Pharmacy Board to not require further action. Forty three (44.8%) required lesser informal actions such as a letters of admonishment or education. Sixteen (16.7%) required formal actions such as suspension or revocation of a license, probation or fines (see Figure 6, page 4). Fourteen (14.6%) of the cases were investigational and referrals for 2007.

**FIGURE 4. PERCENT OF WRITTEN COMPLAINTS BY CATEGORY TYPE
FY2006**

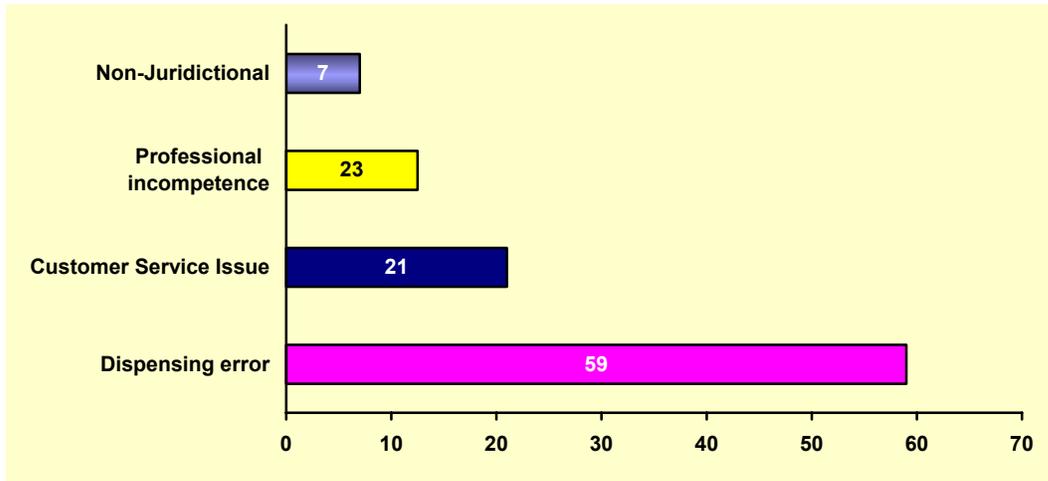
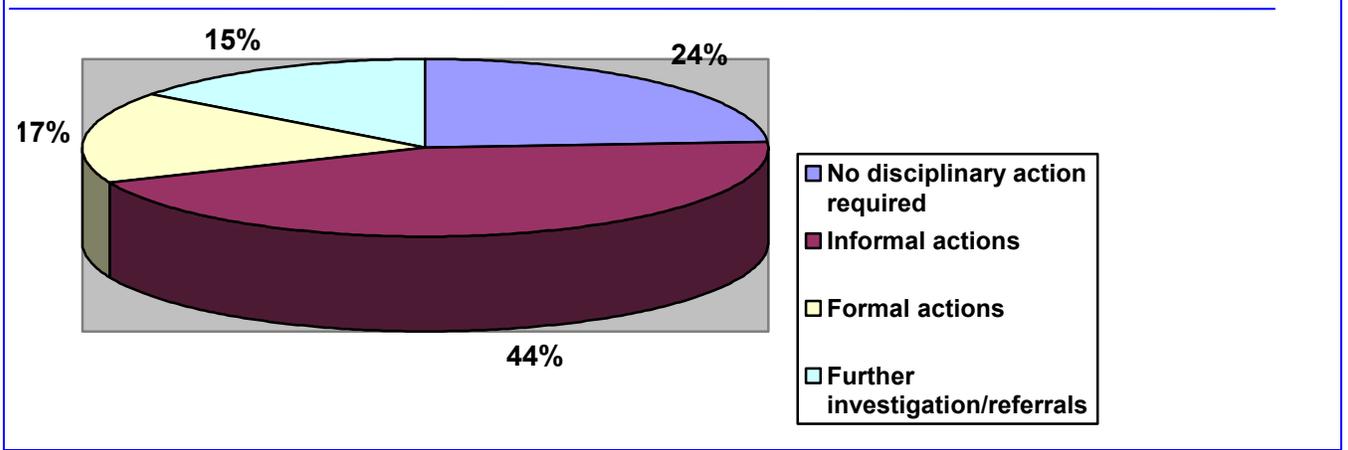
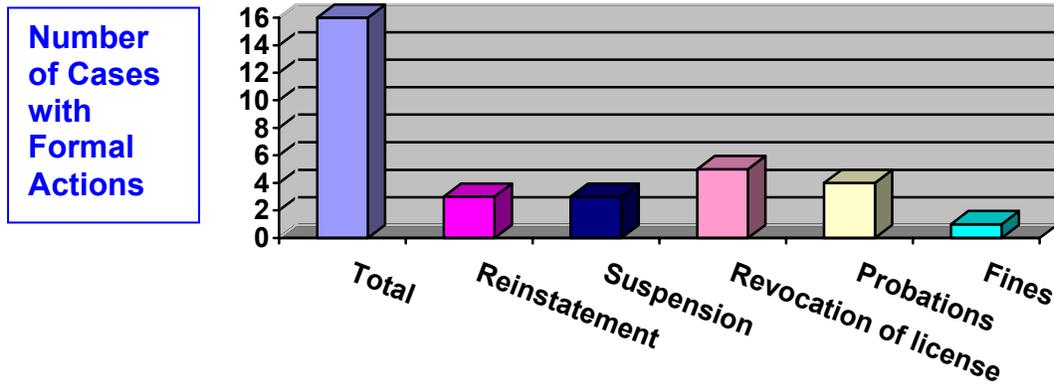


FIGURE 5. PERCENT OF WRITTEN COMPLAINTS AND GENERAL ACTIONS TAKEN BY THE BOARD FY 2006



**FIGURE 6. NUMBER OF CASES WITH FORMAL DISCIPLINARY ACTIONS
FY 2006**

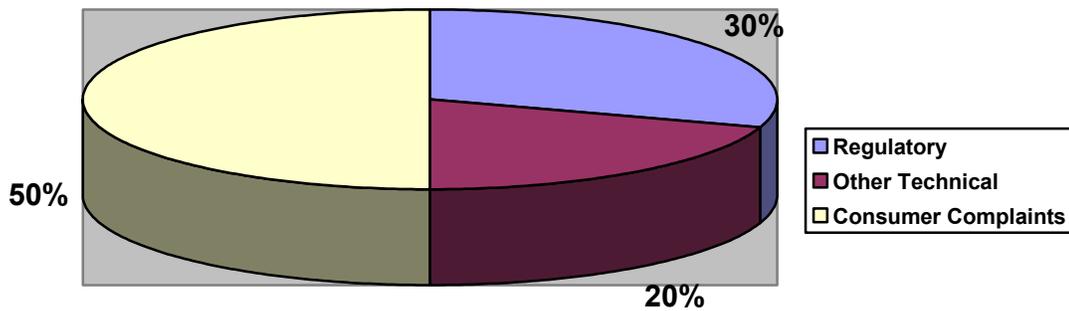


Verbal Inquiries/ Questions

The Pharmacy Compliance Units processed over 2500 calls in 2006 related to either Technical/Regulatory Questions or verbal complaints (see Figure 7). The technical/regulatory questions come from many sources including, but not limited to, the following:

- Other State Boards and National Pharmacy Board
- Other agencies (Food and Drug Administration, local jurisdiction such as police department, private agencies)
- Health Professionals (Pharmacists, physicians, other prescribers, nurses, etc.)
- Regulatory issues and questions on the Pharmacist Code of ethics
- Referrals to other agencies (Medicare Part D, 3rd party Insurance, Dispense as written codes)
- Pharmaceutical Companies (e.g. questions regarding Maryland law, what is required on the label for selected drugs, etc.)
- Consumers (e.g. identification of found medication, use of medication, educating consumer on medication safety, etc.).

FIGURE 7: PERCENT OF VERBAL INQUIRES BY GENERAL CATEGORIES FY 2006



Where appropriate some calls are referred to other agencies such as CMS, poison control center, and third party payers. Our Regulator Manager works in conjunction with the PCU to provide expertise in regulatory issues.

Most of the verbal complaints are from consumers regarding many topics such as use of generic drugs, cost or billing issues, labeling issues, use of brand drugs, concern with medication error or directions are not clear. Consumers are encouraged to complete either a hard copy or electronic complaint form or provide the details over the phone so that the Board can investigate these cases to ensure patient safety. However, many consumers elect not to complete the complain form (verbally or written) and fail to identify the pharmacy or pharmacist that has raised concerns. Complaints concerning the prices of prescriptions are referred to the Consumer Protection Division of the Office of Attorney General.

PHARMACY/DISTRIBUTOR INSPECTIONS

The Pharmacy Compliance Unit works closely with the Division of Drug Control which is the Board's agent in performing annual inspections for pharmacies and distributors. Pharmacy inspections performed by the Division of Drug Control inspectors are reported to the Pharmacy Compliance Unit and reviewed to determine compliance with pharmacy laws. The Compliance Unit considers routine pharmacy inspections important in the educational process of promoting good pharmacy practice, explaining State and federal pharmacy laws, and enforcing these laws. The majority of cases are minor infractions or non-compliance to established requirements. The Permit Holder usually immediately corrects the minor problem and no further action by the Board is required. More serious infractions may lead to further investigations, fines, and possible pharmacy closing. Working with the DCC and Federal agencies, resulted in the closure of two pharmacies FY 2006 that were involved in illegal distribution of drugs by the internet and/or by dispensing.

PHARMACISTS IMPAIRED BY SUBSTANCE ABUSE

Studies have shown that the prevalence of chemical dependency among pharmacists ranges between 10% and 18%

(<http://www.fanlight.com/downloads/Helping%20the%20Impaired%20Pharmacist.pdf>).

The National Institute on Drug Abuse also estimates that 8% to 12% of health care workers have substance abuse problems. To help address this issue the Pharmacy Practice act recognizes the existence of a Pharmacist Rehabilitation Committee, which authorizes the actions of the committee, provides protections for confidentiality of client information and good faith activities of committee members. In addition, pharmacy regulations require that pharmacists have a duty to report members of the profession who are impaired and practicing. These reports must be made directly to the committee rather than the Board of Pharmacy. The Maryland Board of Pharmacy contracts with Pharmacist Educational Assistance Committee (PEAC), a 501(C) tax-exempt organization, to provide services to impaired pharmacists of the State of Maryland. Maryland law authorizes the Board to provide funding to support the activities of the committee.

A Pharmacist using mind-altering drugs of abuse puts the general public at jeopardy. The resulting medication errors and drug misuse caused by an impaired pharmacist can have devastating consequences for the innocent victim, create liability for the employer and impact the pharmacist, his or her family and future career. Some impaired pharmacists refer themselves to PEAC. In addition, the PCU may receive reports of impaired pharmacists from a variety of other sources (e.g., other state boards, consumers, etc) which require further investigation. In that case, if an administrative process determines guilt the Board acts to protect the public by restricting the pharmacist's practice. The Compliance Unit FY 2006 focus is on Board-referred (Case under Order) impaired pharmacists. Conditions for reinstatements and petitions for modifications of terms of probation of pharmacists under contract with PEAC are reviewed by the Disciplinary Committee, which submits recommended actions to the Board.

FORECASTING AND PREPARING FOR EXPANSION OF SERVICES FOR THE PHARMACY COMPLIANCE UNIT SERVICES FOR 2007

As part of the year 2006, the Board realized the importance of recruiting a qualified and competent pharmacist to assist in several changes that will impact the Board and the Pharmacy/Pharmacist Compliance Unit. These include, but are not limited to,

- Compliance issues related to new legislation regarding pharmacy technicians
- Transition of Board Ordered Pharmacist monitoring program from PEAC to the PCU
- Transition of many of the pharmacy inspection functions from the Division of Drug Control to PCU

These changes will require additional personnel to support the following:

- Development and implementation of new policies and procedures, forms;

- Development and implementation of tracking forms and database management both for national database as well a PCU related databases;
- Development and implementation of approved training programs;
- Expansion of direct responsibility for performing pharmacy inspections, as well as distributor inspections;
- Expansion of services to monitor and investigate compliance issues related to pharmacy technicians and inspections of pharmacy and distributor establishments;
- Expansion of services to monitor and track reports from Board referred impaired pharmacists.

Legislative/ Regulations Unit Report

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, Long-Term Care, and Legislative. Special sub-committee and task forces staffed during 2006 included, USP <797> Sterile Compounding, Legibility of Prescriptions Taskforce, Drug Therapy Management and Prescription Drug Repository Program Task Force.

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 2006 the Unit responded to 753 phone calls and provided written responses to 266 email inquiries.

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 presented 61 bills out of approximately 2,856 bills to the Board of Pharmacy’s Legislative Committee for consideration. The Unit drafted position papers and/or letters to legislative committees for 21 of the 61 bills. Below is provided a chart of the 21 bills and the results:

Bill #	Bill Name	Result
HB 41 SB 774	Controlled Dangerous Substances – Pseudoephedrine Products	Both FAILED
HB 135	Prescription Drugs – Label with Audible Capability	FAILED
SB 142	Health Care Providers - Disclosures of Mental Health Records – Subpoenas	FAILED
SB 297 HB 828	Public Health – Licensed Pharmacists – Contraception Dispensing Program	FAILED
SB 333 HB 1287	Prescription Drug Monitoring Program	PASSED Governor Vetoed
SB 371 HB 492	State Board of Pharmacy – Registration of Pharmacy Technicians	PASSED
SB 450	Controlled Dangerous Substances – Dextromethorphan Products	FAILED
HB 493	Pharmacy Benefit Managers Regulation Act of 2006	FAILED
SB 516	State Government – Administrative Procedure Act – Scope of Judicial Review	FAILED
SB 568	Prescription Drugs – Canadian Mail Order Plan	FAILED
HB 626	Prescription Safety Act	FAILED
SB 624	Maryland Medical Assistance Program – Prescriptions	PASSED
HB 1098	Criminal Law – “Meth Precursors” – Restrictions on Sale and Purchase	FAILED
HB 1190	Prescription Drug Safety Act	FAILED
HB 1214	Health Care Malpractice – Emergency Medical Care – Good Samaritan Immunity	FAILED
HB 1295	Health Occupations – Cultural Competency Workgroup	FAILED
HB 1404	State Board of Pharmacy – Disciplinary Grounds – Refusal to Dispense Prescriptions	Withdrawn
HB 1459	Health Occupations – Pharmacists – Return of Unfilled Prescriptions to Retail Customers – Required	FAILED
HB 1510	Public-Private Partnership for Health Coverage for All Marylanders	FAILED
HB 1569	State Board of Pharmacy – Revocation of License – Sale of Drug Different from that Ordered	PASSED
HB 1689 SB 1059	Prescription Drug Repository Program	PASSED

Summaries of major bills from the 2006 Legislative Session are provided below.

SB 371/HB 492 - State Board of Pharmacy – Registration of Pharmacy Technicians

The bill authorized the Board of Pharmacy to regulate pharmacy technicians. It authorized a licensed pharmacist to delegate pharmacy acts to registered pharmacy technicians, pharmacy students, and pharmacy technician trainees under specified circumstances. The bill also altered the grounds for disciplinary action; altered prescription drug labeling requirements; established qualifications for pharmacy technicians, established application requirements, established continuing education requirements, and established the terms of registration for registered pharmacy technicians. In brief, to qualify for registration as a pharmacy technician, an applicant will need to submit to a criminal background check, be at least 17 years old, and either be certified by a national certification program or complete a training program and examination approved by the Board. If an applicant has worked in a pharmacy area of a pharmacy owned by the same permit holder since January 1, 2006, they may be eligible to be "grandfathered" and therefore exempt from training and examination provisions. The bill passed in both houses and became law July 1, 2006.

HB 1689/SB 1059 Prescription Drug Repository Program

The bill authorized a Prescription Drug Repository Program (the "Program") to accept, for the purpose of dispensing only, prescription drugs and medical supplies, to those in need as determined by their physician. The bill provided that any person may donate prescription drugs or medical supplies to the Program at designated drop-off sites and requiring that designated drop-off sites meet certain requirements. The bill authorized the Maryland Board of Pharmacy to approve certain pharmacies to be repositories that meet certain standards. The repositories may charge a fee, not to exceed \$10.00 for each prescription dispensed. The repository may not establish or maintain waiting lists for prescription drugs. The repository will be required to maintain records and submit reports. The bill prohibited certain persons that act in good faith from being subject to certain prosecution or liability. There is a requirement in the bill that the Board adopt regulations that include details for the operation of this Program. The Board will also be required to perform the initial inspection of drop-off sites and repositories and to inspect records. The Board will be required to submit an annual report to the Governor and the General Assembly on the operation of the Program. This bill passed and was signed into law May 2, 2006.

HB 1569 - State Board of Pharmacy – Revocation of License – Sale of Drug Different from that Ordered

This bill required the Board of Pharmacy to promulgate regulations that would provide for the reinstatement of a licensee whose license had been revoked due to a conviction of knowingly selling or delivering a certain substance without authorization under Criminal Law Article, 5-702, Annotated Code of Maryland. This bill passed and was signed into law May 2, 2006.

SB 333/HB 1287 - Prescription Drug Monitoring Program

The Prescription Drug Monitoring Program (the "Program") would have enhanced safety and provided a method for tracking individuals that may obtain multiple prescriptions from multiple providers. The legislation established an Advisory Board on Prescription Drug Monitoring to design, implement and evaluate the program. A multidisciplinary consultation team would have been appointed by the Secretary of the Department of Health and Mental Hygiene to assist in the interpretation of prescription monitoring data. The bill would have required dispensers to submit electronically certain information to the Program except in certain circumstances. It would have made prescription monitoring data confidential and privileged and not subject to certain means of legal compulsion except under certain circumstances. It would have authorized certain agencies and persons to obtain access to prescription monitoring data under certain circumstances and would have established immunity from civil liability for certain agencies and persons relating to the operation and use of the Program. The bill further provided for education and training relating to the Program and would have established penalties for violations of the requirements of the Program. The implementation of the program was contingent on the Advisory Board obtaining certain federal grant money. The bill passed both houses, but was vetoed by the Governor.

HB 1190 - Prescription Drug Safety Act

The purpose of this legislation was to deter diversion and drug counterfeiting. This bill required a wholesale distributor of prescription drugs to hold a license issued by the Board before the wholesale distributor engaged in the wholesale distribution of prescription drugs in the Maryland. The bill authorized the Board to exempt a U.S. Food and Drug Administration licensed drug manufacturer from these licensing requirements. The bill also established pedigree requirements for the wholesale distribution of prescription drugs and required the Board to study electronic pedigrees and other advanced tracking technologies. The bill did not go to vote in the House Health and Government Operation Committee.

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 - .32, revisions effective since July 1, 2005.

COMAR Citation	Title	Effective Date
10.34.32	Pharmacist Administration of Influenza Vaccination	April 24, 2006

Maryland Board of Pharmacy Regulations, COMAR 10.34.01 - .34, currently in the amendment process

COMAR Citation	Title	Proposal status
10.34.01	Reinstatement	Proposed regulation will be promulgated pursuant

		to HB 1569 - State Board of Pharmacy – Revocation of License – Sale of Drug Different from that Ordered, 2006.
10.34.19	Parenteral/Sterile Enteral Compounding	Practice Committee reviewing the proposed revisions recommended by the USP 797 Task Force for Board approval Summer 2006.
10.34.22	Licensing of Wholesale Prescription Drug or Device Distributors	Proposal revisions under consideration.
10.34.23	Pharmaceutical Services to Residents in Long-Term Care Facilities	Published August 6, 2004 and withdrawn December 23, 2005 by operation of law. Proposal revisions under consideration.
10.34.32	Pharmacist Administration of Influenza Vaccinations	Amendment to add fee for pharmacist administration. Approved by the Board of Pharmacy June 21, 2006. Approval by the Board of Nursing and the Maryland Board of Physicians anticipated in July 2006. Will begin the promulgation process Summer 2006.
10.34.33	Prescription Drug Repository Program	Approved by the Board of Pharmacy June 21, 2006. Will begin the promulgation process Summer 2006.
10.34.34	Pharmacy Technicians	Board Subcommittee drafting regulations during scheduled meetings in the Summer of 2006. Board approval anticipated in late summer.
Special Notice	Negative Formulary	The Board of Pharmacy approved language for the Department of Health and Mental Hygiene's recommendation to reinstate the drugs listed on the negative formulary to the FDA's Orange Book of Generic Equivalents.

Summaries of regulatory changes that became effective in 2006 are provided below.

10.34.32 Pharmacist Administration of Influenza Vaccination

The purpose of this action was to adopt regulations to allow pharmacists to administer an influenza vaccination to an individual. The regulations were jointly promulgated by the Board of Pharmacy, Board of Nursing and the Maryland Board of Physicians. An interested licensed Maryland pharmacist will register with the Board after completing appropriate training and obtaining a signed protocol from a licensed Maryland physician.

Management & Information Services (MIS)

The Management & Information Services Unit (MIS) works behind the scenes to provide support for all the Board Units. It is the role of MIS to look at new ways to provide fast and efficient services to Board Units, so they can do their jobs more effectively; Members of Board, who balance their own careers, in addition to taking on the responsibility of providing guidance to the Board in protecting the citizens of Maryland; and to our stakeholders, other Government agencies that the Board collaborates with to resolve a myriad of complex issues. MIS provides statistics, researches historical events, maintains several different systems internal and online that support all daily activities.

It is easy to imagine how MIS supports the Licensing Unit with licensure databases, electronic examination scores, and many services on the Board's web site, such as, downloadable applications, examination scores and verification of licensure. Also behind the scenes, is the services provided to the other units of the Board. In FY2006, MIS introduced several new systems for the Board's "other" Units.

In FY2006, The Legislation and Regulations Unit (the "Unit") was very busy. With 61 bills to process for consideration by the Board, the unit was inundated with inquiries, drafting position papers and tracking the status. The "Unit" requested from MIS a tracking mechanism for inquiries, and 750 telephone calls later, the Legislative/Regulations Unit's 'Leg-Reg Log' database was created for tracking telephone calls and recording responses. Through this database, not only can the "Unit" provide uniform responses but it can also be used to track trends, and clarify certain aspects of the law in our newsletter, on the Board's web site, or through other means. No telephone call is insignificant, from the 1 call regarding Childproof Caps to several calls on the list below.

Sample calls recorded in the Leg/Reg Database in FY2006:

Topic	Number of Calls
CII Guidelines	13
Wholesale Distributors	11
Electronic Prescriptions	8
Pharmacy Technicians	7
Automation & labels	7
Preprinted Rx Pads	6
etc.....	

The same is true for the Compliance Unit, which has a database of disciplinary cases, and uses scanning technology for creating electronic versions of all Final Orders. The Final Orders are accessible on the Board's network by the Licensing Unit and Compliance Staff as necessary to manage disciplinary cases. Want to know how many Medication

Errors occurred at a particular location, the Compliance Unit has begun tracking this through the use of database technology.

In FY2006 the MIS Unit provided support to the Fiscal & Public Relations Unit by printing newsletter labels, and performing mail merges for other notifications. MIS purchased PC equipment specific to the Public Relations Officer, so that she may produce different publications in-house, and significantly reduce the costs of printing other publications such as this Annual Report. MIS provided support for Emergency Preparedness functions, by assisting with the University of Maryland, School of Pharmacy's creation of a login system for the online Emergency Volunteer Continuing Education program. MIS maintains Cash/Mail logs used by the Fiscal Unit for all revenues and assists in preparing reconciliation reports. It is also possible to determine when any piece of mail is received at the Board and track all communication with the Board.

MIS is on call 24 hours to support any Board system or function. We hope to soon fill the Board's Database Specialist position vacated in April 2006 so that we may continue to provide new systems for storing and retrieving important information that helps to complete the overall goal of protecting the citizen of Maryland through regulation of the practice of pharmacy.

Information Services

Log on the Board's web site at: www.mdbop.org

The Board provides information on a wide variety of activities it conducts, including:

- Pharmacists, pharmacies, and distributors licensed by the State of Maryland
- Board meeting schedules, minutes and newsletter
- Pharmacy Board applications (some may be submitted on-line)
- Links to pharmacy assistance and other health organizations
- Report and review information on missing or stolen prescription pads
- Pharmacy store openings and closings
- Summaries of committee activity
- Consumer educational information
- Proposed regulations and legislation
- Forms to file complaints, and
- Opportunities to e-mail the Board

Nothing will replace the customer services provided when the Board is visited in person, or is called on the telephone. However, as new opportunities in Internet services arise, online services offered by the Board for the convenience of the consumer, the Board's licensees and permit holders will also expand.



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