TEXAS STATE BOARD OF PHARMACY

Staff Report

to the

Sunset Advisory Commission

Legislative Budget Office
Program Evaluation
P. O. Box 13066, Capitol Station
Austin, Texas 78711

June 19, 1980

TABLE OF CONTENTS

FOREWORD

The Texas Sunset Act (Article 5429k V.A.C.S.) terminates named agencies on specific dates unless continued. The Act also requires an evaluation of the operations of each agency be conducted prior to the year in which it terminates to assist the Sunset Commission in developing recommendations to the legislature on the need for continuing the agency or its functions.

To satisfy the evaluation report requirements of Section 1.07, Subsection (3) of the Texas Sunset Act, the Program Evaluation section of the Legislative Budget Board has evaluated the operations of the Texas State Board of Pharmacy, which will terminate on September 1, 1981 unless continued by law.

Based on the criteria set out in the Sunset Act, the evaluation report assesses the need to continue the agency or its function and provides alternative approaches to the current method of state regulation. The material contained in the report is divided into seven sections: Summary and Conclusions, Background, Review of Operations, Alternatives and Constraints, Compliance, Public Participation, and Statutory Changes. The Summary and Conclusions section summarizes the material developed in the report from the standpoint of whether or not Sunset criteria are being met, assesses the need for the agency or the agency's functions relative to the findings under the various criteria and develops alternative approaches for continued state regulatory activities. The Background section provides a brief history of legislative intent and a discussion of the original need for the agency. The Review of Operations section combines, for the purposes of review, the sunset criteria of efficiency, effectiveness, and the manner in which complaints are handled. The Alternatives and Constraints section combines the sunset criteria of overlap and duplication, potential for consolidation, less restrictive means of performing the regulation, and federal impact if the agency were modified or discontinued. The Compliance Section combines the Sunset criteria relating to conflicts of interest, compliance with the Open Meetings Act and the Open Records Act, and the equality of employment opportunities. The Public Participation section covers the sunset criterion which calls for an evaluation of the extent to which the public participates in agency activities. The final section, Statutory Changes, deals with legislation adopted which affected the agency, proposed legislation which was not adopted and statutory changes suggested by the agency in its self-evaluation report.

This report is intended to provide an objective view of agency operations based on the evaluation techniques utilized to date, thus providing a factual base for the final recommendations of the Sunset Commission as to the need to continue, abolish or restructure the agency.

I. SUMMARY AND CONCLUSIONS

The beginnings of pharmacy -- the therapeutical use of drugs -- can be traced to extremely ancient origins. In early times, pharmacy was generally combined with the practice of medicine. However, as medical knowledge increased, the role of the physician became more specialized and the need for specialists in pharmacy grew correspondingly.

Recognition of the need to protect the public health, safety and welfare through the regulation of the practice of pharmacy resulted first in the establishment of district boards of pharmaceutical examiners in 1889, and then in the creation of the State Board of Pharmacy in 1907.

The board, composed of six registered pharmacists, presently regulates 11,717 pharmacists, 4,078 pharmacies and 58 drug manufacturers. The agency operates outside the State Treasury and is supported entirely from revenues generated through its licensing and enforcement activities.

Review of the board operations reveals that the regulatory activities of the board generally serve to ensure an adequate level of public protection, however several aspects could be improved.

With regard to the administration activity, the review indicated that the objective of efficient management has been achieved in general, however, four concerns were identified. First, the agency's fiscal operations are not subject to review through the appropriations process and agency funds are maintained outside the State Treasury. The review indicated that agencies with funds in the State Treasury receive a greater degree of legislative oversight with regard to agency receipts, disbursements, and general practices than agencies with funds maintained outside the Treasury. Second, the board is authorized to collect certain fees associated with the regulation of pharmacy. The maximum amounts presently set

by statute are charged, and frequent statutory amendments have been required in recent years to raise these limits. A third administration concern relates to the annual reporting requirements in the Pharmacy Act. The statute requires that the report include the names of all registered pharmacists. The inclusion of a list of pharmacists in the requirements results in a voluminous report which serves little purpose since specific information is readily accessible from the board. A final concern in administration involves the statutory requirement that all board members be engaged in retail pharmacy. According to available data, thirty-one percent of the licensed pharmacists practice in settings other than retail pharmacies. Thus, this provision restricts nearly one-third of the state's licensed pharmacists from membership on the board.

With respect to the licensing activity, the review found that established procedures are effective in ensuring that statutory requirements have been satisfied and that the processes associated with the licensing function are performed in an efficient manner. Three concerns, however, were identified. First, the statute requires that a candidate for licensure complete an internship under a registered pharmacist (preceptor), however it sets no additional standards for preceptors. Thus, the agency is without a means to assure that pharmacist-interns are exposed to proper practice procedures and standards. Second, all of the agency's statutory grounds for removal of or refusal to issue a license do not meet a two-part test: to be clear and related to the practice of the profession, and to be stated in terms of a currently existing condition rather than an absolute condition which exists throughout the lifetime of the individual. Third, the statute provides no penalty for the late renewal of licenses within sixty days from the expiration date, and no requirement to demonstrate competency in order to renew a license which has been expired for a substantial period of time.

In the area of board enforcement activities, the review found that the board is active in pursuing complaints and that the investigation and disposition of complaints are performed in an efficient and effective manner. However, two concerns were noted with regard to the enforcement function. The statute currently authorizes the board to impose and collect fines for violations of the Act. However, the review indicated that the provision allowing the board to receive revenues from fines creates a potential for conflict of interest and subjects the enforcement tool to criticism that it is used as a revenue generator. The second enforcement concern relates to board authority to enforce the Act. The review indicated that the board presently lacks clear enforcement authority to probate license suspensions, to discipline licensees for violations of certain statutes, and to inspect licensed facilities.

In the review of the agency's compliance with general statutes, it was noted that the board's formal hearing process deviates from the requirements of the Open Meetings Act.

Other concerns identified by the review include the absence of public members on the board and the existence of a duplication of effort with regard to the licensure of drug manufacturers by both the board and the Department of Health.

Need to Regulate

As in the case of other regulated activities, regulation of the practice of pharmacy should be undertaken by the state only when there is a continuing need to protect the public health, safety or welfare. Conditions which existed prior to the imposition of regulation in 1889 indicate that the potential harm from improperly filled pharmaceutical prescriptions posed a significant danger to the public. This

danger created the need to regulate the practice of pharmacy to help reduce the potential harm from improperly filled prescriptions.

Conditions which exist today indicate that this need to protect the public has increased, primarily as the result of two factors: the expanded use of pharmaceutical products and the increased potential for misuse and abuse of drugs. Without state regulation, there would be no state determination of minimum qualifications prior to authorization to engage in the practice of pharmacy. The consumers of pharmaceutical services would have only pharmacist association standards and the reputations of pharmacies as indicators of competence. Thus, the public would be subject to an unnecessary risk of harm which could result from improperly compounded prescriptions or improper dispensing of pharmaceuticals. It can be concluded, therefore, that there is a continuing need to protect the public's health, safety and welfare from the incompetent and improper practice of pharmacy.

This need for regulation can be most effectively met through an agency which performs licensing and enforcement functions. Licensure as a method of regulation for pharmacists is currently imposed in all states, including Texas. However, as demonstrated by the regulation of pharmacies in other states, alternative methods exist which allow flexible standards suited to the various settings in which pharmacy is practiced.

Alternatives

If the legislature determines that the regulatory function and/or board should be continued, the following alternatives could be considered:

1. CONTINUE THE BOARD AND ITS FUNCTIONS WITH MODIFICATIONS.

This approach would maintain an independent board to perform licensing and enforcement activities. The review indicated that the following modification would result in more effective regulation of the practice of pharmacy:

a) amend the statute to place agency funds in the State Treasury and include the agency in the appropriations process (page 15);

b) amend the statute to provide for the appointment of at least two public members on the board (page 44);

c) amend the statute to remove the requirement that all board members be engaged in retail pharmacy practice so that any licensee practicing pharmacy will be eligible (page 17);

d) amend the statute to modify requirements for the board's annual report to delete unnecessary provisions (page 17);

e) amend the statute to authorize the board to establish and collect necessary and reasonable fees for the administration of the Pharmacy Act (page 16);

f) amend the statute to authorize the board to establish standards for intern supervisors (preceptors) (page 22);

g) amend the statute to include license renewal requirements which:

1) provide for the automatic suspension of expired pharmacist licenses (page 24);

2) establish a standard penalty for the reinstatement of expired pharmacist licenses (page 24); and

3) establish competency requirements for the reinstatement of pharmacist licenses expired for more than two years (page 24);

h) modify the statute so that grounds for disqualifying an applicant from sitting for an examination and grounds for removal of a license are: 1) easily determined and 2) currently existing conditions (page 23);

i) amend the statute to provide that all revenues generated from fines imposed by the board be deposited to the credit of the General Revenue Fund (page 27);

j) amend the statute to provide greater enforcement authority in the following areas:

   1) authority to probate license suspension (page 27);

   2) authority to apply sanctions against a licensee for a violation of the Pharmacy Act, board rules and regulations, the Controlled Substances Act or the Dangerous Drug Act (page 27);

   3) authority to inspect all licensed facilities with regard to storage, equipment, sanitary conditions and security (page 27); and

   4) authority to inspect the records of all licensed facilities with regard to prescriptions and prescription drug invoices and inventories, but not with regard to financial, sales or pricing data (page 27);

k) amend the statute to remove the board's concurrent authority to license drug manufacturers thereby providing the Department of Health with sole licensing authority (page 35); and

l) direct the board to modify formal hearings procedures so that they fully comply with the Open Meetings Act (page 44).

2. CONTINUE THE BOARD AND MODIFY ITS STATUTORY AUTHORITY TO PROVIDE FOUR CLASSES OF FACILITY LICENSES (page 36).

This approach would provide a means for the board to recognize distinct types of pharmacy settings and to adopt rules and regulations best suited for each type. This approach would expand the scope of pharmacy

regulation to include inpatient hospital care and clinics which are not clearly exempted from provisions of the Pharmacy Act. However, with regard to hospitals and clinics, limitations on board rule-making authority would reduce restrictive elements of present pharmacy regulation while providing a licensing mechanism to protect the public health.

Review of the settings in which the practice of pharmacy is currently performed indicate a need for four distinct classes of facility license:

a) Class A permit for a community (retail) pharmacy;

b) Class B permit for a nuclear pharmacy;

c) Class C permit for an institutional (hospital) pharmacy, restricting the authority of the board to adopt rules which would limit the use of supportive personnel; and

d) Class D permit for a clinic, directing the board to adopt rules which allow persons other than pharmacists to perform pharmaceutical acts under the supervision of a registered pharmacist.

If the legislature adopts this alternative, the structural and substantive changes contained in the preceding alternative should also be made.

II. BACKGROUND

Historical Perspective

Historically, the beginnings of pharmacy -- the therapeutical use of drugs -- can be traced to extremely ancient origins. In early times, pharmacy was generally combined with the practice of medicine. However, as medical knowledge increased, the role of the physician became more specialized and the need for specialists in pharmacy grew correspondingly.

Although regulation of the practice of pharmacy was imposed as early as 1870 in other states, no statewide restrictions existed in Texas until 1889. This lack of regulation posed a significant harm to the public resulting from the improper preparation of prescriptions. The initial effort to regulate pharmacy practice, as provided by the Twenty-first Legislature in 1889, restricted the preparation of prescriptions, compounding of medicines and operation of a pharmacy to qualified pharmacists. Boards of pharmaceutical examiners were established in each judicial district, the members of which were appointed by the presiding judge of the district. Each district board was responsible for determining the qualifications of persons to practice pharmacy within its boundaries.

Because of the development of inconsistent standards through this decentralized approach, the Thirtieth Legislature in 1907 supplanted the district board system through the creation of the State Board of Pharmacy to evaluate the qualifications of applicants as pharmacists and pharmacy assistants on a statewide basis. In general, the Act establishing the board made it unlawful for a person to compound or dispense drugs without being registered by the board or exempted by the Act. Significant among the exceptions to the Act were exemptions for: 1) registered practitioners of medicine and dentistry (later expanded to include

podiatrists and veternarians); 2) persons practicing pharmacy in towns of 1,000 inhabitants or less; and 3) the sale of patent medicines in unbroken packages.

The original scope of the board's authority has been signficantly affected by subsequent legislative amendments. Major changes to the Act have eliminated licensure status for assistant pharmacists, required the licensure of pharmacies and drug manufacturers, and expanded board enforcement authority.

In addition to the Texas Pharmacy Act, the practice of pharmacy is also regulated by other state and federal statutes with regard to the safety, effectiveness, and proper control and distribution of prescription drugs. As a result, pharmaceutical practice is within the jurisdiction, to varying degrees, of several governmental agencies, including: the federal Food and Drug Administration; the federal Drug Enforcement Administration; the Texas Department of Health; the Texas Department of Public Safety; as well as the Texas State Board of Pharmacy.

The State Board of Pharmacy is composed of six registered pharmacists appointed to overlapping six-year terms by the governor. This board oversees a staff of eighteen full-time employees. At present, the board regulates 11,717 pharmacists, 4,078 pharmacies, and 58 drug manufacturers. The agency operates outside the State Treasury and is supported entirely from revenues generated through its licensing and enforcement activities. In fiscal year 1979, the board collected $776,057 and expended $627,140.

Comparative Analysis

To determine the pattern of regulation of the occupation of pharmacy within the United States, a survey of the fifty states was conducted.

The need to regulate the occupation of pharmacy is currently recognized through licensing requirements imposed by all fifty states. From the standpoint of

organizational patterns, thirty-three states, including Texas, meet this expressed need through an independent board or commission. In the remaining states, the regulation of pharmacists is carried out through a board associated with a state agency charged with multiple regulatory functions. In five states, pharmacy boards have advisory functions only.

Board members are appointed by the chief executive in forty-six states. Licensing boards composed entirely of pharmacists administer pharmacy laws in thirty-one states, including Texas. In nineteen states, the regulation of pharmacy is achieved through a board consisting of public members as well as pharmacists.

While fees are collected by all fifty boards, funding patterns vary across the states. Boards in twenty-six states, including Texas, are supported, at least partially, by the fees they collect. Forty-one of the boards, not including Texas, are funded through the legislative appropriations process. Boards in eleven states, like Texas, maintain accounts outside of state treasuries. Unlike Texas, twenty-seven of the pharmacy boards receive general revenue funds.

In all but four states, a national examination is used to determine competency for licensure; this exam is used by Texas. In forty-seven states, including Texas, licensing by some form of reciprocity is also authorized. In all fifty states, pharmacy boards have responsibility for conducting disciplinary hearings.

All pharmacy boards surveyed indicate the need to perform the basic regulatory functions of administration, testing, license issuance, and enforcement.

III. REVIEW OF OPERATIONS

The material presented in this section combines several sunset criteria for the purpose of evaluating the activities of the agency. The specific criteria covered are the efficiency with which the agency operates; the objectives of the agency and the manner in which these objectives have been achieved; and the promptness and effectiveness with which the agency disposes of complaints concerning persons affected by the agency.

Organization and Objectives

Through the enactment of the Texas Pharmacy Act, the legislature mandated the Texas State Board of Pharmacy to regulate all persons who compound, mix, manufacture, combine, prepare, label, sell or distribute any drugs or medicines which are not in original packages. The Act also directs the board to regulate the operation of retail pharmacies and to regulate manufacturers of drugs and medicines. Exceptions to the Act's coverage significantly limit the board's regulatory authority in certain areas. Among the major exceptions to the Pharmacy Act are exemptions for licensed practitioners of medicine, dentistry and chiropody who may either supply or personally administer drugs and medicines to their patients. Additional exemptions are for veterinarians to personally administer drugs or medicines for the immediate needs of their patients, patent medicines which are harmless when used according to instructions, and insecticides and fungicides. Other significant exemptions include those for pharmacy interns and faculty members of reputable colleges of pharmacy as well as hospitals and clinics maintaining a dispensary for the care of patients if a licensed pharmacist is continually employed to compound prescriptions.

As provided in the Texas Dangerous Drug Law (Article 4476-14, V.A.C.S.), an Act designed to regulate and control drugs that are unsafe for self-medication but have a low potential for abuse, the Board of Pharmacy is charged with the enforcement of this Act's provisions. These requirements are primarily directed toward the proper delivery, possession, and recordation of dangerous drugs.

The implementation of these statutory mandates to regulate the practice of pharmacy, the manufacture of drugs, and the delivery of dangerous drugs is accomplished through the licensure of qualified, competent pharmacists and through the issuance of permits to qualified pharmacies and drug manufacturers. Additionally, agency enforcement efforts are aimed at ensuring the continued competence of registered pharmacists, the adherence to health and safety standards by licensed pharmacies and drug manufacturers, and the proper delivery of dangerous drugs.

The Texas State Board of Pharmacy consists of six registered pharmacists appointed to six-year terms by the governor with the advice and consent of the senate. To be qualified for appointment to the board, the registered pharmacist must have been licensed to practice pharmacy for five years immediately preceding appointment and must currently be engaged in retail pharmacy practice. Also, an appointee must not be a faculty member of a school of pharmacy or have a financial interest in any such school. Statutorily required board duties include promulgating rules and regulations, conducting violation hearings, cooperating with state and federal agencies regarding violations of any drug laws, and ensuring that all laws pertaining to pharmacy are enforced.

Staff for the agency consists of eighteen full-time employees. Activities generally performed by the staff in the areas of administration, licensing, and enforcement include maintaining records; processing pharmacist, pharmacy, and

drug manufacturer license applications and renewals; administering examinations; investigating violations of the Act; conducting compliance visits to licensed pharmacies; performing informal conferences relating to violations of the Act; and providing support services to the board.

The board is funded primarily by fees collected through its licensing activities and fines imposed in board enforcement efforts. Currently, all funds accrued by the agency are placed in accounts outside the State Treasury and are available for agency expenditure.

Evaluation of Agency Activities

As with most other licensing agencies, the operations of the Texas State Board of Pharmacy can be broken down into three basic activities: administration, licensing, and enforcement. Below, each of these activities were reviewed to determine the degree to which agency objectives have been met. To make this determination, the evaluation focused on whether the board has complied with statutory provisions, whether these provisions facilitate accomplishment of the objectives, whether agency organization, rules, and procedures are structured in a manner that contributes to cost-effective accomplishment of the agency's task, and whether procedures provide for fair and unbiased decision-making.

Administration

The general objective of any administration activity is to provide for the efficient operation of all agency functions. The review of agency activities indicates that the current board administration is generally conducted in an efficient manner. Licensure application and renewal processes are well organized and function efficiently. Also, agency records and reports appear to be carefully

prepared and organized. A comprehensive policy and procedure manual developed by the board is designed to clearly define board activities and staff duties along with appropriate procedures to be utilized. Although the overall agency management was found to be generally efficient, the review indicated that there are four aspects of agency administration that could be improved.

The first area of concern, relating to agency administration, results from the fact that the agency currently maintains its funds outside the State Treasury and its expenditures are therefore not subject to the state appropriative process. Because the agency is not in the appropriations process, it is not subject to the standard practices and controls developed by the legislature for most state agencies.

Controls, such as voucher approval by the Comptroller of Public Accounts, General Services and Purchasing Commission bidding procedures, and investment of funds by the State Treasurer, have been adopted as standard procedures for most state agencies to assure administrative efficiency and accountability. As applied to the Board of Pharmacy, these controls would provide additional supervision of agency expenditures and operations in such areas as the purchasing or leasing of automobiles and the investment of agency funds. A periodic legislative review of an agency's continuing need for such practices as hiring legal counsel to supplement services provided by the Attorney General's Office and for buying and leasing agency vehicles is not required when an agency is outside the appropriations process. Inclusion within the appropriations process provides a systematic review of agency expenditures including the total amounts of per diem required by board members. No such controls exist when an agency's funds are maintained outside of the State Treasury.

To ensure that the management of this agency adheres to general standards established for efficient and accountable state operations, that agency practices are reviewed on a systematic basis, and that legislative oversight is provided for agency expenditures, the Board of Pharmacy should be included in the appropriations process. This approach is consistent with the Sunset Commission's position that provisions requiring agency inclusion in the appropriations process be recommended on an across-the-board basis.

A second area of concern relates to the fee structure of the agency. Currently, the board has the authority to set certain statutorily authorized fees within fixed statutory limits. Using this authority, the board has currently set all fees at their maximum levels allowable by statute so that revenues generated will balance with necessary agency expenditures. In addition, in each of the past four legislative sessions, the Pharmacy Act has required amendment to authorize fee increases adequate for the agency's budgetary needs.

To eliminate the need for legislative adjustment of maximum fees allowable on a continual basis and to give the board the flexibility to adjust its fee structure to cover the cost of its operations as its requirements change, the Act should be amended to authorize the board to set reasonable and necessary fees. This authority becomes particularly advantageous when viewed in conjunction with the inclusion of the agency in the appropriative process. Flexibility would be available to the agency in modifying its fiscal procedures to correspond with appropriations requirements, while the legislature would retain general control over the fee setting authority through the appropriative process.

Another concern in the area of administration relates to the reporting requirements in the Pharmacy Act for an annual report to the governor. These

requirements provide that the report shall contain receipts and disbursements for the fiscal year, the names of all pharmacists registered during the fiscal year, and the names of all pharmacists whose licenses have been cancelled during the fiscal year. The inclusion of a list of names of registered pharmacists in the report results in a voluminous report and appears to serve little purpose as such information can be obtained from the board on request. Both the state auditor and the agency have recommended the elimination of this requirement.

The annual reporting requirements should be modified to correspond with the general provisions of the appropriation act so that the board's annual report will be consistent with the annual reports prepared by most other state agencies. This change would provide comparable, relevant information to the governor and other decision-makers with regard to the board.

A final concern involves a statutory requirement regarding board member qualifications. This provision requires that all board members be engaged in the practice of retail pharmacy. According to available data, sixty-nine percent of all pharmacists licensed by the board practice in a retail pharmacy setting. The remaining thirty-one percent practice in such other settings as hospitals, clinics, and governmental institutions. Thus, the statute presently restricts nearly one-third of the state's active, licensed practitioners from membership on the board. Elimination of this restriction, as requested by the agency, would make it possible for the board to better reflect the licensee population that it regulates.

Licensing

The objective of the licensing activity of the board is to ensure that minimum qualifications have been achieved by persons authorized to practice pharmacy, operate pharmacies, or manufacture drugs in the state. Consequently, the board is

responsible for the licensure of pharmacists, pharmacies and drug manufacturers. To accomplish this objective, the board evaluates the qualifications of each applicant for licensure as a pharmacist, pharmacy or drug manufacturer to determine whether the standards for licensure have been satisfied.

The licensing standards for pharmacists can be broken down into three basic components: education, experience and examination. With regard to education, the statute requires at least an undergraduate degree from a board-approved school of pharmacy. Practical experience, at least 1,000 hours under the supervision of a registered pharmacist, is also statutorily required. Competency is determined by the examination process which utilizes the National Association of Board of Pharmacy Licensing Examination (NABPLEX) and the board-developed Texas Jurisprudence Examination which is designed to test knowledge of Texas drug and pharmacy laws. Exhibit III-1 presents examination pass/fail rates for the NABPLEX examination.*

Exhibit III-1

LICENSING EXAMINATION PASS/FAIL RATES FISCAL YEARS 1976 - 1979

Year	Total Examined	Number Passed	Percent Passed	Number Failed	Percent Failed
1976					
Theoretical	458	416	91%	42	9%
Practical	435	421	97%	14	3%
1977					
Theoretical	614	540	88%	74	12%
Practical	430	414	96%	16	4%
1978					
Theoretical	556	455	82%	101	18%
Practical	491	470	96%	21	4%
1979					
Theoretical	547	475	87%	72	13%
Practical	532	492	92%	40	8%
Total					
Theoretical	2,175	1,886	87%	289	13%
Practical	1,888	1,797	95%	91	5%

*Results of examination sections developed by the board are reflected in the theoretical totals.

Under the reciprocity provisions of the Act, a person who is licensed in another state may be licensed in Texas, provided that specific requirements are met. Exhibit III-2 displays the number of pharmacist licenses issued by method in the last four fiscal years.

Exhibit III-2

NUMBER OF PHARMACIST LICENSES ISSUED BY METHOD FISCAL YEARS 1976 - 1979

	1976	1977	1978	1979
By Examination	421	414	470	492
By Reciprocity	140	233	264	205
By Renewal	9,938	10,298	10,682	11,020
Total	10,499	10,945	11,416	11,717

Available information (current as of April 1980) suggests that of the total number of pharmacists licensed by Texas, 9,564 or 83 percent reside in Texas. Additionally, 15 percent (1,480) of these licensed pharmacists do not currently practice pharmacy. Exhibit III-3 provides an indication of the practice setting of licensed pharmacists residing in Texas.

Exhibit III-3

PRACTICE SETTING OF LICENSED PHARMACISTS RESIDING IN TEXAS

Practice Setting	Number of Pharmacists	Percent
Community Pharmacy (Independent)	3,798	40%
Community Pharmacy (Multiple/Chain)	2,742	29%
Hospital Pharmacy	1,776	18%
Manufacturer or Wholesaler	182	2%
Governmental Agency	117	1.3%
Educational Institution	54	.6%
Armed Services	46	.5%
Nursing Facility	26	.3%
Nuclear Pharmacy	21	.3%
Other	802	8%
Total	9,564	100%

A second function of the licensing activity involves the issuance of permits to pharmacies and drug manufacturers. The licensing standards established by statute require that the individual responsible for the application 1) be of good moral character; 2) not have been convicted of a felony or a misdemeanor involving moral turpitude; and 3) not have been found to illegally use, dispense, sell, or transport legend drugs and other specifically identified substances. Exhibit III-4 indicates the number of licensed pharmacies and drug manufacturers, while Exhibit III-5 shows the number of pharmacies by type of facility.

Exhibit III-4

NUMBER OF LICENSED PHARMACIES AND DRUG MANUFACTURERS

	1976	1977	1978	1979
Pharmacies	3,797	4,288	3,902	4,078
Drug Manufacturers	97	90	67	58

Exhibit III-5

NUMBER OF LICENSED PHARMACIES BY TYPE OF FACILITY*

Type of Pharmacy	Number of Pharmacies
Community (Independent)	2,231
Community (Multiple/Chain)	1,128
Hospital (Outpatient)	280
Governmental	79
Public Health	10
Nuclear	7
Nursing Facility	3
Other	53
Total	3,791

*Current data as of April 1980.

The board is authorized by statute to collect certain fees for the licensing services provided. The Act sets the fee for drug manufacturers at a specific amount; however, it allows board discretion with regard to the level of remaining fees up to statutory limits. Exhibit III-6 identifies current fee charges.

Exhibit III-6

CURRENT LICENSING FEES

Type of Fee	Pharmacist	Pharmacy	Drug Manufacturer
Application/Examination	$ 75	$ 50	$ 200
License Renewal	35	50	200
Delinquent Renewal Penalty	35	50	200
Reciprocity	250	N/A	N/A

In reviewing the licensing activity, an assessment was made of the effectiveness of statutory provisions and board action in ensuring a minimum level of competency. The review indicated that the functions associated with the issuance of original, renewal and reciprocal licenses are performed in an efficient manner. Additionally, the examination process functions smoothly and appears to serve as an effective screening mechanism with regard to competency. Although the licensing process functions well in general, three aspects of the licensing activity could be improved.

The first concern relates to the statutory requirement that an applicant complete an internship under a registered pharmacist prior to licensure. The purpose of the internship requirement is to ensure that the applicant gains practical experience and the opportunity to further develop appropriate skills, abilities and standards of practice. However, the achievement of this objective is hampered to some extent by the absence of board authority to determine

eligiblity to serve as an intern supervisor or preceptor. At present, the statute requires only that a preceptor be a registerd pharmacist. As a result, situations have occurred in which licensees who have been subject to board disciplinary action have continued to supervise interns. The agency has recommended that it be authorized to establish reasonable guidelines concerning eligiblity to act as a preceptor. Such guidelines would provide additional assurances that pharmacist-interns are exposed to proper practice procedures and standards, thereby increasing the benefits gained from the internship. The statute should therefore be amended to authorize the board to establish reasonable guidelines for the approval of preceptors.

As a second general area of concern, the statutory framework developed for this agency concerning grounds for refusal to issue a license and the grounds for removal of a license contains the same confusion of thought and vagueness of terminology found in the statutes of many other licensing agencies.

The statute erroneously requires the licensing board in many cases to act essentially as a court of competent jurisdiction in determining the legal status of an individual and requires the board to define and apply terms which may have no legal basis. To correct this situation and to place the licensing board in an appropriate setting, the statute dealing with the grounds for disqualification should be structured in such a manner that each of the grounds meet a two-part test. First, the grounds for disqualification should be clear and related to the practice of the profession. As a second part of the test, the grounds for disqualification should be stated in terms of a currently existing condition rather than an absolute condition which exists throughout the lifetime of the individual.

Review of the grounds for denial or revocation of a license set out in the board's statute shows that several fail to meet the test stated above. For example, the applicant is required to be of "good moral character" to be licensed. In addition, the board may refuse to issue a license or may cancel, revoke, or suspend a license for: gross immorality; a felony or misdemeanor which involves moral turpitude; or habitual drunkenness, addiction to certain drugs, or becoming insane. The statute should be restructured so that such provisions comply with the two criteria.

A final concern deals with the delinquency period for the renewal of pharmacist licenses. Although the statute establishes a license expiration date, it provides a grace period which in effect authorizes the continued practice of pharmacy under an expired license without penalty for an additional sixty days. At the end of the grace period, an expired license is automatically suspended and a penalty of one annual renewal fee is imposed in order to renew. This provision does not encourage timely renewal and it authorizes the practice of pharmacy under an invalid license for a period of sixty days. The agency has indicated that as a result of this provision, a significant number of licenses are renewed during this grace period. Also, the statute contains no provisions which require a pharmacist who has failed to renew a license for a substantial period to demonstrate competency in order to renew a license. Given the complex and rapidly-developing nature of pharmaceutical practice, the absence of statutory provisions establishing competency requirements for relicensure of former licensees does not serve to ensure that a minimum level of competency is maintained. To address these concerns, the statute should be modified to 1) provide for the automatic suspension of expired licenses; 2) establish a standard penalty for the reinstatement of expired licenses;

and 3) establish competency requirements for the reinstatement of licenses expired for more than two years.

Enforcement

The basic objective of the enforcement activity is to protect the public by identifying and, when necessary, taking appropriate action against persons not complying with the provisions of the Act or board rules. The workload associated with board enforcement efforts is substantial and often involves coordination with criminal law enforcement agencies. In response to these enforcement needs, the board employs a full-time enforcement staff consisting of a director, six field investigators, and three compliance officers. Additionally, the board has developed a two-component approach to enforcing the Act consisting of both investigation and compliance functions.

Complaints which involve serious violations by licensees are processed through the use of investigations. Action upon these type of complaints usually involve undercover activity and are addressed according to the following priorities: 1) diversion of controlled substances or dangerous drugs; 2) drug-related criminal convictions of licensees; 3) aiding and abetting the unauthorized practice of pharmacy; 4) unauthorized refills; 5) other criminal convictions of licensees; and 6) other violations of related statutes.

The compliance program, which was initiated in 1978, is designed to respond to technical, less serious violations and to encourage voluntary compliance. Compliance functions include routine inspections of pharmacies, disseminating information concerning statutory requirements and board activities, and providing technical assistance.

The agency utilizes two methods to dispose of complaints: 1) informal disposition, as authorized under the Administrative Procedure Act and 2) formal

hearing proceedings before the board. Exhibit III-7 indicates the number and source of complaints while Exhibit III-8 provides dispositional data.

Exhibit III-7

SOURCE AND NUMBER OF COMPLAINTS 1977-1979

Source	1977	1978	1979	Total
Consumer	3	20	40	63
Licensee	23	54	71	148
Referral from Another Agency	29	66	88	183
Agency Inspection	--	4	4	8
General Public	2	3	--	5
Health Practitioner	11	6	13	30
Intelligence Reports	52	14	13	79
Other	4	40	21	65
Total	124	207	250	581

Exhibit III-8

DISPOSITION OF COMPLAINTS

Disposition	1976	1977	1978	1979	Total
Revocation	2	4	19	13	38
Suspension	14	16	14	10	54
Fine Only	--	--	--	19	19
Fine and Suspension	25	15	13	13	66
Warning Notice	43	36	173	119	371
No Action Required	--	--	14	8	22
Total	84	71	233	182	570

Review of the enforcement activity indicates that the compliance, investigation and disposition processes employed by the board provide efficient and effective methods for reviewing and disposing of the complaints filed with the agency. In general, the enforcement activity functions well, however, review of this activity identified two concerns: 1) disposition of the revenue received from disciplinary fines and 2) the need for additional enforcement authority.

With respect to the first concern, current statutory provisions authorize the board to impose on licensees disciplinary fines up to $250 per violation. Additionally, the statute provides that these fines are to be deposited in agency accounts for use by the board in administering the Act. While the authority to impose fines is not commonly found in other licensing agencies, the board has made effective use of this sanction in eighty-five cases during the last four fiscal years. Review of the agency's use of this sanction revealed no evidence to suggest abuse of this authority; however, a potential conflict of interest exists because revenues from fines are available for use by the board. Thus, the authority to impose fines is subject to the criticism that it is used to generate additional revenue. To remove the potential for conflict of interest and eliminate the basis for the criticism that fines may be imposed to generate funds, the statute should be modified to provide that all funds generated through fines imposed by the board be deposited in the General Revenue Fund and not be available for use by the board.

With regard to the second concern, the review indicated that better enforcement of the Act could be achieved if the board were given greater enforcement authority in the three areas discussed below. At present, the statute authorizes the board to impose a variety of sanctions; however, the authority to probate suspensions is not included. Because of the continuous public need for pharmaceu-

tical services and the absence, in many instances, of alternative sources, this authority can often be an appropriate response to violations. To satisfy its need for such a penalty, the board has used a procedure of holding suspensions in abeyance, although no clear authority exists for such a procedure. As a general principle, an agency's range of penalties should be able to conform to the seriousness of the offenses presented to it. Modification of the statute to authorize the probation of suspensions under conditions imposed by the board would provide a flexible intermediate penalty to more effectively address the enforcement needs of the agency.

The second area in which increased authority would assist enforcement efforts relates to the statutory grounds for taking disciplinary action against a licensee. Current provisions identify the basis for pursuing enforcement action, however, violations of the Pharmacy Act, board rules, the Controlled Substances Act, and the Dangerous Drug Act are not specifically included. Similar authority is a fundamental element of most licensing laws and the review indicates that the exclusion of such violations in the Pharmacy Act creates, in some instances, unclear authority for agency action. The board should have clear statutory authority to initiate disciplinary action with regard to such violations. To accomplish this, the statute should be modified to expand the grounds for applying board sanctions to include violations of the Pharmacy Act, board rules and regulations, the Controlled Substances Act, and the Dangerous Drug Act.

The final area in which the need for increased enforcement powers is indicated involves the authority of the board to inspect facilities licensed by the board. Because of its statutory mandates from the Dangerous Drug Act and the Pharmacy Act, the agency is responsible for the adequate control and proper distribution of all prescription drugs by pharmacies. One method for the agency to

ensure that such drugs are properly maintained and accounted for is through the inspection of pharmacies. Such inspections do not require that agency personnel review a pharmacy's financial records, such as sales data; however, adequate inspections do require access to prescription drug records and inventories.

Currently, the board conducts inspections through the voluntary consent of pharmacies. The review indicated that only a small number of pharmacies have refused permission. However, provisions of the statute do not grant expressed authority to inspect the pharmacies licensed by the board. This lack of authority prevents the board from fully satisfying its responsibility to assure compliance with drug laws. Modification of the Pharmacy Act could ensure that the board has authority to investigate and enforce possible violations of statutory provisions. Such modification should clearly authorize the board to inspect licensed facilities with regard to: 1) equipment, sanitary conditions, drug storage and security; and 2) prescriptions, prescription drug inventories and invoices but should exclude financial, sales, and pricing data.

Summary

The Texas State Board of Pharmacy is composed of six registered pharmacists appointed to a six-year overlapping terms by the governor with the advice and consent of the senate. The board is mandated by statute to regulate the practice of pharmacy through the licensure of all qualified pharmacists, pharmacies, and drug manufcturers and the enforcement of statutory provisions.

Operations of the board can be broken down into three activities: administration, licensing, and enforcement. With regard to administration, the board generally meets the objective of effective and efficient management. However, four concerns were identified in the review of the administration activity. The

first concern results from the fact that the agency is currently authorized to maintain its funds outside the Treasury and its expenditures are therefore not subject to the appropriations process. Because the agency is not in the appropriations process, it is not subject to standard practices and controls for efficient and accountable management developed by the legislature for most state agencies. Examples of agency activities which would be subject to greater control in the appropriative process include the purchasing or leasing of automobiles, the hiring of outside legal counsel, and the determining of total amounts available to board members for travel and per diem. To ensure that future agency operations adhere to the state's general standards for efficient management, the board should be included in the appropriations process.

A second concern relates to the fixed statutory limits on the agency's fee structure. To eliminate the need for legislative adjustment of maximum fees allowable on a continual basis and to give the board the flexibility to adjust its fee structure to cover the cost of its operations as its requirements change, the Act should be amended to authorize the board to set reasonable and necessary fees. The third concern relates to the unnecessary annual reporting requirements currently imposed upon the board. These reporting requirements should be modified to correspond with the general provisions of the appropriation act so that the board's annual report will be consistent with annual reports prepared by most other state agencies.

A final administrative concern involves a statutory provision which requires that all board members be engaged in the practice of retail pharmacy. As this qualification restricts nearly one-third of the current licensees from membership, it should be deleted from the statute.

The review identified three aspects of the licensing activity that could be improved. First, the board presently has no authority to determine eligiblity for intern supervisors, other than the statutory licensure requirement. To provide additional assurances that pharmacist-interns are exposed to proper practice and procedures, the statute should be amended to authorize the board to establish reasonable guidelines for the approval of intern supervisors.

Second, grounds for refusal to allow an individual to sit for the examination and grounds for removal of a license once issued should meet a two-part test. Grounds should be clear and related to the practice of the profession and should be stated in terms of a currently existing condition rather than an absolute condition which exists throughout the lifetime of the individual. Some of the grounds in the Act do not meet this test. The statute should be restructured so that such provisions comply with the criteria.

Finally, the current statute authorizes a grace period for the renewal of pharmacist licenses which in effect allows the continued practice of pharmacy under an expired license. Because this provision does not encourage timely license renewals and does not recognize the need to redetermine competence when a licensee has not practiced for a substantial period of time, the Act should be amended to provide for: 1) the automatic suspension of expired licenses; 2) a standard penalty for reinstatement of expired licenses; and 3) competency requirements for the reinstatement of licenses expired for more than two years.

Two concerns were identified with regard to the enforcement activities of the agency. The first concern relates to a potential conflict of interest which may result from making available to the agency revenues generated through the imposition of disciplinary fines. To remove the potential conflict of interest and

eliminate the basis for the criticism that fines may be imposed to generate agency revenue, the statute should be modified to provide that all funds generated through disciplinary fines imposed by the board be deposited in the General Revenue Fund and not be available for board use.

A second enforcement concern involves the board's limited enforcement authority in certain areas. This enforcement authority could be enhanced through the authorization to probate suspensions; the authorization to take disciplinary action against licensees for violations of the Pharmacy Act, board rules, the Controlled Substances Act, and the Dangerous Drug Act; and the authorization to inspect licensed facilities.

IV. ALTERNATIVES AND CONSTRAINTS

The material presented in this section combines several sunset criteria for the purpose of evaluating the activities of the agency. The specific criteria covered are the extent of overlap and duplication with other agencies and the potential for consolidation with other agencies; an assessment of less restrictive or alternative methods of performing any regulation that could adequately protect the public; and the impact in terms of federal intervention or the loss of federal funds if the agency is abolished.

Consolidation Alternatives

In order to identify consolidation alternatives which have potential application in Texas, organizational patterns of regulation used in other states were surveyed. The review indicated that all fifty states regulate the practice of pharmacy through the licensure of pharmacists and pharmacies on a statewide basis. In thirty-three states, including Texas, an independent board is utilized to administer and enforce the licensure of pharmacists. Ten states perform the regulation through a board which is attached to an "umbrella" type regulatory agency. The remaining seven states maintain a board which is organizationally included within the framework of an agency with other substantive responsibilities, such as, the department of health or the secretary of state.

Apart from the regulatory scheme which employs an occupational licensing "umbrella" agency, all of the organizational structures described above which are responsible for regulation in other states, exist in Texas. Additionally, several state agencies in Texas are involved to some degree in the regulation and control of the manufacture, distribution, and dispensing of prescriptive drugs. The Department of Public Safety is mandated through the Texas Controlled Substances

Act to regulate the distribution and possession of drugs which have been determined to have a potential for abuse. Under the Texas Food, Drug and Cosmetic Act and its own enabling legislation, the Department of Health is directed to register manufacturers, wholesalers, and distributors of all drugs, as well as, to protect the public from contaminated, adulterated or misbranded drugs. Also, boards which license practitioners of medicine, dentistry, chiropody, and veterinary medicine regulate professions through which prescriptive drugs are administered or supplied.

To determine whether any of these organizational structures would be suitable in Texas, the consolidation alternatives were examined in light of present levels of regulation to ascertain whether the goals and functions of the agencies involved were consistent with those of the Board of Pharmacy. Also, these alternatives were reviewed in terms of potential benefits which would accrue as a result of the consolidation of functions.

This analysis of organizational alternatives available in Texas indicates that the current independent board best performs the regulation of the practice of pharmacy and that consolidation attempts would impede the effectiveness of regulation. As evidenced by the organization of regulatory efforts in other states, the practice of pharmacy involves a very specialized segment of the drug distribution chain--that of dispensing drugs authorized through prescription--and is appropriately regulated through an independent board which has expertise in the pharmacy field. The review indicates that the transfer of the current functions to another agency which performs similar functions would not appreciably reduce the personnel or expenses necessary to administer the present level of regulation. Thus, consolidation efforts would not appear to increase the efficiency or effectiveness of the agency operation.

One area of regulation performed by the Board of Pharmacy--that of licensing drug manufacturers--constitutes a duplication of the regulation performed by the Department of Health. This area of drug regulation is more closely related to the protection of the public from contaminated or misbranded drugs and thus to the Department of Health's mandate under the Food, Drug and Cosmetic Act than to the drug dispensing function which is of primary concern to the Board of Pharmacy. Therefore, to prevent duplication of regulatory functions and to more appropriately place regulatory responsibility, the sole responsibility for licensure of drug manufacturers should be placed with the Department of Health, thereby eliminating the Board of Pharmacy's authority in this area.

Regulatory Alternatives

In addition to the various organizational patterns which are used to regulate the practice of pharmacy, several methods of regulation exist which could be used to protect the public from incompetent pharmaceutical practices. Currently, the regulatory authority of the board includes the licensure of pharmacists and facilities. To give a clearer focus to the activities currently regulated in light of possible regulatory alternatives, the scope of regulation has been considered in two separate parts--the regulation of pharmacists and the regulation of facilities.

In regard to pharmacists, a single regulatory method is presently in force in all states to protect the public from incompetent pharmacists. This type of regulation involves the licensure of individuals upon fulfillment of statutory requirements.

In the area of regulation of facilities, all fifty states have chosen to license retail pharmacies. Pharmacies which prepare radioactive compounds are generally included in this group. While all states regulate hospital pharmacies on an outpatient basis, thirty-six states also regulate the inpatient practice of pharmacy.

One other area of facility regulation which is not clearly addressed in many states is the clinic practice setting. These facilities are potentially subject to regulation because prescription drugs are regularly dispensed in the provision of services. The types of facilities in Texas that might be regulated in this area include: planned parenthood clinics, rural health clinics, public health clinics and venereal disease clinics.

Before any regulatory alternative reviewed can be considered as a reasonable alternative to current regulation in Texas, the option should offer at least the same degree of public protection as the current method. In addition, the alternative should be less restrictive than the present system. The analysis of alternative regulatory methods with regard to pharmacists indicated that due to the experience in other states and the few safeguards against incompetent pharmaceutical practices afforded through less restrictive approaches, alternative methods of regulation appear to offer little benefit over the current method of regulation through licensure. This approach provides an adequate level of public protection without unnecessarily restricting entry into the profession.

With regard to the regulation of facilities, the analysis indicated that licensure provides an adequate level of public protection. However, in order to provide a less restrictive approach while maintaining adequate public protection, the regulation should conform to the practice of pharmacy in various settings. Under this approach, distinct classes of facility licensure would be established.

Review of the settings in which the practice of pharmacy presently occurs in Texas identified four distinct types. If regulation were to be applied with varying degrees of restrictiveness in Texas, each of these pharmacy settings would require a separate class of license. Under this regulatory alternative, community or retail pharmacies would be regulated under a Class A license and would essentially be

subject to all currently imposed restrictions. The Class B license would provide for the regulation of nuclear pharmacies and would allow the board to promulgate regulations directly relevant to the compounding of radioactive pharmaceuticals. Under an institutional license, Class C, the board would have the authority to regulate hospital pharmacy practice. The board would be authorized to establish standards of practice, but would be prohibited from limiting the use of supportive personnel. The Class D license would regulate the practice of pharmacy in clinics. The board would be authorized to establish appropriate standards of practice; however, persons other than registered pharmacists would be allowed to dispense medications under the supervision of a registered pharmacist. Such an approach to the regulation of facilities in Texas would ensure that the public is adequately protected while allowing a greater degree of flexibility to adjust restrictions and regulations, thereby providing a more appropriate and less restrictive response to the need for regulation.

Federal Constraints

Presently, no specific federal legislation attempts to certify the competency of persons who practice pharmacy in Texas, and no federal funds are channeled to the state for that purpose. There are, however, federal standards in several programs that require services to be provided by pharmacists licensed by the state. For example, Title 19 of the Social Security Act (Medicaid) requires that prescriptions be filled by licensed pharmacists in licensed pharmacies. Should the state discontinue licensing pharmacists and pharmacies, a possible suspension of pharmacy activities in federally-funded programs could occur and result in the loss of federal dollars.

Summary

A review of agencies regulating the practice of pharmacy in other states was conducted to determine the potential for combining the regulation of pharmacy in Texas with the functions of another agency. All states regulate the practice of pharmacy, with independent boards performing the regulatory functions in thirty-three states. The remaining seventeen states accomplish regulation through boards attached to an "umbrella" type agency or an agency with other substantive responsibilities. Review of Texas agencies with related functions indicated that no advantage would result from consolidation of the Board of Pharmacy with another agency. However, in one regulatory area - that of drug manufacturing - licensing responsibility is currently vested in both the Board of Pharmacy and the Department of Health. Sole responsibility for licensure of drug manufacturers would most appropriately be placed with the Department of Health.

With regard to regulatory alternatives, all fifty states regulate the practice of pharmacy through the licensure of pharmacists and retail pharmacies. Thirty-six of these states also regulate hospital drug dispensing facilities for inpatient care. Analysis of regulatory alternatives revealed no practical alternative to the licensure of pharmacists but identified one alternative with regard to the licensure of pharmacies. An adequate level of public protection could be provided in a manner less restrictive than the present statute allows through separate licenses based on the type of pharmacy to be regulated. Review of pharmacy settings in Texas indicated the need for four classes of license: a) Community Pharmacy; b) Nuclear Pharamcy; c) Institutional Pharmacy; and d) Clinic Pharmacy. Such an approach to the regulation of pharmacy would allow the board, through limited rule-making authority, the flexibility to determine and establish procedures most appropriate for the different types of facilities.

With regard to federal constraints, the review indicated that although no federal statutes address the certification of pharmacists, several federal programs, such as Medicaid, require pharmaceutical services to be provided by a licensed pharmacist and pharmacy.

V. COMPLIANCE

The material presented in this section combines several sunset criteria for the purpose of evaluating the activities of the agency. The specific criteria covered are the extent to which the agency issues and enforces rules relating to potential conflict of interest of its employees; the extent to which the agency complies with the Open Records Act and the Open Meetings Act; and the extent to which the agency has complied with necessary requirements concerning equality of employment opportunities and the rights and privacy of individuals.

In its efforts to protect the public, the agency's operations should be structured in a manner that is fair and impartial to all interests. The degree to which this objective is met can be partially judged on the basis of potential conflicts of interest in agency organization and operation, as well as agency compliance with statutes relating to conflicts of interests, open meetings, and open records.

Conflict of Interest

Board members, as appointed state officers, are subject to statutory standards of conduct and conflict-of-interest provisions (Article 6252-9b, V.A.C.S.). A review of the documents filed with the Office of the Secretary of State indicates that the board has only partially complied with the statutory requirements regarding the disclosure of substantial business interests which are regulated by a state agency. Financial disclosure affidavits for two present board members, who have substantial business interests which are regulated by the board, have not been filed with the Secretary of State's Office. The agency has been contacted concerning this matter and has indicated that both board members will comply with this requirement.

The agency's self-evaluation report and the board minutes suggest that board members have not had reason to disqualify themselves from deliberation of matters because of personal or financial interests; however, board members have abstained from voting during violation hearings on cases where the board member had access to prior information regarding the cases.

Open Meetings - Open Records

The regular board meetings conducted by the Board of Pharmacy show general compliance with the requirements of the Texas Open Meetings Act. A review of board minutes and publications indicates that board meetings have been preceded by adequate and timely notice to the public. However, one procedure utilized by the board during formal violation hearings is not in full compliance with open meeting requirements. This procedure improperly allows the board to close a formal hearing to the general public and to the licensee involved while deliberating as to the board's final decision in the matter. Attorney General Opinion H-1269 (1979) specifically states that the Open Meetings Act applies to formal hearing proceedings mandated under the Administrative Procedure Act. Therefore, board policy should be revised so that board deliberations may be closed to the public only when such closed sessions are authorized by the Open Meetings Act.

In response to formal requests for information under the provisions of the Open Records Act, the agency has never refused to make the information available to the requestor. As shown in the agency's self-evaluation report, six types of agency records are considered to be confidential by the agency -- investigative records, compliance records, exam questions and answers, names and addresses of investigators, personnel records, and elements of exam applications. Since no formal requests for the above types of information have been submitted to the board, no official determination (open records decision) regarding the confidential

or public nature of the documents has been made.

Employment Policies

The agency is operating under a current Affirmative Action Plan which includes formal grievance procedures and personnel selection policies. No formal complaints in the area of employment practices have ever been received by the agency.

An analysis of the board's work force at the time of the review indicates that three of the eighteen full-time employees are minorities. Of these three, one is an hispanic male employed as director of investigations, one is a black male employed as an investigator, and one is an hispanic female employed as a clerk. Also, eight of the eighteen staff members are female.

Summary

Although the board generally complies with the requirements outlined in the conflict-of-interest statute, the Open Meetings Act, and the Open Records Act, a review of agency documents and activities indicates that statutory requirements were not fully met in two instances. First, two board members had not filed the requisite financial disclosure affidavits with the Secretary of State's Office. Also, board procedures which allow certain portions of formal hearings to be closed to the public do not conform to the requirements of the Open Meetings Act. In the area of employment practices, no formal complaints have been filed against the agency.

VI. PUBLIC PARTICIPATION

The review under this section covers the sunset criterion which calls for an evaluation of the extent to which the agency has encouraged participation by the public in making its rules and decisions as opposed to participation solely by those it regulates and the extent to which the public participation has resulted in rules compatible with the objectives of the agency.

The extent to which the agency has involved the public in agency rules and decisions can be judged on the basis of agency compliance with statutory provisions regarding public participation, the nature of rule changes adopted, the availability of information concerning rules and agency operations, and the existence of public members on the commission.

Agency Activities

A review of the extensive rule changes proposed and adopted by the board during the last four fiscal years indicates that procedures used for the adoption of these rules have been in compliance with public participation requirements found in general state law. Although the board has experienced only limited public involvement in this rule-making process, agency rule-making procedures are designed to allow an adequate level of public participation. While public hearings on proposed rules are held by the board only when sufficient interest is demonstrated, opinions concerning a proposed rule can be brought to the board's attention through written communications or comments at regular board meetings.

Agency efforts to inform the general public and licensees of board functions have been primarily directed toward licensees and other state agencies involved in related activities. These efforts presently include the publication of a quarterly

newsletter which is distributed to all pharmacists, pharmacy schools, consumer groups, legislators, and interested state and federal agencies. The publication, "Texas Pharmacy Act and Rules of Procedure", also is made available to all examination or reciprocity applicants, pharmacy schools, and professional groups. Single copies of these publications are available upon request at no charge.

Public Membership

A review of the statutory composition of the board shows the absence of any members from the general public. The lack of such members eliminates one means by which the point of view of the general public in the development of rules and the deliberation of other matters can be represented. To provide an adequate level of public representation, the board composition could be modified to consist of four members who are registered pharmacists and two members of the general public. The public members could replace licensee members as their terms expire. This approach would achieve the desired one-third public membership without increasing the size of the board or removing present members during their term of appointment.

Summary

Although the board has complied with the necessary notification and hearing requirements, participation by the general public in the rule-making process of the board has been minimal. Board efforts to inform the public of agency operations have been limited to the distribution of two publications. To help ensure that the public's point of view is properly represented, the board's composition should include one-third public members who could replace current pharmacist members as their terms expire.

VII. STATUTORY CHANGES

The material presented in this section combines several sunset criteria for the purpose of evaluating the activities of the agency. The specific criteria covered are whether statutory changes recommended by the agency or others were calculated to be of benefit to the public rather than to an occupation, business, or institution the agency regulates; and statutory changes recommended by the agency for the improvement of the regulatory function performed. In the period covering the last four legislative sessions, the review focused on both proposed and adopted changes in the law. Prior to that period, the staff review was limited to adopted changes only.

Past Legislative Action

Regulation of the practice of pharmacy in Texas has been substantially modified three times since the passage of House Bill No. 125 by the Twenty-first Legislature in 1889. The legislation of 1889 created a regulatory structure providing for the one-time registration of pharmacists and their assistants by district boards. The practice of pharmacy was defined as compounding medicines and preparing physicians' prescriptions, and the only requirements for pharmacist registration were that an applicant be twenty-one years old and pass a pharmacy examination. Exemptions under this first regulatory effort included practice in towns of less than 1,000 population, pharmacy assistants with three years experience, drugstore proprietors engaged in preparing prescriptions, and medical practitioners.

A new regulatory structure was adopted through enactment by the Thirtieth Legislature of Senate Bill No. 82 in 1907. This legislation created the State Board of Pharmacy and established a licensing structure which continued with only one change for the next twenty-two years. The board, composed of five pharmacists

serving two-year terms, was mandated to regulate the retail dispensing of any drug through the annual licensure of pharmacists and their assistants. Licensure requirements were increased to include both experience and examination, although no specialized education was required. Exemptions continued for pharmacists' aides, medical and dental practitioners, and drug wholesalers. The only modification to the 1907 legislation occurred in 1919 with passage by the Thirty-sixth Legislature of Senate Bill No. 91 which increased license renewal fees to $3 and authorized the board to transfer up to $2 of these fees to the State Pharmaceutical Association.

New legislation (Senate Bill No. 49, Forty-first Legislature), enacted in 1929, significantly modified the regulation of pharmacy. The board was enlarged to six pharmacists with six-year terms and was granted rulemaking authority. Provisions for the licensure of assistants in pharmacy were deleted, and requirements for pharmacists were increased to include graduation from a pharmacy school and one year's experience. Transfer of a portion of licensing fees to the state association was made mandatory; the board's authority to revoke licenses for conviction of specified offenses was increased; and the permitting of pharmacies was mandated. This regulatory design continued for fourteen years with only one modification -- House Bill No. 356, Thirty-fifth Legislature, 1935, eliminated the transfer of licensing fees to the state association.

In 1943, regulation was again restructured through amendments (Senate Bill No. 128, Forty-eighth Legislature) to the 1929 legislation. The scope of board authority was broadened to include such acts as labeling drugs for retail sale. Four-year pharmacy school programs were required for licensure, and the board's revocation authority was made discretionary for such causes as gross immorality, incompetence through negligence, habitual drunkenness, drug addiction, or insanity.

Since 1943, some sixteen legislative changes have modified the regulation of pharmacy. Many of these changes have dealt with increasing fee amounts. Between 1943 and 1979, annual renewal amounts increased for pharmacists from $5 to $35 and for pharmacies from $2 to $50, while per diem for board members also rose from $10 to $75. However, five particularly significant legislative amendments were also adopted during this period, the first of which was Senate Bill No. 268, Fifty-second Legislature in 1951. This legislation exempted hospitals and clinics from regulation of the practice of pharmacy. In 1959, House Bill No. 488, Fifty-sixth Legislature, modified the scope of the Act by authorizing: 1) permits for pharmaceutical manufacturers; 2) revocation of pharmacist licenses for substitution of one brand of prescription drug for another without the prescribers consent; and 3) revocation of pharmacy permits for advertising prices of prescription drugs. The Sixty-third Legislature in 1973 further modified the regulation of pharmacy by adopting Senate Bill No. 369 which authorized the use of board-imposed fines up to $250 per violation, and by passing House Bill No. 750 which restricted the use of price information by pharmacies except for the posting of prices for the 100 most prescribed drugs in a board-approved format. In 1979, the Sixty-sixth Legislature removed all restrictions on advertising except for that which was false or misleading, and repealed the provisions requiring posting of certain prescription drug prices (House Bill No. 2080).

Proposed Legislative Action

A review of the legislation introduced in the last four legislative sessions, reveals that forty bills affecting the board were unsuccessfully submitted. Exhibit VII-1 identifies these proposals by subject area, legislative session, and bill number. A general description of these bills is presented below.

Generic drug substitution (product selection) has been addressed by eleven bills. Several of these proposals would have created a formulary commission to establish guidelines for the substitution of prescribed drugs. Four pieces of legislation were introduced to allow advertisement of certain drug prices and services. The regulation of pharmaceutical salesmen was proposed by two bills. Two proposals would have created a tripartite commission to establish continuing education requirements for pharmacists.

Several pieces of legislation were introduced with regard to prescription drugs: four bills addressed the dispensing of prescription drugs; two bills would have restricted the distribution of drug samples by manufacturers; and two proposals would have required additional manufacturer information on drug labels. Also, controlled substances and dangerous drugs were addressed by four bills.

Proposals which would have affected administrative provisions included: two bills which provided for the board to receive fines for pharmacy law violations; and two bills which would have modified the composition of the board to include hospital pharmacists and public members.

Additionally, three bills would have established other requirements such as: providing for the inclusion of bioavailability data on all drugs; requiring pharmacists to maintain a patient profile; and restricting financial transactions between pharmacists and nursing homes.

The agency has also recommended several changes to its statute in its self-evaluation report. These recommended changes include: providing commissioned peace officer status for investigative staff; granting the board search, seizure and embargo powers; authorizing the board to license drug wholesalers; extending board jurisdiction to include pharmacy supportive personnel; authorizing the board to inspect any facility possessing dangerous drugs; establishing registration and fee

requirements for pharmacist-interns; and establishing biennial license renewal requirements. In general, the changes sought by the agency would significantly expand statutory authority in areas dealing with enforcement, drug distribution, and licensee regulation.

Exhibit VII-1

PROPOSED LEGISLATIVE CHANGES BY SUBJECT AREA

Generic Drug Substitution

63rd Session - H.B. 546
- S.B. 371
64th Session - H.B. 21
- H.B. 1371
65th Session - H.B. 10
- S.B. 33
- S.B. 63
66th Session - H.B. 13
- H.B. 393
- H.B. 445
- S.B. 601

Advertising Provisions

63rd Session - H.B. 750
- S.B 170
- S.B. 400
65th Session - H.B. 11

Controlled Substances and Dangerous Drugs

63rd Session - H.B. 483
- H.B. 497
- H.B. 1399
64th Session - H.B. 1332

Continuing Education

65th Session - H.B. 2211
66th Session - H.B. 1291

Drug Dispensing

63rd Session - H.B. 498
64th Session - H.B. 18
- H.B. 19
- H.B. 1228

Drug Sample Restrictions

64th Session - H.B. 1154
65th Session - H.B. 12

Regulation of Pharmaceutical Salesmen

65th Session - H.B. 1970
- H.B. 2117

Labeling Requirements

65th Session - H.B. 1809
- S.B. 888

Citizenship Requirements

63rd Session - H.B. 964
- S.B. 744

Board Composition

63rd Session - S.B. 668
64th Session - H.B. 64

Receipt of Fines

63rd Session - H.B. 506
- S.B. 369

Other Proposals

Maintaining a Patient Profile
63rd Session - H.B. 756

Requiring Bioavailability Data
63rd Session - H.B. 757

Restricting Certain Financial Transactions
63rd Session - H.B. 414

Summary

Regulation of the practice of pharmacy in Texas has been substantially modified three times since passage of initial regulatory legislation in 1889. However, the Texas Pharmacy Act has been amended sixteen times since its last major restructuring in 1943. Generally these legislative enactments have broadened the definition of those activities constituting the practice of pharmacy, enlarged the number of entities required to be licensed, increased licensure requirements and fees, and augmented board enforcement authority.

During the last four legislative sessions, forty bills to amend the Pharmacy Act have been unsuccessfully introduced. The most frequent subject of this proposed legislation has been generic drug substitution. In addition, several bills have been introduced with regard to price advertising for, dispensing of, and restricting access to prescription drugs.

The Board of Pharmacy recommends several statutory changes in its self-evaluation report. Among these are the following: 1) registering pharmacist interns; 2) regulating pharmacy support personnel; 3) licensing drug wholesalers; 4) commissioning investigative staff as peace officers; and 5) granting the board search, seizure, and embargo powers.