## **Legal Division**

#### **FY2006 SIGNIFICANT ACCOMPLISHMENTS**

- 1. Division staff accomplished all of the Division's Objectives for FY2006.
- 2. During FY2006, the agency continued the initial registration process for all pharmacy technicians and began handling the large number of ongoing disciplinary issues for pharmacy technicians. The Division handled numerous disciplinary cases against the pharmacy technicians who were found to have had a criminal history, who falsified the registration application, or who had some other ground for disciplinary action. The Division initiated 399 disciplinary actions by mailing a Preliminary Notice Letter and entered 268 orders against pharmacy technicians during the fiscal year.
- 3. TSBP continued with the significantly increased number of disciplinary orders in FY2006 over fiscal years prior to the registration of pharmacy technicians, based in large part on the additional cases against pharmacy technicians but also on an increase in cases against pharmacists and pharmacies. The Division entered 207 disciplinary actions against pharmacists and pharmacies and 268 against pharmacy technicians, for a total of 475 disciplinary actions.
- 4. 100% of the disciplinary cases against pharmacists and pharmacies and 99% of the cases against pharmacy technicians were settled through the entry of Agreed Board Orders, which resulted in significant efficiencies, both in terms of complaint resolution time and expenditures.
- 5. The Division initiated more disciplinary actions by mailing Preliminary Notice Letters (PNL) in FY2006 than any prior fiscal year. The Division mailed a total of 654 PNLs, as compared to 618 in FY2005 and the previous record of 652 in FY2004, with 255 PNLS mailed to pharmacists and pharmacies and 399 PNLs mailed to pharmacy technicians. The number of days to mail all PNLs after the case review date, which was 50 days in FY2006, as compared to 37 days in FY2005, fell slightly due largely to the increased complexity of pharmacy technician PNLs and the increased number of pharmacist and pharmacy PNLs, which are inherently more complex.
- 6. The Division conducted a total of 33 days of Informal Conferences for both pharmacists and pharmacies and for pharmacy technicians in FY2006, an increase in number of days from 30 days in FY2005. This large number of Informal Conference days allowed the Division to resolve a large number of disciplinary cases.
- 7. The Division resolved nine cases that were set for administrative hearings at the State Office of Administrative Hearings (SOAH) prior to proceeding to hearing. The cases were resolved through Agreed Board Orders (ABO) through negotiations with the licensees or their attorneys or through the SOAH Mediation process. These resolutions saved the agency considerable resources both in time and expenditures.

8. Four administrative hearings were conducted at SOAH. These hearings involved preparing motions for summary judgment and numerous discovery documents (including interrogatories and requests for admission), preparing for trial and for witness examination, and conducting the hearings. Following the hearings, exceptions were filed and drafts of proposed orders were prepared. The extensive preparation for the hearings and the presentations to the Board required a considerable amount of time, and even with the increase in the number of hearings, the Division was able to maintain a fairly consistent number of cases resolved.

#### PHARMACISTS/PHARMACIES

FISCA L YEAR	NUMBER OF BOARD ORDERS (BOs)	NUMBER OF DEFAULT ORDERS ENTERED BY BOARD	NUMBER OF AGREED BOARD ORDERS (ABOs)	NUMBER OF DISCIPLINAR Y ORDERS (BOs & ABOs)	% CHANGE IN DISCIPLINARY ORDERS	% ABOs OR DEFAULT OF TOTAL ORDERS
FY02	2	0	179	181	25%	99%
FY03	4	0	209	213	17%	98%
FY04	6	0	229	235	10%	98%
FY05	2	5	165	172	-27%	99%
FY06	0	1	206	207	20%	100%
TOTAL	14	6	988	1008	14% OVER 5 YRS.	5 YR. AVG. 99%

#### PHARMACY TECHNICIANS

FISCAL YEAR	NUMBER OF BOARD ORDERS (BOs)	NUMBER OF DEFAULT BOARD ORDERS (BOs)	NUMBER OF AGREED BOARD ORDERS (ABOs)	NUMBER OF DISCIPLINARY ORDERS (BOs & ABOs)	% INCREASE IN DISCIPLINARY ORDERS	% ABOs OR DEFAULT OF TOTAL ORDERS
FY04	0	0	234	234	N/A	100%
FY05	3	0	377	380	62%	99.2%
FY06	4	34	230	268	-29%	98.5%
TOTAL	7	34	841	882	N/A	99.2%

9. General Counsel played an integral role in the coordination and development of the agency's response to Hurricanes Katrina and Rita, in developing the emergency procedures to be used for temporary licensing, developing advisory information on closing of pharmacies in evacuated areas, and disseminating information to licensees and the public.

#### FY2006 SIGNIFICANT DISAPPOINTMENTS/CONSTRAINTS

1. The number of days to resolve a case increased in FY2006 due, in part, to the loss of an attorney approximately one-half way through the year. In addition, the cases against pharmacy technicians became more complicated as the cases began to involve not merely adjudicated criminal offenses, but also cases involving more complicated investigations by TSBP of thefts at pharmacies, which ultimately led to a longer resolution time in the Legal Division due to the longer amount of time to draft and prepare the cases.

#### **FY2006 ANNUAL REPORT**

#### **GOAL**

To prosecute violations of the laws and rules related to the practice of pharmacy. To provide adjudicative information to agency customers. To provide legal services and guidance to the Board and the agency staff relating to the regulation of the practice of pharmacy and the administration of the agency.

## **Objectives (New)**

1. To assist the Executive Director, in cooperation with other Divisions, in updating and preparing the TSBP *Strategic Plan* for the 2007-2011 period, and submitting the plan to the Governor's Office of Budget, Planning, and Policy and the Legislative Budget Board by the due date.

Status: ACCOMPLISHED

**Comment:** At the meeting on November 1-2, 2005, the Board reviewed comments

concerning strategic planning by TSBP from persons who had submitted comments. General Counsel assisted in the review and preparation of the final draft of the TSBP *Strategic Plan*, which was approved by the Board at its meeting, held on May 9-10, 2006. The TSBP *Strategic Plan* was published and delivered to the Governor's office and other applicable agencies by the due date.

2. To assist the Executive Director, in cooperation with other Divisions, in the preparation of the TSBP Legislative Appropriation Request and corresponding performance measures for the FY2008-2009 biennium by the due date.

Status: ACCOMPLISHED

**Comment:** General Counsel assisted the Executive Director and Director of Administrative

Services and Licensing in the preparation of the proposed budget for FY2008-2009, attended a budget meeting with the TSBP Executive Committee on March 29, 2005, and reviewed the final draft of the document, which was subsequently submitted to the Governor and the LBB by the due date. The agency's first budget hearing with the staff of the Governor's Office and Legislative Budget

Board was held on August 21, 2006.

3. To assist the Executive Director, in cooperation with other Divisions, in implementation of the new program to register and regulate pharmacy technician trainees throughout FY2006.

Status: ACCOMPLISHED

#### Comment:

General Counsel participated in meetings with the Executive Director and other Division Directors regarding proposed rules to implement the technician trainee program, which included the following four primary concepts: (1) registration would be on-line at no charge; (2) no person would be able to perform technician duties after the deadline (February 1, 2007), without first obtaining a registration from TSBP; (3) a two-year registration would be issued and would not be renewable; and (4) applicants for registration would be required to submit fingerprint information (and be responsible for all associated costs). General Counsel reviewed and assisted with development of the associated proposed rules.

At its meeting held on February 7-8, 2006, the Board voted to approve the proposed rules as drafted by Board staff, including the four concepts described above. On May 9, 2006, the Board held a public hearing on the proposed rules. On May 9-10, 2006, the Board discussed the proposed rules and comments made at the public hearing regarding the proposed rules. On May 10, 2006, the Board voted to adopt the proposed rules with the four concepts described above.

General Counsel has also participated in several meetings to assist with the development of the computer programming changes that were needed to implement the technician trainee registration program. The process of registering technician trainees will begin in FY2007.

4. To assist the Executive Director, in cooperation with other Divisions, in reviewing and implementing legislation passed by the 79th Legislature that affects agency operations and/or the practice of pharmacy throughout FY2006.

Status: ACCOMPLISHED

**Comment:** Actions taken by the 79th Texas Legislature that had an impact on the Enforcement Division are described below:

- A. During the 79th Legislative Session, the Board was authorized to conduct Temporary Suspension hearings before a three-member panel of Board Members to determine whether a licensee/registration should be temporarily suspended or restricted based on a continuing threat to the public welfare. General Counsel developed policies and procedures for convening the disciplinary panel and a protocol for conducting the hearing. Temporary Suspension hearings were held for two pharmacists in FY2006 based on allegations of impairment while working as a pharmacist. Both cases resulted in the temporary suspension of the licenses, and were ultimately settled with an ABO for an indefinite suspension for a minimum of one year, without the necessity of taking the case before the State Office of Administrative Hearings for a contested case hearing.
- B. The 79th Legislature required that the Board adopt a schedule of administrative penalties applicable to disciplinary sanctions. General Counsel developed an administrative penalty matrix for regulatory violations applicable to pharmacists, pharmacies, and pharmacy technicians, which was translated into administrative rules by the Division of Professional Services and approved by the Board in FY2006.

- C. General Counsel developed procedures to be used for implementing the additional disciplinary sanctions authorized for pharmacy technicians by the 79th Legislature.
- D. General Counsel participated in Pharmacy Compounding Task Force meeting on July 7, 2006, and assisted with development of rules to implement compounding provisions passed by the 79th Legislature in S.B. 492.
- E. In order to implement confidentiality provisions of S.B. 410 relating to personal licensee/registrant information, General Counsel removed certain information contained in agreed board orders and developed new application forms for reinstatement and relicensure.
- F. General Counsel requested an opinion in Fy2005 whether federal law preempted the implementation of sections of S.B. 410 regarding authorization by the board for certain Canadian pharmacies to dispense drugs to Texas residents. The opinion was issued on December 21, 2005, concluding that the Board would violate federal law by "designating" certain Canadian pharmacies, promoting them on its website, and expressly permitting Texas consumers to import prescription drugs that cannot be imported under federal law.
- 5. To assist the Executive Director, in cooperation with other Divisions, in the orientation of new Board Members within 90 days of appointment by the Governor.

Status: ACCOMPLISHED

Comment: On August 10, 2006, the Governor announced the appointment of two new Board Members (Jeanne Waggener, R.Ph., community pharmacist from Bellmead, Texas, and Alice Mendoza, R.Ph., hospital pharmacist from Kingsville, Texas) and the reappointment of Rosemary Combs, public member from El Paso, Texas. After immediate consultation with the new Board members and their approval, the Executive Director scheduled dates for the orientation (September 26-27, 2006). Although the orientation will occur within 60 days of the Governor's appointments, the orientation process will not be completed until FY2007.

## **Objectives (Ongoing)**

1. To coordinate and monitor throughout FY2006 the receipt, assignment, and resolution of all cases accepted by the Division.

Status: ACCOMPLISHED

**Comment:** This objective was accomplished through the following activities:

A. Division staff met approximately once a month to discuss the status of pending cases, to assess workload allocation, and determine the most effective strategies to complete cases in a timely and efficient manner.

- B. Division staff maintained a database system to track the current status of all cases, which has increased efficiency in monitoring cases.
- C. TSBP entered a total of 475 disciplinary orders in FY2006, as reflected in the charts below.

Type of Order	Summary Suspensio ns	SOAH Board Orders	Default Board Orders	ABOs Entered by ED	ABOs Public	ABOs Confidential	Total Number of Orders
Pharmacists and Pharmacies	4	0	1	34	116	52	207
Pharmacy Technicians	0	4	34	118	112	0	268
Total	4	4	35	152	228	52	475

The Division prepared for the presentation of Agreed Board Orders and Board Orders for approval at the four regularly scheduled Board meetings throughout the year.

Information regarding the disciplinary cases entered in FY2006 is set forth in the following charts:

# DISCIPLINARY ORDERS ON PHARMACISTS AND PHARMACIES (FY2006) NATURE OF VIOLATIONS\*

<u></u>	Pharm	ooiete	Dharn	nacies	Total	Total %
Diversion	9	acisis	2	liacies	10tai 11	<i>7</i> % 5%
Unauthorized Dispensing	9	0	2	0	0	J /0
of C/S and/or D/D		6		2	8	
Theft of C/S		2		0	2	
Obtained C/S by		2		U	2	
Fraud		1		0	1	
No Valid Dr-Pt Relationship (Internet)		0		0	0	
Convictions	14		0		14	7%
Felony		1		0	1	
Misdemeanor		4		0	4	
Deferred Adjudication, Felony		7		0	7	
Alcohol-Related		2		0	2	
Audit Discrepancies	14		8		22	11%
Drug		4		8	12	
Continuing Education		10		0	10	
Practice Deficiencies	17		17		34	16%
Dispensing Errors		6		8	14	
Dispensing Errors and No Counsel		10		8	18	
and/or No Drug Regimen Review						
No Counsel and/or DRR		1		1	2	
Unprofessional Conduct	77		35		112	54%
Aiding and Abetting Allow Tech to Practice w/Delinquent		0		1	1	
Registration Supervising Sterile Compounding w/o		19		19	38	
Proper Training		1		1	2	
Falsified Application for Licensure		10		12	22	
Possession of Samples		1		1	2	
Insurance Fraud		1		1	2	
Probable Cause/Chemical Dependency		9		0	9	
Action by Other Boards		8		0	8	
Non-Compliance with Previously Entered Order		28		0	28	
Other	13		1		14	7%
Modification		8		1	9	
Reinstatement		5		0	5	
TOTAL FY06:	144		63		207	

<sup>\*</sup> BOs/ABOs may contain more than one type of violation. The identified violation was selected as the primary violation.

## SANCTIONS IMPOSED BY THE ENTRY OF DISCIPLINARY ORDERS ON PHARMACISTS AND PHARMACIES (FY2006)

	Pharmacist	Pharmacy	Total		(%)
License Removed				16	8%
Revoke	13	2	15		• 70
Retire	1	0	1		
Suspensions				51	25%
Suspension	6	0	6		
Suspension with Conditions	16	0	17		
Suspension/Fine	2	0	2		
Suspension/Probation	1	1	2		
Suspension/Probation/Conditions	8	0	7		
Suspension/Probation/Fine	2	4	6		
Suspension/Probation and Fine w/Conditions	7	5	11		
Restrictions	4	0		4	2%
Other				98	47%
Fine	31	4	35		
Fine with Conditions	10	21	32		
Fine and Reprimand	2	0	2		
Fine, Reprimand with Conditions	8	9	17		
Reprimand	4	0	4		
Reprimand with Conditions	4	4	8		
Issuance License/Regist.				24	11%
Grant with Suspension	0	0	0		
Grant with Probation	3	0	3		
Grant with Probation and Conditions	1	0	1		
Grant with Reprimand	2	0	2		
Grant with Fine	6	12	18		
Deny	0	0	0		
Reinstatements				5	2%
Grant	0	0	0		
Grant with Probation/Conditions	5	0	5		
Deny	0	0	0		
Modifications				9	5%
Grant	8	1	9	-	
Deny	0	0	0		
TOTAL FY06:	144	63		207	

## VIOLATIONS IN DISCIPLINARY ORDERS ON PHARMACY TECHNICIANS (FY2006)

	Pharmacy Technician	Total	(%)
Gross Immorality		17	6
Immoral conduct	0		
with falsified application	0		
Engaging in felony	12		
with falsified application	4		
Engaging in sexually			
deviant behavior	1		
with falsified application			
Falsification		49	18
Conviction		91	34
Misdemeanor	53		
with falsified application	15		
Felony	16		
with falsified application	7		
Drug or Alcohol			
Dependency		26	10
Drug or Alcohol Dependency	20		
with falsified application	6		
Violation of Drug Laws		65	24
Misdemeanor	30		
with falsified application	3		
Felony	28		
with falsified application	4		
Delinquent License		17	6
Violation of Rehab ABOs		3	1
TOTAL FY06:		268	

## SANCTIONS IMPOSED BY THE ENTRY OF DISCIPLINARY ORDERS ON PHARMACY TECHNICIANS (FY2006)

	Pharmacy Technician	Total (%)
License Removed		31 12%
Revoke	31	
Retire	0	
Suspensions		35 13%
Suspension	12	
Suspension with Conditions	1	
Suspension/Fine	0	
Suspension/Fine with Cond	litions 0	
Suspension/Probation	10	
Suspension/Probation/Fine	0	
Probation	12	
Probation/Fine	0	
Restrictions	0	0 0%
Other		40 15%
Fine	40	
Fine with Conditions	0	
Reprimand	0	
Reprimand with Conditions	0	
Fine/Reprimand	0	
Fine/Reprimand with Condi	ions 0	
Issuance License/Regist.		162 60%
Grant with Suspension	70	
Grant with Suspension/Pro	pation 19	
Grant with Probation	49	
Grant with Fine	20	
Grant with Reprimand	0	
Deny	4	
Reinstatements		0 0%
Grant with Probation	0	
Deny	0	
Modifications		0 0%
Grant	0	
Deny	0	
TOTAL FY06:		268

2. To review all cases referred to the Division for potential disciplinary action; and if sufficient evidence exists to warrant action, to institute disciplinary proceedings against licensees within an average of 150 days of the date of the receipt of the case, in accordance with priorities established for the Enforcement Division, throughout FY2006.

Status: ACCOMPLISHED

**Comment:** This objective was accomplished through the following activities:

- A. During FY2006, Division staff participated in 20 case and/or complaint review meetings. These meetings were held approximately twice per month with participation by the Executive Director and Legal and Enforcement Division staff.
- B. Division Staff mailed a record high number of 654 Preliminary Notice Letters (PNLs) in FY2006, in accordance with the priorities established for the Division, as compared to FY2005, when the Division mailed 618 PNLs. Of these PNLs, 255 PNLs were mailed to pharmacists and pharmacies, and 399 PNLs were mailed to pharmacy technicians.
- C. The number of days to mail PNLs after the case review date in FY2006 was 50 days which is a slight increase from the FY2004 number of 37 days. This increase is due to the increase in the number of days for pharmacy technician PNLs (as noted below) and was caused by increased complexity in the pharmacy technician cases.

The number of days for PNLs to be sent to pharmacists and pharmacies averaged 69 days as compared to 82 days in FY2005. PNLs to pharmacy technicians were sent in an average of 37 days from receipt of the case, as compared to 16 days in FY2005.

- D. Total resolution time for cases in FY2006 was 136 days from receipt of the case in the Legal Division to the entry of an Agreed Board Order, which is slightly higher that last year's number of 113 days. Case resolution for pharmacists and pharmacies averaged 186 days, down significantly from 223 days in FY2005, and for pharmacy technicians averaged 100 days, up from 73 days in FY2005.
- E. During the 79th Legislative Session, the Board was authorized to conduct Temporary Suspension hearings before a three-member panel of Board Members to determine whether a licensee/registration should be temporarily suspended or restricted based on a continuing threat to the public welfare. The Division conducted Temporary Suspension hearings for two pharmacists in FY2006 based on allegations of impairment while working as a pharmacist. Both cases resulted in the temporary suspension of the licenses, and were ultimately settled with an ABO for an indefinite suspension for a minimum of one year, without the necessity of taking the case before the State Office of Administrative Hearings for a contested case hearing.

3. To plan and conduct a minimum of 15 days of informal conference sessions in FY2006 to adjudicate violators of pharmacy laws/rules.

Status: ACCOMPLISHED

**Comment:** During FY2006, the Division prepared for 33 days of Informal Conferences for

402 licensees/registrants, as indicated in the following charts. The number of conference days and the number of licensees/registrants increased in FY2006,

from 30 days and 293 licensees/registrants in FY2005.

#### **Informal Conferences for Pharmacies and Pharmacists**

Dates of Informal	# of Days	# of Phy/RPh	# of	# of	# of Licensees
Conferences	-	Licensees	Techs	Cases	Dismissed
9/6-8/05	3	19	6	22	3
10/17-19/2005	3	25	4	21	3
1/10-12/2006	3	29	4	26	4
2/28/2006-3/2/2006	3	27	9	24	2
4/4-6/2006	3	23	5	27	0
6/20-22/2006	3	28	7	23	5
7/11-13/2006	3	26	1	22	4
TOTAL FY2006	21	177	36	165	21

#### **Informal Conferences for Technicians**

Dates of Informal	# of Days	# of Cases	Applicants	Registrants	No-show	Defaults on
Conferences					<b>Applicants</b>	Registrants
9/13/2005	1	18	13	0	5	0
10/24/2005	1	16	12	0	4	0
11/22/2005	1	12	7	1	4	0
12/13/2005	1	9	7	0	2	0
1/26/2006	1	16	13	0	1	2
2/23/2006	1	15	8	2	3	2
3/23/2006	1	11	2	0	5	4
4/19/2006	1	15	5	3	3	4
5/3/2006	1	18	7	5	1	5
6/8/2006	1	17	2	4	4	7
7/18/2006	1	24	12	6	2	4
8/24/2006	1	18	4	8	4	2
TOTAL FY2006	12	189	92	29	38	30

4. To refer disciplinary cases to the State Office of Administrative Hearings (SOAH) throughout FY2006, and file a complaint with SOAH within an average of 120 days of the date that the agency determines the case cannot be settled with an Agreed Board Order.

Status: ACCOMPLISHED

**Comment:** This objective was accomplished through the following activities:

- A. At the onset of FY2006, six cases were either ongoing or pending the filing of a complaint at the State Office of Administrative Hearings. The Division filed formal Complaints at SOAH, within 120 days that the case failed to settle with an Agreed Board Order, for seven additional cases in FY2006.
- B. Nine cases were resolved prior to a full contested administrative hearing being conducted at SOAH. This resolution was beneficial in saving the agency both considerable time and effort in the alternative of preparing for and presenting a full contested case hearing. However, considerable preparation was required for several of the cases because they were not resolved until shortly before the scheduled hearing date.
- C. Four administrative hearings were conducted in FY2006. Five Proposals for Decision (PFD) were issued by the Administrative Law Judges during FY2006, for two hearings conducted in FY2005 and for two hearing conducted in FY2006. In each case, the Board essentially adopted the recommendations in the PFDs by Board Order. One PFD had been received by the end of FY2006 but still required the entry of a Board Order, and one case was anticipating the return of a PFD at the end of FY2006.
- D. SOAH performed 147.15 hours of work on 13 cases for the TSBP in FY2006, totaling approximately \$10,447.96 in direct hearings expenses and \$18,364.71 in total case expenses. These SOAH hours are consistent with the 152.15 hours of work in FY2005.
- 5. To research legal issues and provide legal services and advice to the Board and agency staff; to provide legal services to the Enforcement and Administrative Services and Licensing Divisions regarding interpretation of the laws and rules and to the Division of Professional Services in the development of agency rules and publication of newsletters.

Status: ACCOMPLISHED

- A. Legal Research and Advice on Agency Administration
  - (1) General Counsel reviewed the following for legal sufficiency and effectiveness:
    - (a) Policy and Procedures for Board Members;
    - (b) Interagency Contract with Department of Information Resources;
    - (c) TSBP Employee Handbook;

- (d) Memorandum of Understanding with the Department of Information Resources regarding Austin Disaster Recovery Operations Center;
- (e) Amended Agreement with Northrup Grumman; and
- (f) Supplemental Agreement with Laserlink and the Texas Medical Board for imaging services to include TSBP.
- (2) General Counsel served as Fraud Coordinator and responded to Fraud Survey for the Governor's office.
- (3) General Counsel participated in meetings and provided recommendations in the development of the agency's Risk Management plan.
- (4) General Counsel provided legal advice and consultation on numerous personnel issues during FY2006, including:
  - (a) coordinated and provided recommendations on actions for violations of employment policies and procedures;
  - (b) assisted with issues in various hiring/disciplinary processes;
  - (c) drafted HIPAA release for employee medical information; and
  - (d) interviewed applicants for new positions.
- (5) General Counsel, as part of the management team, participated in meetings to develop implementation of recommendations made by the Agency Change Team and to plan teambuilding seminar for staff.
- (6) General Counsel continued to serve as the agency's Ethics Advisor and continued to assist Board Members and staff with legal and ethical issues.
- B. Technical Assistance to Enforcement Activities
  - (1) Division staff researched numerous issues, including the following issues:
    - (a) Crimes of moral turpitude;
    - (b) Legality of automated prescription delivery devices;
    - (c) Expiration of requirement to register as a sex offender;
    - (d) Applicability of law to applicants;
    - (e) Effect of expunction order on admissibility of evidence;

- (f) Application of retroactive laws and vested rights;
- (g) Requirements for reimbursement to licensees for samples of compounded pharmaceuticals collected by the Board staff during inspections; and
- (h) Securities Exchange Commission procedures for criminal background checks on officers of publicly held corporations.
- (2) General Counsel attended quarterly meetings of Compliance staff and Investigative staff to provide legal guidance on inspection and investigative issues including obtaining evidence and issuing subpoenas.
- (3) Division staff drafted numerous subpoenas to assist with the investigative work of the TSBP investigators.
- (4) Division staff handled numerous legal questions from all staff regarding a myriad of issues.
- (5) General Counsel reviewed numerous complaint files for pharmacists and pharmacies and provided guidance regarding the identification of violations and the resolution of the cases. In addition, General Counsel reviewed numerous complaint files on pharmacy technicians to determine type of violation and appropriate action, as previously determined by the Board.
- (6) Division staff made presentations at all Board meetings held in FY2006. Presentations included information about proposed Agreed Board Orders and proposed Board Orders following SOAH proceedings.
- (7) General Counsel assisted in the review and preparation of minutes of four regularly-scheduled Board meetings and an additional Board meeting.
- (8) Division staff informed the Director of Enforcement of disciplinary actions to be taken by the Board prior to entry of the orders, to ensure the correct information is immediately available on the computer system.
- (9) Division staff assisted the Enforcement Division with issues involving the monitoring of impaired pharmacists, including legal consultation on handling of positive drug screens and interfacing with the PRN program.
- (10) Division staff updated the Disciplinary Index to all actions taken by TSBP on a quarterly basis following each Board meeting.
- (11) Division staff handled response to expunction orders received for criminal convictions on pharmacists.

(12) Division staff participated in a meeting with representatives of the drug screening company used for TSBP licensees and registrants to develop new procedures for drug screening.

### C. Legal Services for Professional Services

- (1) Division staff participated on a committee to develop articles for the TSBP *Newsletter*.
- (2) General Counsel assisted the Division of Professional Services in the review/drafting of proposed rules and preambles for rules, and the review of rule submissions to the *Texas Register* for all rules either proposed or adopted during FY2006, including emergency licensing, administrative penalty guidelines, fee changes, accessibility of records, Class D pharmacy formularies, and rule reviews. In addition, Division staff analyzed and prepared a response to extensive comments on proposed disciplinary process rules.

## D. Legal Services for Licensing

- (1) Division staff assisted with recommendations on eligibility for licensure and registration, verified accuracy of warning letters, and handled cases through the legal process.
- (2) General Counsel developed new application forms for reinstatement and relicensure, in compliance with confidentiality requirements and to standardize attest questions and obtain additional employment information.
- (3) Division staff assisted the Licensing Division with development of procedures for registration of pharmacy technicians in compliance with the Pharmacy Act and Board rules.
- (4) General Counsel attended demonstrations of various licensing systems used by Texas and other state licensing board to determine feasibility of implementing a new licensing system for TSBP.
- (5) General Counsel participated in meetings with the Department of Public Safety to develop the implementation of an electronic fingerprinting system for TSBP applicants.

## E. Other Legal Services regarding Pharmacy Issues

- (1) General Counsel participated in meetings and teleconferences regarding:
  - (a) patient assistance programs;
  - (b) licensure requirements for prior-authorization facilities;

- (c) quality assurance programs; and
- (d) licensure requirements for dialysis centers.
- (2) General Counsel participated in the review of the question pool for the Multistate Jurisprudence Examination to ensure the validity of the questions in the pool.
- (3) General Counsel participated in teleconference meeting of committee to review Wal-Mart's request for pilot project on automated prescription machines.
- (4) General Counsel participated in Pharmacy Compounding Task Force meeting on July 7, 2006.
- 6. To review and monitor the *Texas Register* for Attorney General opinions; to draft requests for Attorney General Opinions throughout FY2006; to serve as liaison for the Board to the Office of the Attorney General (OAG); to monitor and assist with appeals, injunctions, or civil litigation handled by the OAG against pharmacists or non-pharmacists.

Status: ACCOMPLISHED

- A. Division Staff reviewed new opinions of the Office of the Attorney General and the Texas Ethics Commission for applicability to TSBP on a weekly basis, and disseminated any relevant material to appropriate agency personnel.
- B. Liaison with the Office of Attorney General
  - (1) Division staff continued to serve as liaison with the OAG throughout FY2006. Joe Pitner served as the Assistant Attorney General assigned to TSBP from the OAG Administrative Law Division.
  - (2) Appeals; Injunctions; Civil Litigation
    - (a) No disciplinary cases were appealed during FY2006.
    - (b) General Counsel coordinated with Assistant Attorney General regarding settlement of civil case against Internet veterinary pharmacy allegedly dispensing without a valid practitioner-patient relationship.
    - (c) General Counsel drafted proposed settlement and with Internet veterinary pharmacy for an administrative penalty and practice restrictions.

- (3) Requests for AG Opinions
  - (a) General Counsel requested an open records decision regarding the release of a photograph of a former TSBP employee licensed as a peace officer.
  - (b) General Counsel submitted a brief regarding an open records request for TSBP's Planned Procurement Schedule from the Department of Information Resources.
  - (c) General Counsel requested an opinion in FY2005 whether federal law preempted the implementation of sections of S.B. 410 regarding authorization by the board for certain Canadian pharmacies to dispense drugs to Texas residents. The opinion was issued on December 21, 2005, concluding that the Board would violate federal law by "designating" certain Canadian pharmacies, promoting them on its website, and expressly permitting Texas consumers to import prescription drugs that cannot be imported under federal law.
- (4) General Assistance
  - (a) General Counsel informed the Opinions Committee of a federal district court decision regarding the illegality of Vermont's proposed Canadian drug importation program.
  - (b) Division staff coordinated with the Cyber Crimes unit on information regarding prosecution of pharmacy technician applicant who was a registered sex offender.
  - (c) General Counsel assisted Consumer Protection Division with trial preparation against patient assistance program.
- 7. To assist with open records requests throughout FY2006, in accordance with the procedures set forth in the Texas Public Information Act.

Status: ACCOMPLISHED

- A. Division staff was responsible for answering telephonic open records requests on licensees subject to disciplinary action until May 2006, at which time the Division of Professional Services began handling this duty. Division staff responded to approximately 115 verbal requests for complaint and disciplinary information in FY2006.
- B. General Counsel reviewed written responses to open records requests, prepared by the Professional Services Division, for legal compliance with the Public Information Act in FY2006. In addition, the General Counsel assisted with clarifying certain open records requests requiring telephonic clarification, when legal issues were involved.

8. To provide verbal and written information to Board staff and customers, including responses to surveys and questionnaires, as needed and required throughout FY2006; to provide legal assistance and maintain liaison with appropriate local, state, and federal prosecutors, legal divisions, and enforcement agencies involved in the investigation or prosecution of Board licensees, in conjunction with the Enforcement Division, throughout FY2006.

Status: ACCOMPLISHED

- A. Surveys/Questionnaires and Other Correspondence
  - (1) General Counsel and/or Division staff responded to the following surveys:
    - (a) Survey by Structural Pest Control Board regarding enforcement policies.
    - (b) Legal Client Survey for Office of Attorney General;
    - (c) Fraud Survey for Governor's office;
    - (d) On-line legal research services survey for General Counsel division of the Office of Attorney General;
    - (e) Evaluation of mediation services at the State Office of Administrative Hearings; and
    - (f) Annual survey from the State Office of Administrative Hearings.
- B. Technical Assistance to Other Agencies and Organizations
  - (1) Division staff attended State Agency Council meetings during FY2006.
  - (2) General Counsel and Division staff answered inquiries from the following:
    - (a) Houston Community Health Centers regarding receipt of drugs at Class D pharmacies;
    - (b) Texas Medical Association regarding importation of drugs from Canada;
    - (c) Internal Revenue Service regarding prosecution of TSBP licensees:
    - (d) Texas Department of State Health Services regarding prescription requirements, possession of drugs by researchers, and dissemination of disaster recovery information:

- (e) Illinois Board of Pharmacy regarding pharmacist duties that can be performed away from the pharmacy;
- (f) City of Austin regarding possession of weapons in pharmacies;
- (g) United States Probation Office regarding disciplinary procedures;
- (h) Dallas County District Attorney regarding prosecution of pharmacist;
- (i) United States Attorney's office regarding prosecution of pharmacist;
- (j) Travis County Jail regarding licensing requirements and pharmacy operations;
- (k) Drug Enforcement Agency regarding illegal dispensing of dangerous drugs; and
- (I) Texas Medical Board regarding receipt of public input at Board meetings.
- (3) General Counsel met with representatives of various pharmacies to discuss the legality of proposed operations.
- (4) General Counsel assisted the Professional Recovery Network with system to refer participants to TSBP for relapse and positive alcohol/drug screens.
- (5) General Counsel prepared projections for FY2008-2009 on anticipated workload for the State Office of Administrative Hearings.
- (6) Division staff attended Public Service Career Day at the University of Texas School of Law.
- C. Technical Assistance to the Legislature
  - (1) General Counsel answered questions from legislative offices regarding implementation of the provisions of S.B. 410 regarding designation of Canadian pharmacies to ship prescription drugs to Texas residents.
  - (2) General Counsel responded to an inquiry from Rep. Yvonne Davis's office regarding the disciplinary process against a technician with a felony criminal history.
  - (3) Division staff responded to questions from U.S. Rep. Solomon Ortiz's office regarding disciplinary case against pharmacist for numerous violations.

- D. Technical Assistance to the Press and the Public
  - (1) Division staff answered numerous telephone calls from pharmacist and pharmacy technician applicants regarding the application process and the associated disciplinary process, including providing information about denial of registration and options for Informal Conference.
  - (2) Division staff answered numerous questions from licensees, attorneys, and other members of the public regarding legal issues, including:
    - (a) licensing eligibility and requirements; and
    - (b) effect of convictions and deferred adjudications and/or probation for various crimes on registration and licensure.
  - (3) General Counsel responded to requests for information from the following television and newspaper reporters on issues including:
    - (a) Fort Worth Telegram regarding disciplinary history of various pharmacies;
    - (b) KHOU regarding return of prescription drugs; and
    - (c) San Antonio Express News regarding request for photograph of former TSBP employee.
  - (4) General Counsel answered questions from members of the public about public disclosure of complaint information.
- 9. To assist the Executive Director in developing and implementing the objectives of the Health Professions Council (HPC) pertinent to Division activities throughout FY2006.

Status: ACCOMPLISHED

- A. General Counsel served as chair of the HPC Legal Committee, which includes attorneys from other agencies, and provided updates to HPC about Legal Committee activities as requested.
- B. General Counsel coordinated a meeting of HPC attorneys to discuss procedures for disciplinary hearings of applicants and licensees/registrants with criminal histories at the State Office of Administrative Hearings and for modifying proposals for decision issued following such hearings.
- C. General Counsel reviewed referral scheme between HPC agencies to ensure legal compliance.

10. To maintain a staff development program by encouraging Division staff to participate in professional and interpersonal development seminars, cross training, and on-the-job training throughout FY2006.

Status: ACCOMPLISHED

**Comment:** This objective was accomplished through the following activities:

In FY2006, Division staff attended several general staff meetings, and in-house training sessions. In addition, Division staff attended the following programs, seminars, and events:

Kerstin Arnold	9/19/2005	On-line Training on TBPC Recycling Program		
	9/22-23/05	Advanced Administrative Law Course		
	10/25/2005	EAP Presentation on Wellness Program		
	12/2005	On-line EEOC Training		
	2/17/2006	Anatomy of an Administrative Hearing - Administrative Law		
	4/11/2006	Presentation regarding USP 797/795		
	5/17/2006	Austin Bar Association Administrative Law Update		
	5/25/2006	Essential Guide to Employment Law		
	6/15-16/06	State Bar Association Meeting		
	6/29/2006	Webinar on USP 797		
	8/23/2006	All Staff Training on Teambuilding		
Julie Hildebrand	9/22-23/05	Advanced Administrative Law Course		
	10/25/2005	EAP Presentation on Wellness Program		
	12/2005	On-line EEOC Training		
	2/17/2006	Anatomy of an Administrative Hearing - Administrative Law		
	4/11/2006	Presentation regarding USP 797/795		
	5/17/2006	Austin Bar Association Administrative Law Update		
	5/25/2006	Essential Guide to Employment Law		
	6/15-16/06	State Bar Association Meeting		
	7/20-23/06	Texas Pharmacy Association Meeting		
	7/25-28/06	Governor's Management Development Training		
	8/23/2006	All Staff Training on Teambuilding		
Stephanie Chambers	10/25/2005	EAP Presentation on Wellness Program		
	12/2005	On-line EEOC Training		
	4/11/2006	Presentation regarding USP 797/795		

Mitra Woody	12/2005	On-line EEOC Training
2/10/2006		State Bar Mandatory Training for Newly Licensed Attorneys
	2/13/2006	TLETS Training
	4/11/2006	Presentation regarding USP 797/795
	6/15/2006	State Bar Association Meeting
	6/18-25/06	Utah Conference on Alcoholism and other Drug Dependencies
	8/23/2006	All Staff Training on Teambuilding
Cheryl Sepulveda	10/25/2005	EAP Presentation on Wellness Program
	12/2005	On-line EEOC Training
	8/23/2006	All Staff Training on Teambuilding
Georgienne Naussauer	10/25/2005	EAP Presentation on Wellness Program
	12/2005	On-line EEOC Training
	8/23/2006	All Staff Training on Teambuilding
Jing Belfiglio	10/25/2005	EAP Presentation on Wellness Program
<u> </u>	12/2005	On-line EEOC Training
	8/23/2006	All Staff Training on Teambuilding
Charagua Dag	0/00/0000	All Chaff Training on Toombuilding
Sharanya Rao	8/23/2006	All Staff Training on Teambuilding

## 11. To conduct periodic reviews and annual evaluations of all employees under the supervision of this Division during FY2006.

Status: ACCOMPLISHED

**Comment:** This objective was accomplished through the following activities:

Employee	Date of Evaluation	Evaluation By
Kerstin Arnold, J.D.	9/29/06	Executive Director
Julie Hildebrand, J.D.	8/29/06	General Counsel
Mitra Woody, J.D.	8/30/06	General Counsel
Cheryl Sepulveda	8/30/06	Assistant General Counsel
Georgienne Nassauer	8/30/06	Assistant General Counsel
Jing Belfiglio	8/30/06	General Counsel

Other activities related to Division personnel are listed below:

- A. General Counsel conducted team meetings approximately once a month with Division staff.
- B. The Division had a law clerk during the summer of 2006 from the University of Texas School of Law, who provided assistance with the preparation of legal cases.

- C. General Counsel prepared and conducted orientations of all new TSBP employees and interns during FY2006 regarding the Legal Division, the legal process, ethics, and Public Information and Open Meetings Acts.
- D. Staff attorney, Mitra Woody, was hired in December 2005 to fill the position created by the 79th Legislature. Ms. Woody previously served as an intern for TSBP, and therefore, she required little training.
- E. Former staff attorney, Stephanie Chambers, resigned in FY2006, and the position was replaced with a legal assistant, Sharanya Rao, who was hired, effective August 14, 2006. She was trained in agency and Division policies and procedures by Division staff.
- 12. To destroy records in accordance with the agency's record retention plan throughout FY2006; to update the Division's Policies and Procedures Manual as needed and submit any substantive revisions to the Executive Director for approval throughout FY2006.

Status: ACCOMPLISHED

**Comment:** This objective was partially accomplished as follows:

A. Records Management

During FY2006, Division staff destroyed records, in accordance with the TSBP record retention schedule, including general correspondence. Division staff also prepared and indexed material for transfer to the State Library.

- B. Policies and Procedures
  - (1) Division staff updated and maintained Disciplinary Notebooks and Index containing all Board Orders and Agreed Board Orders.
  - (2) Division staff documented procedures for handling disciplinary process against pharmacy technicians and developed samples for preliminary notice letters and agreed board orders.
  - (3) Division staff developed notebook of samples of preliminary notice letters for pharmacist and pharmacy disciplinary actions.
- 13. To recommend policies and procedures to the Executive Director that will enhance the efficiency and effectiveness of the agency throughout FY2006.

Status: ACCOMPLISHED

**Comment:** This objective was accomplished as follows:

- A. General Counsel played an integral role in the coordination and development of the agency's response to Hurricanes Katrina and Rita, in developing the emergency procedures to be used for temporary licensing, developing advisory information on closing of pharmacies in evacuated areas, and disseminating information to licensees and the public.
- B. General Counsel served on the agency's Wellness Committee. She coordinated the Maintain No Gain program during the winter, the Heart Health Awareness program and the agency's Texas Roundup participation in the spring, in conjunction with the Director of Professional Services, and the 5-A-Day Challenge in the summer.
- C. Division staff recommended new format for rehabilitation orders for pharmacy technicians that provides for monitoring of the technicians, as allowed by the changes made to the disciplinary sanctions in the 79th Legislature.
- D. General Counsel developed an administrative penalty matrix for statutory and rule violations applicable to pharmacists, pharmacies, and pharmacy technicians, which was developed into administrative rules by the Division of Professional Services and approved by the Board in FY2006.
- E. General Counsel developed a disciplinary scheme for criminal violations for applicants for licensure and registration, which provides guidelines for the type of sanction that is appropriate for each type of criminal violation. The scheme was developed by analyzing the sanctions previously imposed by informal conference panels and then applying the sanctions consistently to various criminal violations.
- F. General Counsel drafted a standard revocation order for use by field investigators for licensees and registrants seeking voluntarily revocation.
- G. General Counsel suggested procedure to verify notification of employers by impaired pharmacists under a standard rehabilitation order.
- H. Division staff implemented the presentation to the Board of a summary of agreed board orders for continuing education audit violations rather than each individual order at Board meetings for greater efficiency and costsavings.
- General Counsel removed certain personal information contained in agreed board orders to comply with confidentiality provisions of S.B. 410 of the 79th Legislature.
- J. Division staff developed Calendar of Events for FY2007 for informal conferences and reserved conference rooms accordingly.
- K. General Counsel participated in meetings to develop implementation of computer system for pharmacy technician trainees and recommended enhancements to the system to track individuals by social security number.

14. To recommend changes to the Texas Pharmacy Act and rules, which will enhance the agency's ability to protect the public health, safety, and welfare, or will improve the efficiency and effectiveness of the agency's operations, and forward the recommendations to the Executive Director throughout FY2006.

Status: ACCOMPLISHED

**Comment:** This objective was accomplished through the following activities:

A. Texas Pharmacy Act

General Counsel and Division staff recommended numerous changes to the Texas Pharmacy Act, including, to:

- (1) Add violation of a disciplinary order as a ground for disciplinary action against pharmacy technicians/trainees.
- (2) Require that an applicant for pharmacy technician/trainee registration be of good moral character.
- (3) Add commission of criminal offense that requires registration as a sex offender as a ground for disciplinary action for all types of licenses and registrations.
- (4) Allow licensees/registrants to report impairment by other licensees/registrants.
- (5) Provide the full range of disciplinary sanctions for pharmacist-interns.
- (6) Require that applicants for licenses and registrations be in the United States legally and legally able to work.
- (7) Add disciplinary action by another health licensing board in Texas or in any other state as a ground for disciplinary action for pharmacist and pharmacy technician/trainees.
- (8) Provide for mandatory evaluations by a mental health professional if probable case for impairment exists.
- (9) Add disciplinary grounds for pharmacy technicians/trainees for impairment (similar to that for pharmacists), for unprofessional conduct (similar to that for pharmacists), and for performing acts outside their scope of duty.
- (10) Clarify the burden of proof in licensing, reinstatement and modification cases at the State Office of Administrative Hearings.
- (11) Allow Board the discretion to make subsequent orders for impaired pharmacists public.

#### B. Board Rules

- (1) The Act was amended to require the Board to publish rules setting forth the types of violations that would be subject to an administrative penalty (fine) and the amount (or range) of the penalty. General Counsel developed a proposed matrix to ensure that the amounts of penalties imposed were appropriate to the violation. The proposed matrix, in the form of a proposed rule, was presented to the Board at its meeting held on November 1-2, 2005. The Board voted to propose the rule, and it was subsequently published in the *Texas Register* on December 9, 2005. At its meeting held on February 7-8, 2006, the Board voted to adopt the proposed rule regarding the administrative penalty schedule. This rule became effective on March 6, 2006.
- (2) Division staff restructured the disciplinary guidelines in chapter 281 to incorporate required statutory and rule changes applicable to contested case hearings at the State Office of Administrative Hearings and to make the chapter easier to understand and use.
- (3) Division staff researched laws and rules applicable to patient access to healthcare records for presentation to the Board and developed proposed rules in compliance with these laws and rules defining applicable guidelines for patient access and reasonable charges for pharmacy records.
- 15. To prepare and submit a report on the accomplishment of Division objectives, for incorporation into the agency's FY2005 *Annual Report* to be presented to the Board by its May 2006 Board meeting.

Status: ACCOMPLISHED

**Comment:** The Division's first draft of the FY2005 *Annual Report* was submitted to the

Executive Director by the due date. The final draft of the Annual Report was presented to, and approved by, the Board at its meeting held in May 2006.