TEXAS STATE BOARD OF PHARMACY

STRATEGIC PLAN

...or the Fiscal Years 1999-2003 Period

Board Member	Dates of Term	Hometown
Gilbert Acuna, R.Ph.	3/22/1994-8/31/1999	Kingsville
Kim A. Caldwell, R.Ph.	10/27/1997-8/31/2003	Plano
Wiki Erickson	10/27/1997-8/31/2003	Waco
Roberta W. High, R.Ph.	2/13/1996-8/31/2001	Haskell
Susan H. Jacobson	3/22/1994-8/31/1999	El Paso
Wayne McConnell, CPA	2/13/1996-8/31/2001	Houston
Oren M. Peacock, Jr., R.Ph.	2/13/1996-8/31/1999	Sachse
...ll C. Pittman, R.Ph.	2/13/1996-8/31/2001	Austin
...onna Burkett Rogers, R.Ph.	10/27/1997-8/31/2003	San Antonio

June 15, 1998

TEXAS STATE BOARD OF PHARMACY STRATEGIC PLAN 1999-2003

TEXAS STATE BOARD OF

STRATEGIC PL

For the Fiscal Years 1999-2

Board Member	Dates of Term	Hometown
Gilbert Acuna, R.Ph.	3/22/1994-8/31/1999	Kingsville
Kim A. Caldwell, R.Ph.	10/27/1997-8/31/2003	Plano
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June 15, 1998

Signed: _____
Gay Dodson, R.Ph.
Executive Director/Secretary

Approved: _____
Susan H. Jacobson
President

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THE VISION OF TEXAS STATE GOVERNMENT

Together, we can make Texas a beacon state. A state where our children receive an excellent education so they have the knowledge and skills for the next century. A state where people feel safe in their communities, and all people know the consequences of committing a crime are swift and sure. A state where our laws encourage jobs and justice. A state where each citizen accepts responsibility for his or her behavior. A state where our greatest resource — our people — are free to achieve their highest potential. We envision a state where it continues to be true that what Texans can dream Texans can do.

THE MISSION OF TEXAS STATE GOVERNMENT

The mission of Texas state government is to support and promote individual and community efforts to achieve and sustain social and economic prosperity.

To realize the vision of a better Texas, state government must focus on its key responsibilities to its citizenry. State government should concentrate its energies on a few priority areas where it can make a difference, clearly define its functions within those areas, and perform those functions well. State government must look for innovative ways to accomplish its ends, including privatization and incentive-based approaches. Our imperative should be: "*Government if necessary, but not necessarily government.*"

THE PHILOSOPHY OF TEXAS STATE GOVERNMENT

State government will be ethical, accountable, and dedicated to serving the citizens of Texas well. State government will operate efficiently and spend the public's money wisely.

State government will be based on four core principles that will guide decision-making processes.

Limited and Efficient Government

Government cannot solve every problem or meet every need. State government should do a few things and do them well.

Local Control

The best form of government is one that is closest to the people. State government should respect the right and ability of local communities to resolve issues that affect them. The state must avoid imposing unfunded mandates.

Personal Responsibility

It is up to each individual, not government, to make responsible decisions about his or her life. Personal responsibility is the key to a more decent and just society. State employees, too, must be accountable for their actions.

Support for Strong Families

The family is the backbone of society and, accordingly, state government must pursue policies that nurture and strengthen Texas families.

Texas state government should serve the needs of our state but also be mindful of those who pay the bills. By providing the best service at the lowest cost and working in concert with other partners, state government can effectively direct the public's resources to create a positive impact on the lives of individual Texans. The people of Texas expect the best, and state government must give it to them.

RELEVANT STATEWIDE GOAL AND BENCHMARK

Priority Goal

To ensure that Texas consumers are effectively and efficiently served by high quality professionals and businesses by setting clear standards, maintaining compliance, and seeking market-based solutions.

Benchmark

- Percent of state professional licensee population without documented violations.

AGENCY MISSION

To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of: the practice of pharmacy; the operation of pharmacies; and the distribution of prescription drugs in the public interest.

AGENCY PHILOSOPHY

The Texas State Board of Pharmacy will assume a leadership role in regulating the practice of pharmacy and act in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and openness. We affirm that regulation of the practice of pharmacy is a public and private trust. We approach our mission with a deep sense of purpose and responsibility. The public and regulated community alike can be assured of a balanced and sensible approach to regulation.

EXTERNAL/INTERNAL ASSESSMENT

Statutory Basis and Historical Perspective

The Texas State Board of Pharmacy is an independent state health regulatory agency, operating under the authority of its enabling legislation, the Texas Pharmacy Act (Article 4542a-1, V.T.C.S.) and the Texas Dangerous Drug Act (Health and Safety Code, Chapter 483).

The Pharmacy Act states:

> *"It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy and the licensing of pharmacies engaged in the sale, delivery, or distribution of prescription drugs and devices used in the diagnosis and treatment of injury, illness, and disease."*

The Act goes on to say:

> *"The board shall enforce this Act and all laws that pertain to the practice of pharmacy and shall cooperate with other state and federal governmental agencies regarding any violations of any drug or drug-related laws."*

Legislation that first recognized the need for regulation of the practice of pharmacy in Texas was passed in 1889. That year the legislature established boards of *"pharmaceutical examiners"* which were three-man committees in each senatorial district of the State. Pharmacists were examined and certified by these committees, although there was much inconsistency as to standards. Few records were kept and there was no central authority to coordinate the committees' activities.

To bring consistency and centralization to pharmacy practice regulation, the legislature passed the first Texas Pharmacy Act in 1907. This Act established the Texas State Board of Pharmacy as an independent state regulatory board. The first Board members took the oath of office on August 27, 1907, and in September of 1908, the agency was represented for the first time at the annual meeting of the National Association of Boards of Pharmacy (NABP). The agency joined NABP that year and thus reciprocal privileges were established with other member state boards.

The original Texas Pharmacy Act was amended many times from its enactment in 1907 until 1981, when the Act was repealed and replaced with a new practice Act (Article 4542a-1, V.T.C.S.), patterned after NABP's Model Pharmacy Act. In the 1981 Act, the concept of more patient-oriented pharmacy practice began to be recognized. Included in the Act was the following definition for the "*Practice of Pharmacy.*"

> "*Practice of pharmacy means interpreting and evaluating prescription or medication orders, dispensing and labeling drugs or devices, selecting drugs and reviewing drug utilization, storing prescription drugs and devices and maintaining prescription drug records in a pharmacy, advising or consulting when necessary or required by law about therapeutic value, content, hazard, or use of drugs or devices, or offering or performing the services and transactions necessary to operate a pharmacy.*"

Between the passage of the 1981 and 1997 Pharmacy Acts, several major events occurred that had a substantive impact upon the agency. These events are recounted in *Organizational Perspective*. One key area of significant change in the 1993 Pharmacy Act was the inclusion of an updated definition of pharmacy practice which included the concept of pharmaceutical care and established the legal basis for pharmacists' increased involvement in patient care. This definition was again amended during the 1995 and 1997 legislative sessions. The following are key definitions from the Act.

> *"Practice of pharmacy means:*
> *(A) provision of those acts or services necessary to provide pharmaceutical care;*
> *(B) interpretation and evaluation of prescription drug orders or medication orders;*
> *(C) participation in drug and device selection as authorized by law, drug administration, drug regimen review, or drug or drug-related research;*
> *(D) provision of patient counseling;*
> *(E) responsibility for:*
> *(i) dispensing of prescription drug orders or distribution of medication orders;*
> *(ii) compounding and labeling of drugs and devices, except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged prescription drugs and devices;*
> *(iii) proper and safe storage of drugs and devices; or*
> *(iv) maintenance of proper records for drugs and devices;*

(F) performance of a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes); and

(G) administration of immunizations and vaccines under a physician's written protocol.

"Pharmaceutical care is the provision of drug therapy and other pharmaceutical services defined in the rules of the board and intended to assist in the cure or prevention of a disease, elimination or reduction of patient symptoms, or arresting or slowing of a disease process.

"Patient Counseling means the communication by the pharmacist of information, as specified in the rules of the board, to the patient or caregiver, in order to improve therapy by ensuring proper use of drugs and devices.

"Drug regimen review includes the following activities:

(A) evaluation of prescription drug or medication orders and patient medication records for:
- *(i) known allergies;*
- *(ii) rational therapy-contraindications;*
- *(iii) reasonable dose and route of administration; and*
- *(iv) reasonable directions for use;*

(B) evaluation of prescription drug or medication orders and patient medication records for duplication of therapy;

(C) evaluation of prescription drug or medication orders and patient medication records for:
- *(i) drug-drug interactions;*
- *(ii) drug-food interactions;*
- *(iii) drug-disease interactions;*
- *(iv) adverse drug reactions; and*

(D) evaluation of prescription drug and medication orders and patient medication records for proper utilization, including overutilization or underutilization.

"Prospective drug use review means a review of the patient's drug therapy and prescription drug order or medication order, as defined in the rules of the board, prior to dispensing or distributing the drug."

Under the Texas Sunset Law, all state agencies have a limited life. The agency's life cycle is established in the Texas Pharmacy Act for a period of 12 years. As a result of 1993 amendments to the Act, the agency's existence was extended for another 12 years or until September 1, 2005.

The Key Service Population Perspective

In consideration of the agency's Mission Statement, and through the agency Internal and External Assessment, our key service populations are, in priority order:

- **The Citizens of Texas** — directly and indirectly through service to Texas Legislators, who represent their constituents;
- **Licensees** — pharmacists and pharmacy owners; pharmacy students and pharmacist interns;
- **Executive and Judicial Officials and Other State and Federal Agencies;**
- **The Pharmacy Education Community**; and
- **Health-Related Corporations and Professional Associations.**

In focusing on our #1 key service population, the citizens of Texas, the agency recognizes the changing demographics of the state's population as stated in *Forces of Change*, published in March 1994 by the Texas Comptroller of Public Accounts:

> *"Texas has grown feverishly from its days as a fledgling state, and it'll continue to grow during the next 30 years. Although slower economic growth will stem the tide of newcomers, the Texas population will undergo marked changes and, like the economy, become increasingly diverse.*
>
> *"The huge Baby Boom generation, now entering middle age, will be approaching retirement . . .*
>
> *"One reason that the fastest-growing age group in Texas will be those 65 years and older is that we will be living longer. With better access to health benefits and improved medical care, for example, life expectancy for Texans born in 1990 was 75.1 years, up 3.2 years from 1970, according to the state Department of Health.*
>
> *"The single most important factor causing the elderly population to*

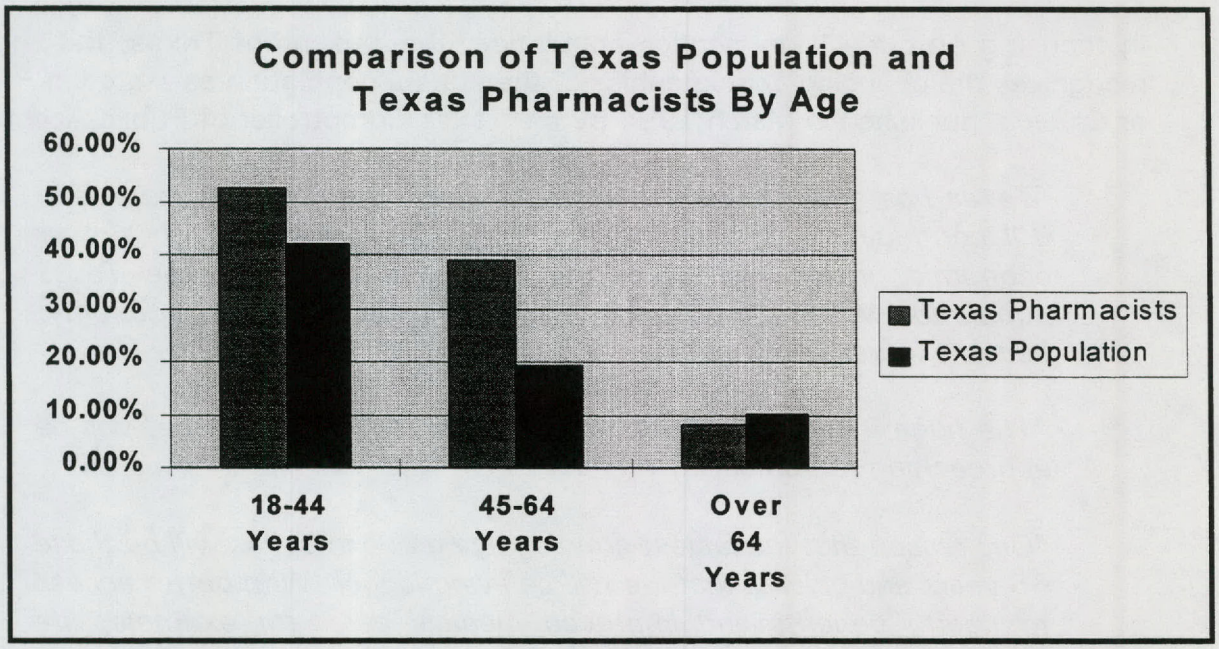
swell will be the graying of the Baby Boomers, the largest generation in U.S. history. Early in the next century, the Boomers' leading edge will begin settling into retirement, causing the 65 and older Texas population to balloon from a current 1.7 million to 3.9 million by the year 2025. . . . And along with economic clout will come political power, pushing the call for more health care and other programs or services for older Texans.

"The fastest-growing major racial or ethnic group by far will be Hispanics, whose numbers will jump from 26 percent of the population in 1990 to 38 percent in 2025. Meanwhile, the Anglo percentage of the population will fall from 61 percent to 47 percent.

"By 2025, no discussion of racial or ethnic majorities will ring true; all Texans will be members of a minority group."

With the above trends, the agency is presented with a challenge and a demand that we explore and respond to the patient care needs of every age and ethnic group, literacy level, and income level. **Chart 1** below shows a comparison of age distribution among the overall Texas civilian labor force, and the Texas pharmacist population.

Chart 1



Based on 1997 Texas Population of 19,128,261 and a Pharmacist Population of 19,182

The perception of the agency by its customers ranges from one end of the spectrum (the agency being nonexistent) to the other (the agency being extremely effective and dynamic) — all of which seem to be directly related to the knowledge base of the customers in question. The majority of general consumers have limited knowledge of the agency, and seem to perceive that we only exist to *"punish"* incompetent pharmacists. More informed consumers, however, realize that the agency can serve as an advocate for consumer groups throughout Texas' communities, not only in the adjudicative (reactive) sense, but in the educational (proactive) sense.

Other state agencies, other pharmacy-related organizations, the Legislature, and other law-enforcement entities routinely view the agency as a model of efficiency, effectiveness, and innovation. Following in this tradition, increased customer input has been sought in developing this *Strategic Plan*. A list of the organizations whose comments we solicited and a list of those responding to our invitation to comment appear in Appendix A.

The Main Functional Perspective

Of paramount consideration to the agency are the vitality and health of Texas' citizens, with a particular emphasis on consumer protection. The agency is acutely aware of its overall responsibility to regulate the practice of pharmacy in the State of Texas in the public interest.

In fulfilling its statutory mandate (and mission), the agency emphasizes five primary services which are delivered to a variety of customers:

- **Information** — the provision of information on pharmacies, pharmacists, and related laws and rules; information on consumer issues such as generic drugs, patient counseling requirements; and the concept and implementation of pharmaceutical care;

- **Licensing** — the licensing and review of interns, pharmacists, pharmacist preceptors, and pharmacies, to ensure uniform standards, competency, and public safety;

- **Compliance** — the monitoring of pharmacies, interns, and pharmacists for compliance with the laws and rules, including specialized requirements regarding the handling, safeguarding, and distribution of prescription drugs and devices;

- **Investigation** — the investigation of alleged violations of pharmacy laws and rules; and

- **Adjudication/Legal Support** — the oversight of the complaint process, prosecuting licensees found in violation of pharmacy laws and rules, and monitoring licensees who are subject to disciplinary orders.

The Agency Approach

The Texas Pharmacy Act gives the agency exclusive responsibility in Licensing services, but does not give such exclusivity in its Information, Compliance, Investigative, or Adjudicative/Legal Support Services areas. Information Services regarding the profession are, in part, provided by the colleges of pharmacy, professional associations, and consumer advocacy groups. Enforcement (Compliance, Investigation, and Adjudication) Services are provided by the agency, together with other state, federal, and local agencies associated with law enforcement.

Although agencies such as the Texas Department of Health, the Department of Public Safety, the Federal Food and Drug Administration, the Drug Enforcement administration, and local police departments have specific jurisdiction over various aspects of the practice of pharmacy in Texas, their jurisdictions do not usurp or preclude the authority of the agency in carrying out its responsibility. In fact, licensure of pharmacists and pharmacies by the agency is a prerequisite to other agencies' jurisdiction and regulation. As a result, and in line with the agency's statutory responsibility, the Board has historically taken a *"lead agency"* role in the regulation of the practice of pharmacy. It has informal cooperative arrangements with the other agencies having regulatory impact on the practice of pharmacy (*e.g.*, the Department of Public Safety, the Drug Enforcement Administration, the Food and Drug Administration, the Department of Health and Human Services, and local law enforcement agencies). Additionally, the agency has formal cooperative arrangements with other state and federal agencies, such as a *Memorandum of Understanding* with the Texas Department of Health and the Texas Department of Mental Health and Mental Retardation; and formal *Memorandums of Agreement* with the Texas Department of Human Services and the U.S. Consumer Product Safety Commission.

The agency has also developed excellent working relationships with the Texas State Board of Medical Examiners (TSBME), Board of Nurse Examiners (BNE), and other state health profession regulatory agencies. An example of the success of these close working relationships is cooperative rule-making efforts with the Texas State Board of Medical Examiners to implement requirements of legislation passed during the 74th and 75th Legislative Sessions. Each agency was required to develop rules to implement drug therapy management and administration of immunizations by pharmacists under written protocols of physicians and to cooperate in the development of a list of drugs subject to legislation regarding *"narrow therapeutic index drugs."*

Another example of the agency's *"lead agency"* role occurred during statewide strategy discussions concerning the importation of drugs from Mexico that are not approved for use in the United States. The initial concern of state and federal agencies focused entirely on controlled substances (drugs of abuse). The Board of Pharmacy quickly realized that none of the drugs from Mexico are approved for use in the United States and that many of the drugs entering the United States are not controlled substances. The agency initiated discussions with the Operational Command Group of the Narcotics Control Program from the Criminal Justice Division of the Office of the Governor, the Texas Department of Public Safety, the Texas Department of Health, the federal Food and Drug Administration, and U.S. Customs.

By taking this initiative, the agency fostered an awareness that drugs from Mexico present a public health concern far beyond just the controlled substances. In a similar manner, agency initiative has prompted cooperative efforts between state and federal law enforcement agencies to identify and take action against mail order pharmacies which illegally mail Mexican drugs to U.S. residents.

This *lead agency* approach implements Section 6 of the Texas Pharmacy Act which states: "*The Board shall enforce this act and all laws that pertain to the practice of pharmacy and shall cooperate with other state and federal governmental agencies regarding any violations of any drug or drug-related laws.*"

In the meantime, the agency continues (and aspires) to build ever-increasing, dynamic partnerships and coalitions in meeting the challenges that lie ahead for the agency as a whole and in the addressing of each of the Policy Issues. One of the greatest strengths the agency has in being able to form these coalitions is the fact that the agency is an independent state agency. The advantages of the current Texas structure of independent health licensing regulatory agencies is reinforced through the following.

- An article in the March/April 1994 *Professional Licensing Report* stated:

  "The state of Oregon went from an independent board structure to a centralized agency approach, and is now returning to independent boards because of problems with lower levels of service being provided to consumers under the centralized regulatory agency. New York is another example of centralized organization which is not working. Consumers constantly complain that they are not dealt with either effectively or efficiently when they call the central agency."

- In an April 1994 report to the California Senate, the Subcommittee on Efficiency and Effectiveness in State Boards and Commissions stated: *"**DO NOT** eliminate separate boards, bureaus, and programs as independent entities and consolidate under the Director of the Department of Consumer Affairs. There is no evidence that this action would improve effectiveness or efficiency of these licensing agencies."* The California subcommittee cited *Florida* as a state where centralization led costs to skyrocket and gave the following to support this conclusion:

  > *"Florida consolidated its licensing boards in 1979 under a centralized agency called the Florida Department of Professional Regulation . . . In 1979, when the department was established, the appropriation was a little over $5 million. In 1980, the second year of operation, the appropriation to the department was approximately $13 million, a 150% increase in one year. Texas, which has merged or eliminated particular boards, but maintained their independent status, has had better success. If a comparison was made of 1991 appropriations of all licensing agencies of Texas with that of Florida, it cost Florida $15 million more to regulate the same occupations and professions as Texas."*

The Board believes that the cost-effectiveness of the "*umbrella agency*" concept for health professions' regulation is subjective at best and, in fact, has shown evidence of being counter-productive to consumer protection. In a 1989 report entitled "*Structural Reforms and Licensing Board Performance,*" the authors from the University of Southern California (USC) reported that:

> *"For the health occupational licensing boards studied, centralization of board responsibilities do not improve board performance in disciplinary actions — one of the main consumer protection functions."*

The report also suggested that:

> *" ... movement toward the complete centralization of licensing board functions may be adverse to consumer interests."*

The review of the overall performance in these states, although somewhat cursory, indicates a definite failure of consolidation to positively impact the statewide goals of protecting the public and promoting the efficiency of services. In fact, when comparing efficiency measures with the other similar-size state boards of pharmacy, California and Florida, the agency has documented superior performance in licensing (time to issue a license) and enforcement (time to resolve a complaint).

As stated in the Texas Sunset Advisory Commission Staff Report (October 1992), efforts throughout the past 40 years to create a centralized licensing agency in Texas have received only lukewarm support. During development of legislation to implement the recommendations of the Texas Performance Review, the Sunset Commission took another approach, and questioned what result the consolidation efforts were trying to achieve, other than simply that of ending up with one large, bureaucratic organization. The Sunset staff analysis indicated that a majority of the following positive benefits can be achieved in a constructive manner:

- coordination of overall policy;
- economies of scale;
- standardization of functions;
- improved public access to services; and
- the potential for better enforcement.

A further review indicated, however, that a majority of these measures could be achieved in a constructive manner, without consolidating regulatory agencies under one *"super-agency."*

With these thoughts in mind, a structure was created by the 73rd Legislative Session, to be called the *Health Professions Council (Council)*. The purpose of the Council is to provide a means for the agencies represented to coordinate administrative and regulatory efforts. The Council is made up of representatives from the following agencies:

- Board of Chiropractic Examiners;
- Board of Dental Examiners;
- Board of Medical Examiners;
- Board of Nurse Examiners;
- Board of Vocational Nurse Examiners;

- Board of Occupational Therapy Examiners;
- Texas Optometry Board;
- Board of Pharmacy;
- Board of Physical Therapy Examiners;
- Board of Podiatry Examiners;
- Board of Examiners of Psychologists;
- Board of Veterinary Medical Examiners;
- Department of Health, Professional Licensing and Certification Division; and
- Office of the Governor.

The Council has provided a valuable forum for health licensing agencies to discuss and reach consensus on ways for agencies to operate together in a more effective and efficient manner, without sacrificing the independent efficiency and effectiveness of each agency.

The Council has made tremendous strides in accomplishing efficiency and effectiveness through administrative sharing and cooperative teamwork. Eleven Council committees involving approximately 40 staff members from member agencies were appointed to study and make recommendations on the functional and programmatic assignments of the priority objectives. The following is a summary of accomplishments from FY94-97 and a projection of accomplishments for FY98.

- Implementation of a plan to collocate the Council agencies to the state-owned William P. Hobby Jr., Building. The accomplishment of this objective was a major success for the council agencies during fiscal years 1994 and 1995.
- Establishment of a *"1-800"* complaint system to provide assistance and referral services for persons initiating a complaint related to a health profession regulated by the state.
- Development of a Training Manual for board and commission members.

- Increase efficiency of mail processing by establishing a centralized processing center for outgoing mail.

- Increase shared purchasing and accounting functions.

- Consolidation of library resources by centralizing audio and video staff development tapes for use by all boards.

- Sharing of legal library resources through the issuance of library cards to key staff in boards for access to the legal libraries of the Pharmacy and Medical boards.

- Establishment of a shared document management center to provide copying services to Council agencies at a low cost.

- Establishment of a Payroll/Personnel Project has allowed for the establishment of consolidated payroll operations between the two largest Council agencies; enhanced human resources information to all Council agencies; established an Employee Assistance Program for interested agencies; and improved sharing of job opening information.

- Development of a Risk Management Manual and Disaster Recovery Plan for all Council agencies.

- Coordination of Legal Services to discuss legal issues of joint concern to Council agencies. Committee recommendations of shared legal services for agencies without current in-house counsel were implemented with two boards now sharing one attorney position.

- Coordination of computer services and resources has enabled seven Council agencies to share LAN support provided by a General Services Commission employee. A technology workgroup is planned to assist smaller agencies in the development of websites.

- Development of core policies and procedure statements for common areas such as travel, open records, and records retention. These statements are resources for Council agencies to use in developing individual agency manuals, saving staff time, and assuring consistent quality.

- Reduce paper files by determining the feasibility of sharing an electronic imaging system for data storage.

- Reduce the costs of the licensing process by studying existing license systems and processes to determine the potential for savings in the generation and mailing of renewal notices.

In its December 1995 report entitled *Reforming Health Care Workforce Regulation,* the Pew Health Professions Commission cited the Health Professions Council as an innovation. The *results* of this cooperative structure have already been demonstrated by the many aspects as described previously. As the Council pursues additional opportunities for improvement among member agencies, the primary goals envisioned by the legislative leadership should be met.

The Organizational Perspective

Board Structure

The policy-making body of the agency is a nine-member Board appointed by the Governor, with concurrence of the Senate, for overlapping six-year terms. Six members must have been registered pharmacists in Texas for five years immediately preceding appointment, be in good standing with the Board, and continue to actively practice pharmacy while serving. In addition, the Board must have representation for licensed pharmacists who are primarily employed in Community and Institutional pharmacies. Three members of the Board must be non-pharmacist, consumer representatives.

An ongoing significant part of the policy-making structure of the agency is the Board's use of professional ad hoc task forces in its pre-rulemaking process. These ad hoc task forces are composed of individuals who possess expertise helpful to the Board, both in the initial development and modification of agency rules. The result is that the rules governing pharmacy practice are formulated in the best interest of the public and, at the same time, represent an appropriate level of regulation.

The Executive Director/Secretary serves as the executive officer of the agency, and as such is an ex-officio member of the Board. The Executive Director/Secretary is responsible for advising the Board on policy matters, implementing Board policy, and managing the agency on a day-to-day basis.

Agency Divisions and Staff Management

The agency's office headquarters is located at 333 Guadalupe Street, Suite 3-600, Austin, Texas, in the central quadrant of the city. Agency staff totals 42 positions, consisting of five management, 27 professionals, and 10 administrative support staff. Five of the seven Compliance Officers, and five of the six Investigators operate in field areas outside the main office and function under the supervision of their respective Division Directors.

Pharmacy practice regulation is unique since it is the only professional area to regulate individuals (pharmacists), facilities (pharmacies), and products (prescription drugs). Therefore, interaction and coordination between the Divisions of the agency and their staff members are crucial and integral parts of the effectiveness of our efforts.

The agency licenses approximately 19,000 pharmacists and 5,400 pharmacies over a land area of approximately 270,000 square miles. Limited Compliance and Investigative staff are challenged in the regular monitoring of these licensees by travel distances. In addition, medically under-served areas present specific challenges for comprehensive inspection/investigative efforts. These areas are defined as locales where medical care and specifically pharmacy services may be inaccessible due to distance and lack of transportation, and lack of (or inadequate) insurance coverage. Such situations may occur in rural, sparsely populated areas of the state and, conversely, in some densely populated urban areas of Texas.

The agency operates under a modified system of Management-By-Objectives (MBO). Goals and objectives are reviewed and approved annually by the Board members. These objectives are directly tied to the agency's *Strategic Plan* and "*operationalize*" the *Strategic Plan*. The Executive Director manages the staff to accomplish the adopted objectives.

Regarding management structure, the Director of Administrative Services and Licensing is responsible for overall supervision of the Licensing and Administrative Services programs. The Directors of Compliance, Investigation, and Adjudication/ Legal Support are responsible for their respective programs and personnel. Information program services are shared among the Divisions of the agency. An organizational chart of the agency can be found in *Appendix C*.

Human Resource Investments

Human resource investments are crucial to the continued efficiency and effectiveness of agency operations. In Texas government, as in the private sector, we must pay adequate wages if we expect to attract and retain quality employees. ***Our employees are our most valuable resource and Texas cannot afford to have less than the best.*** In addition to the initial investment of hiring qualified staff, the meeting of each employee's ongoing professional development and training needs is also crucial to the success of agency operations. (*See Policy Issue #4* for further discussion of this issue.)

Board members are dedicated to their role as policy-makers, and the staff to their role as implementers of this policy. Through these complementary roles, the Board and staff form an efficient team, achieving consistently effective agency performance.

Human resource investments, such as provision of up-to-date technology and ongoing training for agency staff, help position the agency as public and private sector employers compete for the same workforce pool. The agency had a distinct advantage in that it has a highly educated and qualified staff who carry out their responsibilities in an efficient and effective, customer-service oriented manner. This proactive, progressive work environment, along with the general reputation of the agency, has definitely been an asset when recruiting staff. However, Texas' continued fiscal crisis, as it relates to salaries and funding for staff development has and continues to impact agency operations. This impact is most keenly evidenced by the agency staff turnover rate and by the hours of staff overtime required to cope with the work overload of the agency.

A significant loss of resources and opportunities can be found in the cost of stress and burnout. The Japanese, who are the only persons to put in longer work hours than Americans, recognize the detrimental impact that stress can have in the work place, and now health officials in Japan even label it as a cause of death. *Karoshi* (death by overwork) was formally recognized in Japan in 1989 as a fatal illness that results from extreme amounts of job stress and the pressures of overtime work.

Excessive and enduring stress can contribute to *burnout*, or feelings of extreme mental exhaustion, which can have devastating consequences for an organization. The *Survey of Organizational Excellence* collected information on employee perceptions of *"Personal Demands." "Personal Demands"* include employee perceptions of *Time and Stress Management, Burnout, and Empowerment.* The data derived from agency employees, indicate that the current working conditions are conducive to employee *burnout*. Clearly, personal pressures may impede the organizational effectiveness of the agency.

Staffing Pattern and Profile

Agency employee turnover increased from 3% in FY88 to 15.2% in FY92, dropped in FY93-95 to 9%, and increased to 15% in FY96-97. Field Compliance Officer turnover was an alarming 40% in FY92, and 22% for FY97. The reason for this high turnover rate can be directly attributed to salary dissatisfaction and the lack of availability of extrinsic rewards in state government. We expect that employee turnover will continue to remain high and employee morale will decline unless additional human resources and compensation shortcomings are addressed.

The growth in Texas' minority populations may have significant ramifications for the agency's workforce, specifically in the pharmacist (Compliance/Enforcement Officer) category. Attempts to recruit qualified minority pharmacists have been difficult due to the significant differences in salaries compared to private sector employment, and to the pool of licensed pharmacists who are minorities. The agency has, however, recently succeeded in employing minority pharmacists. **Table 1** shows a comparison of race distribution among the overall Texas civilian labor force, the Texas pharmacist population, and the agency non-manager pharmacist positions for FY96.

Table 1

Race	Texas Population Race Distribution	Texas Pharmacists Population Race Distribution	Agency Non-Manager Pharmacists Population Race Distribution
Anglo	61%	73%	72%
Hispanic	25%	8%	14%
Black	12%	9%	14%
Other	2%	10%	0%

The agency's overall workforce profile, as shown in **Table 2**, indicates that the agency needs to increase its efforts to recruit and retain qualified minority applicants at all levels of job categories.

Table 2

Total Agency Employees	Anglo		Hispanic		Black		Other		Total	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Official/Admin.	2	3	0	0	0	0	0	0	2	3
Professionals	10	9	1	1	0	1	0	0	11	11
Para-Profes.	0	3	0	4	0	2	0	0	0	9
Admin. Support	0	2	0	0	0	0	0	0	0	2
Totals	12	17	1	5	0	3	0	0	13	25

***Data reflects actual staff as of 2/28/98. Unfilled positions are not reflected.**

Historically Underutilized Businesses

It is the intent of the Legislature that each state agency receiving appropriations shall, in acquiring, constructing, or equipping new or existing facilities, and in the operational implementation of each strategy funded, make a good-faith effort to include historically underutilized businesses (HUB) in the following categories:

Category	Actual FY97	Statewide Goal for FY97
Professional Service Contracts	0.0%	20.0%
Other Services Contracts	12.8%	33.0%
Commodities Contracts	35.3%	11.5%

The agency attempts to use every HUB listing in bidding for delegated services. The agency must also satisfy requirements listed in the overall bid process for delegated services. Other constraints in implementing the overall goals are the following:

- Expenditures that are proprietary in nature and must be awarded to a single vendor. For example, the agency contracts with the Grumman Technical Services for computer services. The contract with Grumman Technical Services compliments the original Statement of Work, Terms and Conditions between the Department of Information Resources and the Grumman Technical Services. If payment for these expenditures was excluded from the FY97 HUB Report - Other Services Contracts, the actual percent spent with HUB would equal 16%.

- Another example of a contract that has significantly influenced the actual percent spent in Other Services is the agency's annual contract for its Peer Assistance Program. Although this contract has been competitively bid, only one vendor submitted a bid and this vendor was not HUB-certified. If payment for these expenditures was excluded from the FY97 HUB Report - Other Services Contract, coupled with the above Grumman Technical Services contract, the actual percent spent with HUB would equal 34%.

The agency has made a dedicated effort to satisfy the requirement for soliciting at least one HUB-certified minority and one women-owned business in the three bids solicited for each delegated spot purchase. The above constraints notwithstanding, the agency will increase its good faith efforts by developing and using an agency HUB Policy as the basis for obtaining the HUB participation goals.

Statewide Capital Planning

Article IX, General Appropriations Act, 75th Legislature, defines capital expenditures as expenditures for land acquisition; construction of building and other facilities; renovations of building and other facilities estimated to exceed $1 million in the aggregate for a single state agency; or major information resources projects estimated to exceed $1 million. Based on these definitions, the agency does not anticipate any needs in this area.

Information Resources Management Strategic Planning

The agency Strategic Plan for Information Resources, as well as the Agency Biennial Operating Plan, outlines any additional or updated information resources necessary to continue to regulate effectively in the coming years. The discussion titled "*The Technological Perspective*" in this document, outlines the Information Resource Goals and the major initiatives requiring resources to accomplish these goals. The Agency also submitted the Year 2000 Project Plan and Year 2000 Progress Report to the Department of Information Resources and will continue to keep the Year 2000 Project Office informed of any Year 2000 issues.

Key Agency Events/Areas of Change and Impact Since the Last Update of the Strategic Plan

Since the publication of the 1996 agency *Strategic Plan*, the following events and changes have impacted the strategic and operational planning of the agency, and are referenced (where applicable) to areas within this *Strategic Plan* where they are specifically addressed:

- By far the most far-reaching impact on the agency is the increase in demand for agency services and lack of a corresponding increase in agency funding for the past two bienniums (fully discussed in *Policy Issues #1 and #4).*

- The loss of key professional staff due to non-competitive salaries for these positions; and the legislative assessment of across-the-board mandates/recommendations such as the FTE cap, reductions in travel and travel restrictions, and management-to-staff ratio, have severely limited the ability of the agency management staff to effectively manage the agency (fully discussed in *Policy Issue #4).*

- Continued enforcement efforts aimed at establishing compliance with the federal mandate for pharmacists to perform drug use review (DUR) and counseling for Medicaid patients and Board rules which mandate that pharmacists provide DUR and counseling on new prescriptions for all Texans.

- The passing of amendments to the Pharmacy Act in 1997, specifically as the amendments relate to its provisions for:

  - pharmacist administration of immunizations and vaccines under a physicians protocol;

  - the authority for the Board to establish standards for the curriculum of training programs for pharmacy technicians and maintain a list of programs that meet these standards; and

  - the authority for the Board to impose a probation fee on licensees and the authority to use this fee to offset the cost of monitoring the probation.

- The development and implementation of rules, in conjunction with the Board of Medical Examiners, for:

  - drug therapy management by a pharmacist under written protocol of a physician;

  - pharmacist administration of immunizations and vaccines under a written protocol of a physician; and

  - non-therapeutic index drugs.

- The move of the agency to the William P. Hobby Building with the other health licensing boards.

- The success of the Health Professions Council in accomplishing efficiency and effectiveness through administrative sharing and cooperative teamwork.

- The development and implementation of an agency page on the world wide web.

The Fiscal Perspective

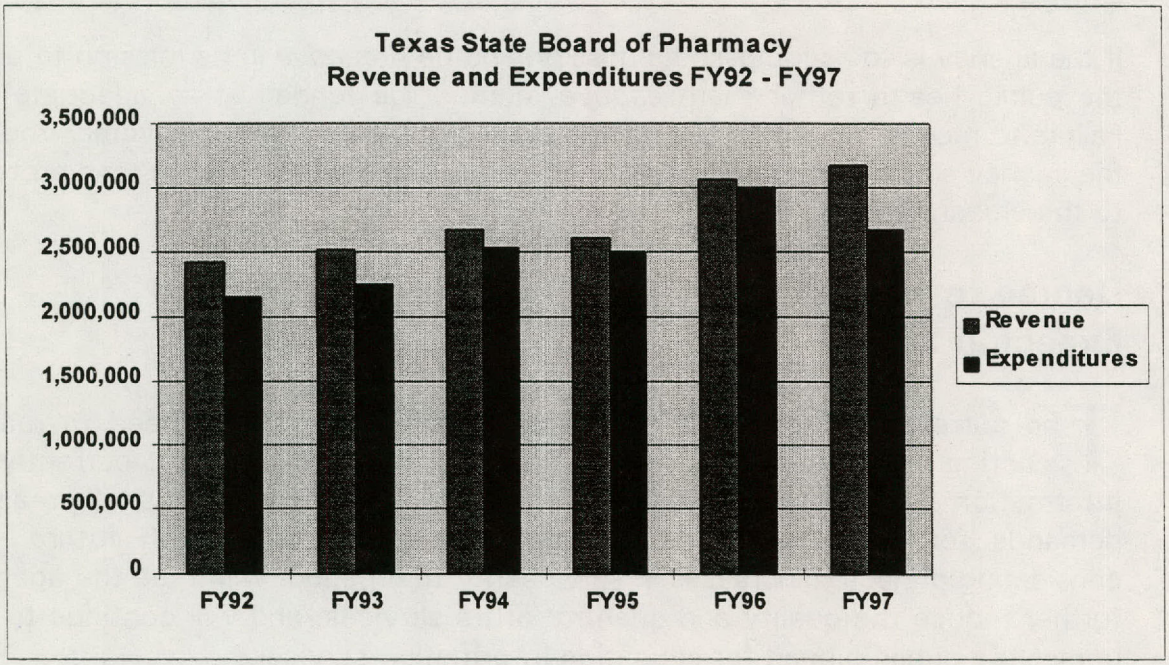
Current Funding

The agency's operating budget for fiscal year 1998 is approximately $2.4 million. This includes Legislative appropriations of $2.3 million, and indirect costs of approximately $548,000. The indirect costs include such items as the agency's payroll related costs, bond debt service payments, and indirect costs relating to the Statewide Cost Allocation Plan.

The agency is totally self-supporting, in that the operations of the agency are supported primarily from statutory fees related to licensing, reciprocity, and examinations. The general operating fund of the Board is considered a special revenue fund account within the State Treasury.

Chart 2 analyzes the agency's revenues and expenditures for a six-year period (FY92 - FY97).

Chart 2



The agency also maintains a Fines Account for fines collected by the agency which are deposited in the State's General Revenue Fund. From FY92 through FY97, the agency collected and deposited $372,087 of fine revenue into the General Revenue Fund.

Future Funding

One key factor that continues to affect the ability of the agency to serve and protect the public interest is the increased demand for agency services in every area of its operation. Dramatic increases in the demand for licensing, enforcement, and information services are well-documented throughout this *Strategic Plan* and in the agency's budget requests. This continued increase in demand for services, together with the increase in the complex nature of modern health and pharmaceutical care, is taxing the agency's ability to respond not only to future challenges, but to maintain its current level of service.

Although the State of Texas projects major deficits in the general revenue fund, the agency has the authority and mechanisms necessary to generate the revenue needed to support its *Strategic Plan* and Budget Requests. However, in the past, Legislative appropriations have represented a level of funding that is hampering the agency's ability to maintain an acceptable level of performance.

If the agency is to accomplish its mission and be *proactive* in its mission to protect the public health rather than *reactive*, it must be funded at an adequate level. Failure to receive this funding over the past two bienniums has severely impacted the agency's ability to provide quality customer service, information, and protection to the citizens of Texas.

Degree to which Current Funding Meets Current and Expected Needs

The current level of funding does not meet the agency's need to maintain existing services in Licensing or Enforcement, and does not currently fund Information Services. This funding, therefore, does not address increases in demands for services. Failure to provide increased funding in future years, considering projected increases in services for that period, will force the agency to further reduce the quality and quantity of its services, and will continue to leave unmet the public's need for education/information services.

The Technological Perspective

The agency has developed, through its planning process, an overall *Strategic Plan for Information Resources*, which is consistent with the agency's overall *Strategic Plan*. This plan includes the ongoing review of agency operations to determine if additional or updated information resources are necessary to continue to regulate effectively in the public interest. To achieve this overall plan, the agency will pursue three Information Resource Goals:

- To provide all agency staff and management with efficient and effective automation tools, facilitating the best quality services possible to all agency customers. This includes education and information dissemination to agency customers, as well as the provision of open access to other appropriate entities and state agencies.

- To provide additional means for information dissemination and education. This will include, but will not be limited to, further implementation of a TSBP WEB site for licensing and disciplinary information, posting of proposed rule changes and consumer information.

- To continually review agency operations to determine if additional or updated information resources are necessary to continue to regulate effectively in the public interest, and to secure the necessary resources.

A major initiative and information resource pursuit will be to continue evaluating alternative technologies which might allow the agency to incur lower information resource costs, while providing better service to agency customers. This initiative will include, but will not be limited to:

- investigation and research of an alternative to contracting with the Department of Information Resources for the agency's cash, licensing, and enforcement systems. This initiative has moved to the forefront of the agency's planning efforts with the recent outsourcing of the Information Technology Services section of DIR Business Operations to an outside vendor.

- implementation of public access technologies for licensing information;

- research and possibly implement a means of establishing electronic licensing services;

- review of available imaging systems for records management and/or other document storage and retrieval systems;
- further implementation of remote access technologies to the agency's Local Area Network (LAN) facilities.

The agency's current information resources environment includes an office automation system comprised of a LAN accessing a host computer located at the Department of Information Resources for all Fiscal, Licensing, and Enforcement needs. The LAN also serves as the agency's in-house automation system by networking 32 personal computer workstations with word processing, electronic mail, and other application needs.

The agency's aspiration is to achieve a level of open systems, providing the greatest number of options in the area of information resource technology, vendors, and service providers. This could have a long-term effect of reduced information resources costs, while allowing the agency to provide a consistent, high level of quality service to its customers. In summary, a major method to achieve agency goals is that of effective and increased use of information resource technologies.

Self-Evaluation, Progress, and Opportunities for Improvement

Agency Self-Evaluation

As covered in the section titled *The Organizational Perspective*, the agency continually operates by implementing and measuring performance against strategic and operational Goals and Objectives and through customer feedback. Therefore, the agency is continually self-evaluating, through each Division and every employee. This process always ties into the agency Goals and Objectives, which tie into the *Strategic Plan*. In addition to this continuous process, and in preparation for this *Strategic Plan*, the agency sought the input of Board Members, staff, officials of national and state pharmacy organizations, pharmacy academicians, and officials of state consumer advocacy groups. The list of the recipients of the survey letters is included in Appendix A with a list of the questions asked of these *"interested parties."*

The strategy for the continued success of the agency consists of three distinct but interrelated elements:

- **Leadership** — The creative process comes from the ability of the organization and all its members to learn, improve, and innovate. The Board leadership sets and maintains the conditions necessary to permit this process to cultivate, and in fact *"leads by example,"* with results that ensure quality improvements.

- **Feedback from Employees** — The *Survey of Organizational Excellence* (Appendix D) (Survey), administered by the School of Social Work at The University of Texas at Austin in 1994-95, and 1996-97 provides a uniform benchmark for all Texas government to compare employees' perceptions of organizational achievement from agency to agency and over time. The Survey results identified the *Texas State Board of Pharmacy* as an agency that represents the highest standards of openness, focus, and commitment to the process of continuous quality improvement. Survey results suggest that agency employees believe that quality principles such as *customer focus, continuous improvement, and teamwork/employee involvement* are some of the strongest attributes of this agency.

- **Feedback from External Customers** — The 1996-97 General Appropriations bill reflects the state leadership's efforts towards determining customer satisfaction with the initiation of pilot customer satisfaction surveys with eight state agencies. Although the agency has not been invited to participate in this effort, the Board may consider a future project to determine customer satisfaction through the use of a survey instrument.

  Customer satisfaction can, however, be measured by the agency's progress in establishing credibility and recognition. The Board of Pharmacy has been recognized for its efficiency and effectiveness within Texas through:

  - three consecutive exception-free financial audits by the State Auditor and continuous exception-free audits by the General Services Commission on the Delegated Service Certification Program;

- an exceptional Management Audit from the Office of the State Auditor in FY93. The final report stated in part, *" . . . The Texas State Board of Pharmacy is operating efficiently. . . . The agency actively seeks ways to determine how to improve its operations. . . . We commend the agency's personnel for their efforts to improve both agency operations and the practice of pharmacy throughout the State";*

- recognition in a 1995 Legislative Budget Board report entitled *"Summary Assessment of Agency Performance"* that the Texas State Board of Pharmacy attained or exceeded *100 percent* of the agency's established performance targets. The report also noted that although the number of complaints filed with the agency increased by nearly *50 percent* between fiscal years 1994 and 1995, the agency re-engineered enforcement processes to manage the additional workload, resulting in the average time to resolve a complaint to increase by only six days;

- a statement by the Director of the Sunset Advisory Commission during the 1993 Sunset Review of the Texas State Board of Pharmacy that the agency is *"one of the most consumer-oriented health regulatory agencies";*

- recognition in a 1991 Legislative Budget Board survey on Adjudication Performance, including the following statement:

  "Over 90% of the Board of Pharmacy's contested cases were resolved in settlement conferences for each year of the 3 year period under review. These data would suggest that the agency is effective and efficient in processing contested cases . . . .";

- the certification of savings in FY92, FY94, and FY95 for the agency Productivity Bonus Plan;

- the receipt of the *Gold Safety Award* in 1992 and 1995 from the Texas Workers' Compensation Commission for promoting and furthering the occupational safety and health of state employees;

- comments from external customer organizations, both national and statewide, were solicited in the strategic plan external assessment. The comments received were not only instructive, but extremely positive and complimentary to the agency; and

- published results in the *Survey of Organizational Excellence (Appendix D)*, administered by the School of Social Work at The University of Texas at Austin in 1994-95 and 1996-97, which provides a uniform benchmark for all Texas government to compare employees' perceptions of organizational achievement from agency to agency and over time. The Survey results identified the *Texas State Board of Pharmacy* as an agency that represents the highest standards of openness, focus, and commitment to the process of continuous quality improvement. Survey results suggest that agency employees believe that quality principles such as *customer focus, continuous improvement, and teamwork/employee involvement* are some of the strongest attributes of this agency.

The agency has also been an innovator in the field of proactive health regulation. This is well-documented in that the Texas State Board of Pharmacy was the first board of pharmacy in the nation to:

- use ad hoc task forces in its pre-rule-making process (The agency began using these task forces in 1981);

- publish a *Newsletter* which is distributed to all licensees and other interested customers (The *Newsletter* has been continuously published since 1977 and is directed at educating pharmacists about the laws and rules relating to the practice of pharmacy; it also discloses the names of all pharmacists and pharmacies disciplined by the Board);

- implement a preventive enforcement program which encourages pharmacists' voluntary compliance with governing laws and rules, through a combination of routine inspections and education efforts (the Compliance program began in 1977);

- develop and implement a strategic plan (the first agency *Strategic Plan* was developed in 1986); and

- hold full membership in the National Council on Patient Information and Education, a national, non-profit, consumer health advocacy organization in Washington, D.C.

Statewide Benchmarking

Michael Spendolini defines "*Benchmarking*" as "*the continuous systematic process of evaluating the products, services, or work processes of organizations that are recognized as representing best practices for the purposes of organizational improvement*" (Benchmarking Book, 1992). The Board supports the concept of benchmarking and procedural changes which would improve the agency's work processes. The desired end result would be **meaningful** change.

Section 67, Article IX, of the 1998-99 General Appropriations Act, requires that agencies and institutions engage in an internal performance benchmarking process which will provide for the identification and development of agency-specific performance benchmarks and their linkage to state-level benchmarks. Each agency and institution is required, for each goal, to either identify an existing performance measure or develop a new measure which could be considered a performance benchmark (*i.e.,* a measure capable of comparison over time and/or against other entities to some objective standard). Administrative goals are exempt from this requirement as are goals for which a performance benchmark is unavailable or clearly inappropriate.

Description of Agency Benchmarking Process

To begin the benchmarking process, TSBP needed to find a way to compare its performance measures to another agency or organization, either in the private sector, another state, or at a national level. Accordingly, the agency reviewed the following sources for information with regard to performance measures:

- **National Level** — TSBP has contacted the National Association of Boards of Pharmacy (NABP) to determine if national standards exist for any of the performance measures reported on a regular basis to the Legislative Budget Board (LBB) and Governor's Office (GO). NABP collects information from other

state boards of pharmacy, but does not have data with regard to performance measures.

- **Private Sector** — The process of licensing and enforcing the laws and rules governing the practice of pharmacy are not carried out by the private sector. Accordingly, TSBP was unable to review similar service providers in the private sector.

- **Other States** — TSBP has contacted other state boards of pharmacy and have determined that data collection for performance measures is not readily available or doesn't exist.

- **Other Agencies in Texas** — TSBP conducts services similar to other health licensing boards in Texas, which are required to collect and report data to LBB and GO with regard to performance. TSBP is a member of the Health Professions Council (HPC), as are all other Texas health licensing agencies. TSBP will work through HPC to benchmark with one or more of the other member agencies. However, TSBP recognizes that there may be limited value in attempting to develop a statistical correlation of outcome-type performance measures with other HPC member agencies, in that there are a myriad of differences in the licensure and regulation of different professions. For example, the resolution of complaints against one type of professional may be more complex, thereby taking longer to resolve, which, in turn, increases the respective agency's complaint resolution time. The most important part of benchmarking is not comparison of "*raw numbers*" but rather, comparisons of **processes**. Accordingly, TSBP supports the concept of ***process benchmarking***, instead of ***performance benchmarking***. By finding and adapting "*best practices*" to improve a particular process, TSBP may be able to improve its performance on a specific measure.

Identification of Performance Measures to Benchmark

The process of performance benchmarking first involves the identification of a specific performance measure for each TSBP goal. TSBP has identified the measures listed below.

- **Licensing Goal** — the time to issue an intern registration. This performance measure is not one of the agency's key or non-key performance measures, but a new measure identified by the agency. This measure was selected for process benchmarking, because the agency believes that this process is one that lends itself to improvement.

- **Enforcement Goal** — the percent of licensees with no recent violations. This performance measure was selected for performance benchmarking because it is the only statewide benchmark that is applicable to regulatory agencies such as TSBP.

- **Public Information Goal** — no performance measure will be identified, in accordance with the Governor's office instructions, in that this goal has not been funded by the Legislature.

- **HUB Goal** — no performance measure will be identified, in accordance with the Governor's office instructions, in that this goal is an Administrative goal.

Opportunities

The Texas State Board of Pharmacy is in a unique position to be able to impact the delivery of pharmaceutical care to the citizens of Texas. Indeed, the characteristics requiring internal improvement in the agency are few. However, we constantly strive to improve on our performance and responsiveness to our customers. In order to fulfill that goal, we hope to see advancement in expanding and enhancing our capabilities for encouraging the delivery of pharmaceutical care, to improve the quality of life for Texas consumers.

Obstacles

As referenced throughout this overview, and as specifically discussed in each Policy Issue, the agency believes its obstacles to be mainly external. The Board and staff are committed to a vision of quality pharmaceutical care, and agency management and activities reflect that value.

The last several legislative sessions have produced a disturbing trend towards a management style of legislative direction, rather than a leadership style. Leadership is not management. As quoted by Stephen Covey, "*Management is a bottom line focus: How can I best accomplish certain things? Leadership deals with the top line: What are the things I want to accomplish?*"

A flurry of legislative mandates, ranging from rules relating to when and how much to award a merit salary increase, to how many people may travel and how much can they spend, have literally paralyzed the executive management of state agencies. State agencies are more in need of a vision or destination and a compass, and less in need of a road map. Perhaps the legislative leadership will soon change its thinking of control, efficiency, and rules, to a philosophy of direction and purpose.

The following is a listing of obstacles that prevent the agency from meeting customer needs:

FISCAL — the agency has not been adequately funded to achieve even its current goals, and has been left without additional funding to address future initiatives. In addition, all state agencies continue to grapple with a "*spend it or lose it*" mentality as it relates to agency funds that are unexpended at the end of the fiscal year. Agencies have no incentive to save funds if funds are swept into the General Revenue Fund. It would be advantageous, efficient, and effective to establish a program that rewards agencies and employees for saving funds without the fear of losing those dollars at the close of each fiscal year.

A recommendation entitled the "*Year End Savings*" *(YES)* program has been introduced by the Texas Real Estate Commission and the Small Agency Task Force Committee. The *YES* program will allow agencies, employees, and the General Revenue Fund to share in unexpended balances at the end of a fiscal year. The Board of Pharmacy certainly supports this concept.

Finally, the Board of Pharmacy and the Health Professions Council have identified the below-listed sections of the General Provisions (Article IX) of the General Appropriations Act as having the possibility to impact adversely the fiscal operations of an agency. Also listed are recommendations for possible solutions to reduce the likelihood of such adverse impact.

- Subsection 2, Section 60, Article IX, General Appropriations Act, addresses payment of judgements against state agencies. Subsection 2 provides a state agency may be required to pay up to $250,000 or 10% of its annual appropriations, whichever is less, for judgement in federal or state court. Generally, this pertains to lawsuits under either Section 101 or Section 104 of the Civil Practice and Remedies Code, and certain suits in federal courts. Further, Subsection 3 of Section 60 provides that up to 50% of any judgement requiring a

special legislative appropriation of the judgement amount shall be paid by the agency. Thus, agencies have some exposure to payment of judgements and/or settlements with some amounts, be it 10% or 50%, coming out of an agency's appropriation.

Possible solution: Provide for payment of these settlements from revenue collected by an agency in excess of the agency's appropriations.

- Section 80(1), Article IX, General Appropriations Act, provides that General Revenue-Consolidated shall be reimbursed for one-half of unemployment benefits paid to former state employees whose payroll warrants were issued from General Revenue-Consolidated. This requires the payments to come from an agency's appropriation rather than the fund cash balance.

Possible solution: Provide that such payments could be made from revenue collected by an agency in excess of the agency's appropriations.

- Section 81(1), Article IX, General Appropriations Act, provides General Revenue shall be reimbursed for 25% of Worker's Compensation benefits and the payment shall come from an agency's appropriation.

Possible solution: Provide that such a payment could be made from revenue collected by an agency in excess of the agency's appropriations.

- Section 64, Article IX, General Appropriations Act, limits travel expenditures to 90 percent of the agency's FY97 travel expenditures. This limit impedes regulatory agencies in the performance of statutorily required activities. Consumer complaints against professional licensees continue to be received at a rate equal to or greater than prior years. Therefore, travel for investigation and compliance activities cannot be reduced without decreasing the effectiveness of the agency in carrying out statutory requirements. Travel for board members to participate in official board meetings is also a necessity in order to meet statutory requirements.

Possible solution: Recommend that travel of board members to participate in official board meetings and for employees engaged in statutorily required activities related to licensing examinations, licensee compliance, and investigation of complaints not be subject to the expenditure reduction.

HUMAN RESOURCES — the agency has not been adequately funded to hire and maintain the staff needed to maintain and enhance services to agency customers. In addition, several legislative mandates significantly affect state employee morale, retention, and turnover rate as follows:

COMPENSATION LIMITATIONS:

- A new Position Classification Plan which allocates all positions into three Salary Schedules has been introduced. The majority of positions, however, are above a group B14 and are agency specific for larger state agencies. Small state agencies are in a unique position of having employees required to assume multiple responsibilities and be experts in three or four fields. As a result, the agency is not able to compensate its key professional and managerial staff at a rate that is competitive with similar positions in the private sector or even other state agencies.

  The State Auditor's Office is currently reviewing this area with efforts towards ensuring that the state's Position Classification Plan is able to meet the growing demands of the State and labor market. Hopefully, the recommendations that are submitted, will make significant inroads into reducing the number of unnecessary classes, while revising and adding classes that can assist management in its ongoing competition with the career tracks and corresponding salaries of the private sector.

  - Although state employees did receive a $100 across-the-board salary increase in FY98, this was the *only* increase in compensation for state employees in *five years*. State executives and employees must be adequately compensated in order to attract and retain quality personnel. These personnel are the backbone to the effective operation of state government.

- The social security benefit replacement pay was eliminated in September 1995 for new employees. This has created two types of state employees with one group receiving greater benefits than another. The benefit replacement pay was a program used to enhance the agency's ability to hire employees that would otherwise not consider the State as an employer.

- The maximum annual expenditure for merit salaries and promotions awarded during a fiscal year has been limited. This limit has had a negative impact on the ability of smaller agencies to retain qualified staff. The agency lacks the opportunities for career ladder promotions available in the state's largest agencies. Therefore, employees must seek other employment to gain needed financial compensation for their efforts and abilities. Such turnover is not cost beneficial and is a special hardship in small agencies where there are fewer people to share increased workload caused by position vacancies.

MANAGEMENT LIMITATIONS

- Senate 645, 75th Legislature, states that agencies "*shall develop procedures for use in achieving a management-to-staff ratio of one manager for each 11 staff members.*" Small agencies have several diverse functional areas requiring managers with different knowledge, skills, and abilities. The one-to-eleven ratio was proposed by the Comptroller in the 1996 report of the Texas Performance Review. The report stated, "***About half of Texas' 210 agencies have fewer than 100 FTE's. These smaller agencies should be exempt from this span-of-control requirement.***" *(Disturbing the Peace,* p. 589)

- The number of employees employed by an agency for a fiscal quarter has been capped. This cap limits an agency's ability to manage their appropriated funds by hiring additional staff in needed program areas. The cap also severely undermines the basic principals of leadership and management.

STATUTORY — The Pharmacy Act needs to be amended to:

a. give the agency the authority to inspect financial records of pharmacies. Without this authority the agency is unable to investigate complaints relating to:

   i. "*kickback*" arrangements with practitioners and other health care providers;

   ii. "*grey market diversion*" and other violations of the Federal Prescription Drug Marketing Act; and

   iii. substitution of a lower priced generic drug and charging the patient the price for the brand name drug.

b. Allow the Board the discretion to discipline pharmacists on any deferred adjudication.

c. Clarify that pharmacists have professional discretion when deciding to dispense a prescription or medication order.

d. Authorize the Board to sustain a pilot project beyond its termination date when results support a permanent change in the Board's rules and the Board initiates the rule-making process.

e. Prohibit the use of the term "*apothecary*" in advertising a facility other than a pharmacy.

f. Amend the Act to make a second order against a person who has a chemical, physical, or mental impairment a non-confidential order.

g. Authorize the Board to renew a pharmacy license on a biennial basis.

h. Clarify that 12 hours of continuing education are required to renew pharmacist license each year, regardless of whether the license is renewed on an annual or biennial basis.

i. Clarify that the board may charge each license an annual surcharge of not more than $10 for each license, regardless of whether the license is renewed on an annual or biennial basis.

j. Authorize the agency to exceed the full-time equivalent employment cap for positions associated with the Summer Intern Program of the Board of Pharmacy.

k. Give the Board the authority to register technicians.

l. Give the Board the authority to regulate Pharmacy Benefit Managers.

m. Give the Board the authority to allow a pharmacist to use the term "*Board Certified*" only if the pharmacist has completed a certification program which meets minimum standards set by the Board.

CULTURAL — the agency faces the challenge of minority hiring into specialized fields.

SOCIAL — the agency has not been given resources to respond to increased demand for improved services, and our ability to respond is steadily deteriorating.

TECHNOLOGICAL — the agency must stay on the cutting edge, not only in capabilities for using in-house technology, but must keep up with technological advances throughout the profession of pharmacy and related drug delivery systems development.

The agency's opportunities in these areas are virtually boundless. It is an exciting and demanding era, because of the uncertainty in the environment due to health care reform and quickly changing market conditions. Never before in the nation's — or profession's history — have we been presented with such an opportunity to positively impact the health care of the citizens of Texas and the promotion of pharmaceutical care through proactive regulatory initiatives. The problem is certainly not lack of opportunity.

The agency has built credibility, momentum, and innovation in the advancement of patient care. Organizations don't stand still — they either progress or regress. For the agency to take advantage of its momentum, it must have the necessary resources.

POLICY ISSUE #1

The Crucial Role of Pharmacists in Improving Patient Health Through Pharmaceutical Care

Issue Statement

The aging of Texas' population, advances in drugs, devices, and drug dosage forms, managed care, and economics are all forging rapid change in our health care system. In fact, these forces are driven, both by new governmental strategies and marketplace issues, and are directly causing an evolution in the practice of pharmacy. Pharmacists are shifting their practices away from the *traditional practice of pharmacy* and the provision of commodities toward providing patient care, information, and drug therapy management. Pharmacists are progressing toward a more patient-oriented practice, and they must provide not only the product, but ongoing information to meet the varying needs of other health care professionals and individual patients in order to improve — or maintain — each patient's quality of life.

In addition, the development of new diagnostic tests, drugs, medical devices, and sophisticated medication dosage forms are placing an increasing demand on pharmacists to understand these systems, and to convey an appropriate amount of this understanding to their patients. Texas pharmacists need to understand the mechanisms of action of all new drugs, devices, and administration forms in order to properly manage a patient's drug therapy, dispense the medications and devices, to fully advise consumers (and other health professionals) about the safe and successful use of these products, and, when appropriate, to administer these medications and devices directly to patients.

Pharmacists need to be aware of, and committed to, the patient's interest and the direct outcomes of their individual drug therapies. A November 1995 Pew Health Professions Commission report titled *Critical Challenges: Revitalizing the Health Professions for the Twenty First Century,* described pharmaceutical care as:

> ". . . *the practice philosophy through which pharmacists assume responsibility for the outcomes of drug therapy in their patients. Rather than focusing on the procurement and dispensing of drugs, pharmaceutical care centers on the care of the patient and a collaborative, cross-professional patient care process. It encompasses a variety of services and functions, some new to pharmacy and others traditional.*"

The Pew Health Professions Commission Report concludes that:

> *"Pharmaceutical care is consistent with the major themes of health care reform and the movement to a managed care environment, quality improvement and cost reduction, and holds the potential for serving as a model for professional evolution within a changing health care system."*

Pharmacists have the knowledge and opportunity to help patients achieve better outcomes from drug therapy and in turn provide a significant cost savings to Texas' health care system. The cost of this pharmaceutical care can be recovered from the savings it generates, but only if an environment is created by health care reform that recognizes that the savings are likely to be generated not at the pharmacist-patient level, but at the level of patients' therapeutic successes and the resulting reductions in hospitalizations, surgeries, repeated office visits, nursing home admissions, and prolonged illnesses that result from patients using their medications improperly.

Explanation of Issue

In recent years, the complexity of the health care system and the changing ways in which health care is delivered have similarly changed the way pharmacists practice. Within the next five years the practice of pharmacy will continue to be changed by many factors such as the aging of Texas' population, increasingly complex and expensive drugs, drug regimens, and diagnostic technologies emerging from the biotechnology industry, and health care reform. This will necessitate the viewing of pharmacy by professionals and patients in a way different from our century-old image of the pharmacist *"behind the counter"* inside the pharmacy.

In particular, the buyers and sellers of health care will continue to scrutinize the system to ensure that care is being provided in the most *"cost-effective"* manner. The role of pharmacists will be viewed in the context of what level of care and services a patient receives. Financiers will be monitoring pharmacy practice in all settings to determine if pharmacists' services are cost-beneficial, or if these services could be provided at reduced costs (*e.g.*, could pharmacist services be provided by a less-qualified pharmacist, or another health professional?). If the profession of pharmacy does not move toward a cost-effective, patient-oriented practice, it can expect pharmacy technicians and/or technological advances to replace any pharmacists who dedicate themselves solely to the dispensing and sale of medications and other products.

Policymaker, third-party payers, the public, and pharmacists need to be continually reminded that appropriate drug therapy is generally safer and more cost-effective than other forms of treatment and that the personal and economic consequences of inappropriate drug use are enormous.

A recent study titled "*Drug-Related Morbidity and Mortality - A Cost-of-Illness Model*" published by Johnson and Bootman in the October 9, 1995, issue of the *Archives of Internal Medicine* estimates the annual costs of medication-related morbidity and mortality in the community-based population alone to be $76.6 billion, with the largest component of this total cost associated with drug-related hospitalizations. Such morbidity and mortality can occur through inappropriate prescribing, poor implementation of drug therapy regimens, inappropriate patient adherence, adverse drug reactions or interactions, and inappropriate monitoring and assessment of outcomes. This study estimated that pharmaceutical care could reduce the cost of drug-related mortality and morbidity by more than $38 billion in the primary care settings.

As mentioned before, the term pharmaceutical care recognizes both aspects of pharmacy practice — the delivery of a product and the delivery of clinical services (drug therapy management, counseling patients, and monitoring patient outcomes, *etc.*). In a study conducted by the U.S. Department of Health and Human Services (DHHS), the Office of the Inspector General (OIG) of DHHS focused on clinical services available in the community to elderly ambulatory patients.

The OIG report defined clinical pharmacy as *"pharmacist functions to identify, resolve and prevent patients' drug-related problems."* Among the findings, the study reported that *"there is strong evidence that clinical pharmacy services add value to patient care and reduce health care utilization costs."* The added value includes:

- improvements in patients' clinical outcomes;
- improved patient compliance; and
- reductions in health care costs associated with mismedication problems.

The added value of *"clinical"* pharmacy services applies not only to ambulatory outpatients, but also to hospitalized patients. Studies have proven that hospital pharmacists' clinical services are cost-effective. Examples of ever-expanding pharmacist roles are:

- drug therapy management, including selection of drug products and determination of doses and dosage schedules;

- providing drug-related information and education to patients and caregivers, including education for chronic disease management, health promotion, and disease prevention;

- monitoring and assessing patients to maximize adherence to therapy and to detect adverse reactions and drug interactions; and

- monitoring and assessing outcomes of drug therapy.

In a move which confirms the evolution of the practice of pharmacy to a more patient-oriented clinical practice, the 74th and 75th Texas Legislatures amended the definition of the practice of pharmacy to include drug therapy management and administration of immunizations and vaccines under a written protocol of a physician. These amendments do not limit these practices to institutional settings but allow them to be performed by any competent pharmacist in any setting.

To fully apply the concept of pharmaceutical care, pharmacists must be knowledgeable of the new diagnostic tests, drugs, medical devices, and sophisticated medication systems. Advances in biotechnology are leading to the development of new diagnostic agents and a wide variety of new therapeutic agents. Increasingly, drug therapy will be aimed at the prophylaxis, or prevention, of disease rather than at the treatment of disease.

In the future, Texans may take specific medications throughout their lives to prevent disease. New drugs (or therapeutic agents) are predicted to be more specific, more complicated, more potent, and more related to basic biochemistry. Fewer adverse reactions, quicker drug action, and less frequent administration are some advantages of increased specificity. However, increased expertise and competence of pharmacists will be required in the use of these agents.

Pharmacists must be knowledgeable about new medications, devices, and delivery systems so they can advise patients (and other health practitioners) about their appropriate uses. The pharmacist will be required to understand not just doses and administration schedules, but the mechanisms by which the medications act. More complex drugs and devices will make continuing education essential for any pharmacist dealing with these products.

The pharmacist will also be a focal point in distributing self-test products and in interpreting results from diagnostic tests used by the public at home. Many of these self-test products are already on the market, or will be in the near future; *e.g.*, blood glucose monitors, HIV (AIDS virus), and cholesterol tests.

As more test products reach the market, pharmacists are increasingly in demand to assist consumers in understanding their proper uses and interpretation. Further, as these new drugs, dosage forms, delivery systems, and diagnostic tests become more readily available, the *"traditional"* dispensing function provided by a pharmacist is altered. The pharmacist may need to add medications to implantable pumps and program timing mechanisms for the pumps to deliver the correct doses to patients. Since these pumps are implanted within patients, one could consider the process of filling the pump as *"administering,"* rather than dispensing.

To effectively and properly provide clinical services, a pharmacist must, above all, be competent. In five and six-year entry-level college degree programs, pharmacy students are currently educated and trained to provide pharmaceutical care, including patient counseling and monitoring of patients' reactions and outcomes. However, as time passes after their graduation from formal college training, pharmacists' continuing competency becomes an issue. In addition, the continuing change and expansion of the health care system is creating opportunities for pharmacists to assume new practice responsibilities for which they were not prepared in their undergraduate pharmacy education. These changes to the profession are generating need for educational programs to enable pharmacists to acquire new practice competencies so that they may advance their pharmacy careers and continue to meet patients' health care needs. For these reasons, many in the profession believe that pharmacy needs a curricular-based continuing education which links learning and training to the achievement specific outcome goals.

The OIG report recognized this need and recommended that the National Association of Boards of Pharmacy (NABP) explore ways to ensure pharmacists' competence through periodic testing. However, the OIG also recommended that national and state professional pharmacy organizations work together to develop other appropriate methods for assessing the continued competence of pharmacists.

In addressing this need, NABP, in conjunction with the American Council on Pharmaceutical Education, is developing a Pharmacist Continued Competence Assessment Mechanism (PCCAM). PCCAM is intended to be a complement to pharmacist continuing education and other practice development activities by identifying areas of practice that the pharmacist may need additional training. The Texas State Board of Pharmacy supports the use of the PCCAM as a tool to direct continuing education prior to licensing pharmacists who are reinstating a license by Board action.

Another method to monitor continuing compliance of pharmacists is through voluntary certification. Traditionally, certification is provided by a non-governmental entity, such as a professional association, in recognition that an individual practitioner has met certain predetermined standards or qualifications.

However, because not all pharmacists participate in voluntary programs, and because of the lack of standards for the numerous certification programs available, the agency may be required to address this important area. Some have suggested that the Board of Pharmacy should be given the authority to allow pharmacists to use the term "*Board Certified*" only if the pharmacist has completed a certification program which meets minimum standards set by the Board of Pharmacy.

Equally as important as competency is the pharmacists' need to access patients' medical information in order to properly and effectively manage their drug therapy. Access to information could be provided through direct contact with the prescriber, a personalized patient ID card *(smart card),* a centralized health information and patient profile, or other mechanisms. Concerns regarding intervention into the patient-doctor relationship and confidentiality of patient records will certainly emerge as issues to be addressed.

Some of these issues were addressed by the 75th Texas Legislature, and resulted in positive changes. For example, the Texas Pharmacy Act was amended to provide confidentiality to any patient-specific information contained in a health-related record maintained by a pharmacy or pharmacist, such as a patient medication record, a prescription drug order, or a medication order.

Patients respect the information given to them by pharmacists. A Gallup poll has rated pharmacists as the most trusted professional in the nation for the past nine consecutive years. Couple this with the fact that pharmacists are the most accessible health care professionals, and it follows that pharmacists are in an excellent position to fulfill an expanded service role to the public. With increased documentation showing that pharmaceutical care will benefit the patient, the expanding role of the pharmacist will be more widely accepted. However, since non-pharmacists (corporate managers, managed care officials, *etc.*) make many policy decisions about how pharmacy will be practiced, the delivery of true pharmaceutical care will be threatened unless health care policy-makers and payers determine that pharmaceutical care is cost-effective and establish methods to compensate pharmacists for this service.

As mentioned earlier, compliance by patients with their medication therapy is a major problem in the United States. Every year, 243,000 of the nation's elderly are hospitalized for adverse reactions to prescription drug misuse, which causes or worsens mental impairment in more than 163,000 elderly, and kills some 30,000 elderly a year. Mis-medication of the elderly, in particular, is a critical health issue. Studies find that from one-third to one-half of all elderly stop taking their medications too soon, take them at the wrong times, and/or take them in the wrong amounts. Misuse generally stems from ignorance about medications, about the ways they work, and about the results we should expect from them.

Therefore, pharmaceutical care (the combination of delivering a drug product with appropriate clinical services and counseling) will have a positive impact on public health by achieving desired medical outcomes, thereby improving patients' quality of life and reducing health care costs.

Impact on Agency

In the past few years, court decisions have been mixed on whether or not pharmacists have a "*duty to warn*" patients about side effects, contraindications, and other information regarding their prescription drugs. Some decisions indicate that, absent specific statutory requirements, pharmacists do not have a "*duty to warn,*" while others indicate that pharmacists do have this responsibility. However, recently the trend is for the courts to find pharmacists responsible for patient counseling. The turnaround in court decisions appears to be related to the enactment of the Omnibus Budget Reconciliation Act (OBRA '90) which requires pharmacists to obtain patient histories, perform drug utilization reviews (DURs), and offer counseling to Medicaid patients.

In January 1993, the Board adopted rules which required pharmacists to perform these functions. However, the agency's rules are more stringent than the federal (OBRA '90) requirements, in that Texas pharmacists are required to provide oral counseling to ALL patients (unless the patient refuses the counseling) and supplement this counseling with written drug information.

As roles are expanded, the pharmacist may need to acquire certification in specialty areas. If certification is required, the Board needs to determine if this process is more appropriately handled by professional organizations or if the Board should set the related minimum standards. The Pharmacy Act may need to be amended to give the Board authority to assess continuing competency of pharmacists and the authority to require certification in specialty areas.

The increased complexity and potency of medications, and the complexity of delivery systems increase their potential benefits as well as their potential dangers to the citizens of Texas. These facts make it imperative that Board members and staff continually monitor development of the more sophisticated drugs, devices, and drug delivery systems to be aware of potential dangers to the public. If the agency is aware of potential dangers, it is better able to recommend laws and rules to assure that pharmacists are able — and willing — to provide competent advice and assistance to other health practitioners and to the patient.

The use of infusion pumps on ambulatory patients has blurred the distinction between *dispensing* and *administering* a drug product. For example, is a physician *dispensing* a drug product if he/she *loads* a pump, starts the pump on the patient and releases the patient to return to his/her normal daily routine, while the pump *administers* the drug over a two- or three-day time period? Likewise, if a pharmacist *loads* one of these pumps while it is on the patient, is this considered *administering*

the drug? Conversely, if a physician is dispensing the product, the provisions of the Texas Pharmacy Act would be applicable, and would come under the jurisdiction of the agency.

In order to answer many of the questions which arise concerning the use of these new drug products, devices, therapies, and delivery systems, the agency will need to seek input from other health professions to assure that the patient is properly served. The Board will be faced with determining appropriate modifications to laws and rules to assure that the patient's health is protected. For example, the Pharmacy Act may have to be amended to clarify that pharmacists are authorized *to administer* or *to load* medications into these delivery systems and *to interpret* test results from self-diagnostic tests.

Trends indicate that pharmacists do not have control over their pharmacy practice environment. Since corporate control exists in virtually all practice settings, non-pharmacists are making decisions about how pharmacy is to be practiced. The agency may be required, in the best interest of Texans, to implement rules mandating certain aspects of pharmaceutical care.

The federal government could establish these standards in the absence of appropriate actions by state boards of pharmacy given the precedent set by OBRA '90. The goals of health care reform include greater individual security, improved access to care, more cost-effective care, and maintenance of quality. This reform is an evolving process that will ultimately rewrite all the relationships in health care delivery and financing. Health reform will also be occurring at the state level, as well as the federal level. The agency must monitor activities at the state level and provide input into any state legislation, ensuring that pharmaceutical care is incorporated into Texas' overall health plan.

Furthermore, as the role of the pharmacist expands to include shared responsibility for the quality of patient care and patient outcomes, the agency will need to adapt its enforcement efforts to ensure that pharmacists are being effective. For example, the Board may need to implement measures to ensure that pharmacists are performing (and are competent to provide) such functions as:

- drug utilization review;
- drug therapy management;
- monitoring their patients for drug abuse;
- providing effective counseling; and
- directly monitoring drug use in certain settings.

Such efforts would represent a departure from the traditional focus of pharmacy regulation, structure, and process to a focus on the results instead of the process. The goal would be not to abandon structure and process, but to link them with the final outcome. David B. Brushwood in an article titled "*The Quality-Related Event*" in the November 1997 issue of the *NABP Newsletter*, has stated the following concerning outcome-based regulation.

> "*Regulating for outcomes can be done only if licensees are required to make records of their failures of quality and to adopt programs that improve quality based on activities that are known to have caused problems in the past. . . . State boards of pharmacy should require that licensees keep records of quality-related events.*"

Hospital pharmacists are currently defining quality of care in terms of outcomes as a result of standards from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). As community pharmacy practice moves to incorporate the concept of pharmaceutical care, regulatory and enforcement activities must also move to regulate based on quality assurance standards, not just performance of process-oriented tasks. The laws and rules must be structured such that they specify the desired outcome but not detail all of the steps necessary to obtain that outcome. This type of structure will allow pharmacists the flexibility to use innovative practice ideas while protecting the public by specifying positive patient outcomes.

The Texas State Board of Pharmacy's support of the use of outcome-based regulation may require retraining of enforcement personnel for review of quality related records and procedures. In addition, the agency may need to employ "*clinical consultants*" or retrain compliance officers in these areas so they can assess whether clinical services provided by the pharmacist helped or harmed the patient. In addition, compliance inspections of pharmacies will most likely take additional time if compliance officers are performing assessments (*e.g.*, reviewing patient profiles to see if pharmacists have performed appropriate drug utilization reviews, including observation of adverse drug reactions, inappropriate drug therapy, and drug interactions) and/or conducting quality assessments of pharmacy records.

Finally, although many studies are being conducted to prove the cost benefit of pharmaceutical care, if these studies do not result in the development of methods to adequately compensate pharmacists for providing pharmaceutical care, the number of pharmacists providing this care will decrease. The agency may be faced with deciding if it is reasonable to require pharmacists to provide a service (pharmaceutical care) when the marketplace is not willing to pay for this service.

Agency Strengths and Opportunities

- The current definition of the *practice of pharmacy* in the Texas Pharmacy Act:
  - includes *provision of those acts or services necessary to provide pharmaceutical care, drug therapy management, and administration of immunizations and vaccines under the written protocol of a physician*; and
  - is broad enough to include new responsibilities and activities necessary for pharmacists to *dispense/administer* advanced technological drug products and devices in the delivery of pharmaceutical care.
- The Texas Dangerous Drug Act gives the agency the authority to regulate prescription drugs and devices regardless of where these drugs are used or delivered.
- Various organizations are promoting pharmaceutical care to the public and to the profession, including the following:
  - The National Council on Patient Information and Education conducts public information campaigns and prepares/distributes promotional materials on an ongoing basis, such as "*Communicate Before You Medicate,*" "*Communication is the Best Medicine,*" and "*Medicine: Before You Take It, Talk About It.*"
  - The Coalition for Consumer Access to Pharmaceutical Care (a national organization) was formed in March 1993 to create understanding that pharmaceutical care is part of the solution, and has adopted the following positions:
    - pharmaceutical products and pharmaceutical care should be included as a core benefit in a reformed health care system;
    - pharmacists' services and proper management of medications can generate significant savings to a reformed health care system;

- quality assurance programs administered by pharmacists can significantly improve the effectiveness of medications in achieving positive patient outcomes; and

- integrated information systems that include pharmacists offer the potential for cost savings and better patient outcomes.

- A precedent exists for expanded roles for Texas pharmacists, because:

  - the federal government, through the Department of Health and Human Services' Office of the Inspector General, has supported the clinical role of community pharmacists;

  - the Texas Pharmacy Act now recognizes drug therapy management under protocol from a physician in any practice setting and the administration of drugs, under certain conditions, as a role of the pharmacist. In addition, this amendment to the Act was supported by the medical and nursing community; and

  - the federal government, through the Omnibus Budget Reconciliation Act (OBRA '90), has mandated prospective drug utilization review (DUR) by pharmacists (patient counseling and maintenance of patient profiles) for patients receiving Medicaid assistance.

- Current Board rules require patient counseling for patients at the pharmacy, Drug Use Review (DUR), and provision of written information about prescription medications. The agency's support for expanded roles, coupled with its reputation and credibility, may lend to the acceptance by consumers, legislators, and the profession of expanded roles for pharmacists.

- Current Board rules require patient outcome monitoring in some practice settings.

- The pharmacist's credibility with the public in terms of honesty and integrity will help the profession and the agency to move pharmacists toward new or expanded roles.

- All Texas pharmacy schools have implemented a six-year curricula, conferring the Doctor of Pharmacy (Pharm. D.) degree upon successful graduates. The new curricula provides a knowledge base on which pharmacists can expand their current and future roles, such as those in education/training in patient assessment skills. In addition, the Texas colleges of pharmacy are working to offer a uniform "*external*" degree program for current pharmacists to obtain the Doctor of Pharmacy degree.

- The agency has the authority to establish task forces composed of pharmacists and other professionals who have special expertise to advise the Board.

- There is a vast pool of knowledgeable resource persons in Texas' pharmacy educational institutions and in its health professions available to the agency.

- The agency has recognized and anticipates the potential for difficulties in regulating new medications, devices, dosage forms, and delivery systems in the public interest.

Agency Weaknesses and Constraints (Threats)

- Pharmacists may not be compensated for expanded pharmaceutical care services. Can the Texas State Board of Pharmacy require services for which the pharmacist will not be reimbursed, even if those services are crucial to the public health? Policy makers may view pharmaceutical care as *too expensive* to include in federal or state health care reform initiatives, and thus, the fragmented delivery of health care will continue even in *managed care* settings. The agency must encourage and educate policy makers to recognize the value of pharmaceutical care and its benefit to the public and its contribution to significantly reduce health care costs.

- In spite of the need for health care to be based on a multi-disciplined health care delivery system, expanded roles for pharmacists may be perceived as threatening the *turf* of other health professionals such as physicians and nurses. Resolution of problems related to advanced technological drugs, devices, and dosage forms may, in some cases, be thwarted by *turf* battles between the health professions.

- Some pharmacists may perceive that providing *pharmaceutical care* increases their liability. In addition, some pharmacists may be limited in the extent of *pharmaceutical care* services they are able to effectively provide because they don't have access to information in the patient's medical records (*e.g.*, pharmacists may not know the patient's diagnosis or the outcome sought by the physician).

- If pharmacists are not allowed to fully use the assistance of technology and/or pharmacy technicians, but are required to provide *pharmaceutical care,* the cost of pharmacy services could rise significantly.

- Although there is a documented need, the agency has virtually no resources to address the need for consumer education about the use, abuse, and misuse of prescription drugs so critical to positive patient outcomes.

- There is a need for appropriate agency rules on delivered prescriptions (mail order and local). With any type of prescription delivery service, patients do not get the benefits of personal interaction with the pharmacist and, more importantly, the burden of receiving counseling is then unfairly shifted to the patient (and is therefore dependent on the assertiveness of the patient in asking for the information).

- The agency may have difficulty dealing with advanced technological drugs, devices, and dosage forms due to rapid development and complexity of products, and due to its lack of clear regulatory authority to address related issues.

- The pharmacy profession has only limited mechanisms for voluntary certification of pharmacists who specialize in drug therapy management or the use of advanced technological drugs and dosage forms.

- The current definition of dangerous drugs includes *devices which require a prescription*, but does not include other types of devices.

- The current structure of the agency may not be the best for implementation of "*outcome based*" enforcement.

- Although the current definition of the *practice of pharmacy* in the Texas Pharmacy Act is broad enough to include new responsibilities and activities for pharmacists to *dispense/administer* advanced drug products and devices, the Act may have to be amended to clarify that these activities are included.

- Some of the "*corporate*" (independent and chain) entities that own pharmacies in Texas give a great deal of "*lip-service*" to the concept of pharmaceutical care, but the experience of the agency is that the main emphasis of these corporations is on the "*bottom-line*" or the number of prescriptions dispensed. Therefore, when it becomes apparent that additional resources are necessary to provide pharmaceutical care, these resources may not be readily provided.

POLICY ISSUE #2

"Traditional" and *"Non-Traditional"* Pharmacy Practice Settings and The Delivery of Full-Access Patient Care

Issue Statement

The same forces affecting the role of pharmacists are also impacting the delivery of pharmacists' services. The health care system is continually striving for more effective, less expensive mechanisms by which supplies and services can be delivered to the patient. Consequently, the provision of pharmaceutical care is now occurring, and will increase, in both "*traditional*" and "*non-traditional*" settings. To better meet the needs of the patient for accessible care, pharmacists must be allowed to be responsive in these settings.

Some managed-care networks and third-party payers are recognizing the value of pharmaceutical care. Although willing to pay for cost-effective programs, there is a reluctance to provide reimbursement until pharmacists can show cost savings to the payers. In spite of the fragile status of reimbursement, some pharmacists have implemented programs which provide comprehensive education and monitoring for patients with special health problems such as diabetes or hypertension. Some of these programs include educational classes, laboratory testing, and personal one-on-one educational and goal-setting visits. These services are provided by pharmacists, nurses, dietitians, or nutritionists. As these types of cognitive services are established and proven to improve patient health at a lower cost, more pharmacists will orient their practices to provide these services. Many of these services can be performed in locations not licensed as pharmacies.

Explanation of Issue

Market demands for health care are propelling the development of new mechanisms for health care delivery. Changes in the delivery of pharmaceutical care will continue to develop over the next five years and will include the following:

The *"Blurring"* of Community and Hospital Pharmacy Practice Settings

As facilities search for new sources of revenue, hospital pharmacies have implemented outpatient departments and have become involved in *"nursing home operations."* In addition, community pharmacies are now providing *"home health care"* services.

Pharmacy Networks

Hospitals are also becoming increasingly involved in the provision of primary care to communities from facilities located apart from the licensed hospital (*e.g.*, rural health clinics, radiology departments, magnetic resonance imaging facilities, indigent health clinics). Many of these facilities have a need for both prescription medications and pharmaceutical care services. There is a strong desire for these facilities to be serviced from a pharmacy network located within the hospital in a manner which resembles an inpatient rather than an outpatient setting. Hospitals have recently acquired the statutory ability to license multiple locations within a 30-mile radius under one hospital license. Although this networking approach for pharmacy services has not been allowed in the past due to statutory possession and accountability issues, technology may play a role in resolving those issues.

In the community pharmacy setting, high volume facilities are looking for ways to spread the workload associated with the operation of a pharmacy. Some pharmacy managers have looked to centralized refill centers as a way to improve working conditions and improve the provision of pharmaceutical care. Refillable prescriptions for patients who indicate that they will pick up their prescriptions the following day will be dispensed by the centralized refill center. Technology allows prescription information to transfer between the two facilities and for proper records to be maintained. This frees the pharmacist at the primary pharmacy to spend more time providing pharmaceutical care.

The Rapid Growth of Pharmacy *"Specialization"*

- Health Maintenance Organizations — Pharmacists in a *"closed"* system, often with formularies and increased routine interaction/teamwork with physicians and the nursing staff.

- Hospice, Home Health Care, and Oncology Pharmacies — Pharmacists using more technical expertise in the preparation of parenteral medications and in the use of sophisticated devices designed to deliver medications to seriously ill patients. This also means more pharmacist interaction with the nursing staff and physician(s) in order to manage the patient's drug regimen.

- Mail Order Pharmacies — The following conditions may exist:

    - There is no face-to-face communication between the patient and the pharmacist, and therefore the burden of receiving counseling is shifted to the patient and becomes dependent on the assertiveness of the patient in seeking the information;

- Non-pharmacist personnel may be handling customer complaints about prescription drugs and prescription errors;

- Patients of mail-order pharmacies may ask their local pharmacists questions about the mail-order medications, since local pharmacists are more accessible;

- Insurance plans encourage patients through financial incentives to obtain maintenance medication from a mail-order pharmacy but allow immediate need prescriptions to be obtained from local pharmacies. This system forces patients to receive their prescriptions from more than one source; therefore, pharmacists at either of the pharmacies do not have the entire patient drug history and are not able to monitor for drug interactions, contraindications, etc.;

- Some mail order pharmacies are opening "*counseling centers*" that are staffed by pharmacists and non-licensed customer service representatives. Pharmacists in the counseling center do not dispense any prescriptions but respond to patient questions about their prescriptions dispensed by a pharmacy owned by the mail-order company.

- Drug Therapy Management Under Protocol — With the adoption of rules for drug therapy management under protocol, pharmacists are forging relationships with physicians and patients to manage a patient's drug therapy under protocol. Drug therapy management under protocol is not limited to a licensed pharmacy location and may occur anywhere the patient, physician, and pharmacist have established a need and a protocol relationship.

- *"Closed"* Pharmacies — Pharmacies that are serving specific types of patients, *e.g.* nursing home patients. By limiting the types of patients served by the pharmacy, the pharmacy is able to obtain special discount prices from drug manufacturers. As a result, the pharmacies are not open to the general public.

- *"Compounding"* Pharmacies — Pharmacies that dispense a large number of compounded medications directly to patients. These pharmacies include the following:
  - Hospice, Home Health Care, and Oncology pharmacies, in which pharmacists compound sterile pharmaceuticals;
  - Non-institutional-based pharmacies in which pharmacists compound nuclear pharmaceuticals. (*"Nuclear"* pharmacists are required by Board rules to obtain additional education and training.); and
  - Community pharmacies, in which pharmacists compound specialized topical, oral, and inhalation medications.
- Pharmacist Administration of Immunizations and Vaccines — The 75th Legislature amended the Texas Pharmacy Act to allow pharmacists to administer immunizations and vaccines under a written physician's protocol as a part of the practice of pharmacy. Although the medication will most likely be provided by a pharmacy, administration of the immunization or vaccine may occur at a location other than the pharmacy.

The Proliferation of *"Non-Traditional"* Settings

There has also been a rapid growth in the different types of facilities where drugs may be stored, administered, and dispensed (*e.g.*, ambulatory care centers, ambulatory surgical centers, abortion clinics, birthing centers, rural health clinics, public health clinics, and drug abuse/alcohol rehabilitation/treatment centers). Currently, most of these facilities are operating as a physician's office or with a *"special"* pharmacy license, which allows the facility to provide limited types of drugs without having a pharmacist on-site, but requires a consultant pharmacist to oversee and manage the drug delivery system.

Recently, there has been an increase in the number of residential/assisted living centers for senior adults. Although these facilities are primarily treated as a patient's home and their medications are provided by local pharmacies, there is a strong desire to have emergency or convenience drug carts available in these facilities.

Under the current statutes, pharmacists located in another state may provide clinical services to Texas residents without being licensed to practice pharmacy in Texas. Therefore, pharmaceutical care will be provided to Texas residents from facilities other than pharmacies which are located not only in-state but out-of-state.

The Increased Demand for *"Clinical"* Pharmacists

As pharmacists become more recognized as drug experts and *"Clinical"* pharmacists, they will have more opportunities to deliver *"pharmaceutical care"* in situations not involving the delivery of a drug product. Examples include nursing home consultant pharmacists; pharmacist consultants to hospitals, clinics, and managed care settings; pharmacokinetic consultants; independent pharmacist consultants; and providers of drug information services to health professionals and consumers. Drug therapy management under protocol, as previously discussed, requires a pharmacist with good "*clinical*" skills. The adoption of rules specifically for this professional practice will allow pharmacists and physicians to better manage a patients's disease. This clinical role, as a manager of patients' drug therapies, is expected to increase dramatically over the next five years.

One example of increasing demand for *"clinical"* pharmacists is the Safeguards for Seniors program, operating under the Greater Dallas Section of the National Council of Jewish Women. Their program promotes proper use of medications by older adults and is concerned that patients do not know how to take their drugs. To underscore this concern, this organization recently published a participation survey which provides the following alarming statistics concerning medication use by senior adults. From 1992 through 1997, 54% of the seniors participating in medication reviews sponsored by this organization were in need of some kind of intervention. Almost 27% required a change in the way they used their medications. These concerns should be reduced as pharmacists provide patient counseling and monitoring services.

In all these settings, it is important to note that a key component of the success of such efforts will be the pharmacist's reimbursement for the provision of such care, and not just for the provision of the medication product. Although this concept of payment for cognitive services has been around for a while, there are still many issues between the purchasers of health care and the profession that have not been resolved. Even in this uncertain reimbursement climate, a few pharmacists have managed to obtain payment for cognitive services. However, progress in this area has been agonizingly slow.

Professional organizations have developed and are continuing to develop programs which assist pharmacists as they redirect their practices. The Texas Pharmacy Association has established The Texas Center for Pharmaceutical Care (TCPC). The purpose of TCPC is "*to prepare and support the pharmacists to develop a contemporary practice which is more patient-centered, and outcomes oriented, with special emphasis on drug therapy management and direct patient care.*" This effort is also occurring at the national level. One example is the American Pharmaceutical Association's "*Concept Pharmacy Project*."

This professional display uses multimedia presentations, direct meetings with innovative practitioners, interactive kiosks, and computer simulations as educational tools. The purpose is for participating pharmacists to gain a better overall understanding of what pharmaceutical care is and how they can incorporate it into their own practice to provide better patient care.

Meanwhile, as these positive changes occur, the Board is concerned that in many *"traditional"* and *"non-traditional"* pharmacy settings consumers may have little control in their access to quality pharmaceutical care. The pharmacist, as an employee, may have little control over his/her pharmacy practice environment. Consumers' access restrictions can surface by way of *"managed care"* program limitations. For example a managed care organization may force a patient to obtain all maintenance medication from a distant "*mail-order*" pharmacy or pay a higher fee or copayment for their prescription drug. Further, these consumers' pharmacists may be *"employees"* and thus their pharmacists may not be involved in decisions or policy-making processes regarding delivery or accessibility of pharmacy services. If management or policy-makers fail to see a direct cost-benefit or short-term gain/profit to FULL-ACCESS pharmaceutical care, it is likely that providing an environment in which the pharmacist can practice pharmaceutical care might also be overlooked.

In the past 12 years (1986 to 1998), the number of chain community pharmacies has increased by 18%, while the number of independent community pharmacies has decreased by almost 19%. Since chain operations employ a large number of pharmacists and operate large numbers of pharmacies, the policies and decisions of corporate management have a significant impact on pharmacists and on the delivery of their pharmaceutical services and, thereby, on the health of the citizens of Texas.

At times, pharmacists may find themselves in a pharmacy environment where working conditions lead to high levels of stress. Often pharmacists are not involved in the decision-making process which leads to stressful or even dangerous working conditions. Although not directly under the jurisdiction of the Board of Pharmacy, if working conditions adversely affect public health by increasing dispensing errors, compromising drug use reviews, or decreasing the availability and effectiveness of patient counseling, the Board must get involved. A discussion on the impact of working conditions on the public, pharmacists, and the Board may be found in Policy Issue #3.

When a pharmacist or a practice setting is accountable to a third party for reimbursement (*e.g.*, insurance company, federal government), the third party may establish practice standards outside the auspices of the Board which may be more restrictive or expansive in scope. Examples of these "*practice standards*" include:

- participation in the program requires certification for the pharmacist(s) in specialty areas of pharmacy practice;

- pressure on physicians by pharmacy benefit managers (PBM) to switch to a different drug product because of a cost advantage to the PBM or employer; and

- the practice of some corporate owners of pharmacies to accept insurance pharmacy plans at a reimbursement rate that these corporate owners know will not allow the pharmacy to employ sufficient staff to comply with the current laws and rules relating to patient counseling and drug use review. The corporation is looking only at the bottom line and the increase in the number of prescriptions the pharmacy will dispense.

This trend will not decrease as Congress and other entities continue to look for ways to improve the cost-effectiveness of health care. These new mechanisms for delivery of pharmacy and health care services will need to address the health care needs of the poor and the elderly, as well as the needs of those Texans living in rural areas. Due to various factors, hospitals in many rural areas have closed. As a result, rural areas are unable to attract and retain physicians, nurses, and, in some cases, pharmacists. As rural hospitals close and physicians move out of these areas, the people of the community are unable to access many medical services, including pharmaceutical care. These *"medically underserved"* areas provide excellent opportunities for *"physician extenders"* (nurse practitioners and physician assistants) to serve the public. This trend fuels innovation which results in the formation of new non-traditional pharmacy practice settings. The agency should foster pharmacist involvement, so that *"physician extenders"* will form coalitions with pharmacists in the best interest of patients.

In addition to the development of less expensive alternatives to traditional health care delivery systems, other economic factors will continue to affect the delivery of pharmaceutical services over the next five years. These economic factors include "*multi-tiered*" pricing by drug manufacturers, and special financial "*arrangements*" (*e.g.*, cooperative ventures in which physicians own or receive profits from clinical laboratories or pharmacies, and receive profits from referrals of their own patients).

Also, economics in the form of limited drug distribution systems, increased use of generic drugs, and third-party reimbursement policies will affect what kind of pharmaceutical care is delivered. Traditionally, the agency has not dealt with **economic issues**; however, since economics is a crucial aspect in the delivery of health care, it **cannot be ignored**, especially if economics negatively impacts the delivery of quality pharmaceutical services to Texas citizens. If pharmacists are not reimbursed for services, there could be a significant negative impact on patient care for Texas citizens.

Impact on Agency

With diversification and deregulation, new arrangements will be forged and new types of settings will be established where drugs and associated services can be provided, administered, and/or dispensed. In addition, pharmacists will be working in and delivering pharmaceutical care services to patients from locations other than licensed pharmacies. These new locations or practice sites will create additional settings and a challenge for the agency to regulate. Staff education and training will have to include drug accountability and drug delivery issues to techniques for the evaluation of patient outcomes. Inspection processes will have to change to accommodate the shift from drug delivery to the provision of pharmaceutical care.

Many of these settings will involve the practice and delivery of pharmaceutical services in ways unprovided for in existing laws and regulations. Keeping abreast of the latest market developments will require constant planning and monitoring by the Board and staff. When statutory authority exists to develop rules, the Board may seek recommendations from "*ad hoc*" task forces for the appropriate level and method of regulation. One example is the Task Force on Pharmacists' Administration of Immunizations and Vaccines. Although these task forces are invaluable to the Board's regulatory efforts, they tax available personnel resources.

The agency will need to develop methods for dealing with complaints regarding how pharmaceutical services are delivered. Examples of these types of complaints are:

- complaints alleging that pharmacists have failed to provide patient counseling or drug use reviews or have provided improper patient counseling/drug use reviews;
- complaints concerning the pharmaceutical care provided by pharmacists involved in purely clinical roles from facilities not licensed as pharmacies located both in-state and out-of-state;
- complaints about mail-order pharmacies (in- and out-of-state), compounding pharmacies, and other types of *"non-traditional"* practice settings;
- complaints from third-party payers alleging fraud (as third-party auditors detect fraud and abuse in their respective programs);
- complaints involving violations of the Federal Prescription Drug Marketing Act of 1987 (*e.g.*, "*grey-market*" diversion of prescription drug samples and/or institutionally-priced prescription drugs outside of the normal chain of distribution);

- complaints alleging diversion of prescription drugs and controlled substances (drugs of abuse/addiction) to the public as a result of the increased numbers and types of settings where drugs are provided;

- malpractice reports filed by insurance companies, as required by the Health Care Quality Improvement Act; and

- increased demands to assist other federal and state agencies reviewing pharmacies whose operations may seem to cross into their jurisdiction(s); e.g., the Federal Food & Drug Administration (FDA) may consider pharmacies in which drugs are compounded as manufacturers, which are under FDA jurisdiction.

The anticipated increased numbers of complaints will place resource demands on the agency that will be difficult, if not impossible, to meet, given current resources. In addition, the agency may have to hire new personnel or retrain existing personnel to handle complaints regarding pharmaceutical care services. For example, if a patient is injured because a pharmacist fails to identify a problem during a drug use review, agency personnel investigating this complaint will need to be pharmacists or the agency will have to contract with pharmacists to evaluate these types of complaints.

These increased numbers of complaints will add to the additional demands already placed on the agency's complaint process by recommendations of the Sunset Advisory Commission which were incorporated into the Texas Pharmacy Act during the 73rd Texas Legislative Session. For example, the Act now requires pharmacies and pharmacists practicing "*in*" or "*out-of*" a non-licensed facility to notify consumers of the name, address, and telephone number of the agency, so they can direct complaints to the agency. In addition, the other legislation developed during the 73rd and 74th Sessions required the agency, in conjunction with the Health Professions Council, to implement a 1-800-number for consumers to use when filing complaints against health professionals. This 1-800-number is now operational and posted in every out-patient pharmacy in Texas.

The Act was also amended during the 73rd and 74th Texas Legislative Sessions to allow the agency to inspect any facility where the practice of pharmacy occurs, whether or not the facility is licensed as a pharmacy. This amendment was crucial to the agency's enforcement efforts since pharmacists are beginning to practice in sites other than licensed pharmacies.

One issue that remains unaddressed, however, is the agency's inability to inspect financial records. Without this authority, the agency is unable to investigate complaints relating to *"kickback"* arrangements between pharmacists and other health care providers, *"grey market diversion"* (previously defined), and generic drug substitution (*i.e.*, complaints alleging that pharmacists charge the same price for a brand name drug as they charge for a generic drug). The agency's attempts to obtain this authority through Legislative action have been unsuccessful.

Agency Strengths And Opportunities

- The agency has the statutory authority to regulate the majority of practice settings through the five classes of pharmacy licenses. In addition, recent amendments to the Pharmacy Act give the agency the authority to regulate the practice of pharmacy wherever it occurs.

- Through its current rule-making authority, the agency has established standards for various types of practice settings. As a result, a precedent exists for regulating non-traditional settings through rules which are flexible and appropriate to the particular setting involved.

- The authority to regulate Pharmacist Drug Therapy Management under Protocol and Pharmacist Administration of Immunizations and Vaccines under Protocol has provided experience with drafting regulations for pharmacy practice not associated with specific practice settings.

- The agency has assumed a "*lead agency*" position among other state agencies with regard to the regulation of pharmacists and pharmacies, which gives it the credibility it needs to effectively regulate delivery of pharmaceutical services through traditional and non-traditional settings. This "*lead agency*" position encourages cooperation and effective coordination of activities with other agencies that impact the practice of pharmacy (*e.g.*, Department of Health, Department of Public Safety, Drug Enforcement Administration). Specifically, the agency has worked closely with the Federal Food and Drug Administration (FDA) to inspect pharmacies in Texas which FDA believed to be manufacturing, rather than compounding, pharmaceuticals in violation of the Federal Food, Drug, and Cosmetic Act. Through joint inspections, the two agencies were able to successfully resolve the complaints.

- With the passage of the federal Food and Drug Administration (FDA) Modernization Act, the agency will be allowed to enter into a memorandum of understanding (MOU) concerning "*compounding*" pharmacies. This MOU should clearly establish the enforcement areas of FDA and the agency with respect to compounding by pharmacies within this state contributing to the "lead agency" position.

- The agency has developed standards for pharmacies that compound sterile and non-sterile pharmaceuticals, and thus, has experience in the development of standards for compounding pharmacies.

Agency Weaknesses and Constraints (Threats)

- As practice settings become more diverse and increase in number, the complexity of regulation and enforcement will increase and, in turn, severely strain the human resources of the agency's enforcement divisions.

- The Board is statutorily unable to directly regulate pharmacists located in other states who provide pharmaceutical care services but not prescription medications to Texas residents. This severely hampers the Board's ability to protect the public if the activities of these pharmacists result in harm to a patient.

- Without appropriate regulation of unfair economic practices, such as multi-tiered pricing, and inadequate reimbursement of pharmacists by third-party payers, the integrity of the delivery of pharmaceutical services may be eroded. However, the agency does not currently have the authority to address economic issues even if they affect patient care and, further, doesn't have the authority to inspect financial records and data.

POLICY ISSUE #3

The Effects on Pharmacy Practice and Patient Care of Technology, Pharmacy Technicians, Pharmacist Manpower and Working Conditions

Issue Statement

Use of computers, robotics, and other forms of automation, as well as increased use of pharmacy technicians, will increase in pharmacy practice over the next five years. Meanwhile, Texas is currently experiencing a manpower shortage and there are not enough pharmacists to fill the demands of the citizens of Texas, particularly in areas typically identified as *"medically underserved"* areas. The manpower shortages may have an impact on working conditions in pharmacies, in that pharmacies may be operating with an insufficient number of pharmacists and competent, trained technicians.

However, some predictions for the next 10 years seem to indicate that this trend will change to an oversupply of pharmacists. With these trends, pharmacy practice and regulation will be altered. Regulatory agencies will be forced to determine appropriate levels of regulation necessary to protect and promote the public health and welfare, while allowing for the roles of advanced technology and pharmacy technicians in caring for increasing patient needs.

Explanation of Issue

Advanced Technology

Within the past few years, the use of automation in pharmacy practice has become the *"norm."* Today, pharmacies of all types use computers to store prescription records and many also use automatic counting devices to dispense drugs. The trend toward automation and the use of other advanced medical technologies show no signs of slowing and, in fact, gives every indication of increasing. As the industry demand for automation increases, more resources are focused on design and development of effective, cost-efficient technology.

The Board supports the increased use of technology to enable pharmacists to better serve the public health, safety, and welfare. Over the past five years, the Board has implemented rules which permit licensees to use technology for transmitting prescription orders, dispensing prescriptions, and keeping records relating to prescriptions. As new technologies become available, the Board will continue to review rules in the future to determine if changes are needed.

Technology, as it relates to the practice of pharmacy, can be identified into three general areas: Information Storage and Data Entry Technology; Information Transfer (Communication) Technology; and Automated Dispensing Devices (Robotics).

Information Storage and Data Entry Technology

The improvements in storage technology over the past ten years have been significant. Currently, high capacity hard drives and other direct access storage devices are capable of storing large amounts of information in a very small space. CD Rom technology allows access within a pharmacy to whole libraries. In addition, the cost of these systems is such that the technology is accessible to average users.

Use of these storage technologies will greatly increase the availability and accessibility of information to pharmacists and other health care providers. For example, *a smart card* (the size of a credit card), containing microprocessors or optical memory, is capable of holding a patient's entire medical history. In fact, several proposals to the U.S. Congress during the discussions on health care reform in 1993 and 1994 included the use of a *universal* health care card which would eventually include some, if not all, of the patient's medical history.

Using such a card, a pharmacist could access the patient's entire medical and drug therapy history. Access to this information is necessary if pharmacists are to realize their potential as *clinical pharmacists* and provide the patient with comprehensive pharmaceutical care.

In a related area, data entry technology is moving beyond the keyboard. The use of bar coding is a tool that rapidly and accurately inputs data into computer systems. Bar codes used to identify drug products, prescriptions, and personnel can be scanned prior to dispensing to ensure accuracy and identify personnel. In addition to maintaining an actual written prescription, the Board has had rules since March 1991 allowing prescription records to be stored on microfilm, microfiche, or any other system which is capable of producing a direct image of the original prescription record (e.g., digitalized imaging system). Other devices such as optical scanners and voice recognition may also find data entry applications in pharmacies.

Information Transfer (Communication) Technology

The development of more efficient, affordable, and rapid communication technology is also having an effect on the delivery of health care. Electronic communication technology (either facsimile or computer-to-computer) is now affordable for small businesses and can be used to transmit patient information, including prescriptions, between physician and pharmacy. Many believe that electronic communication between physician and pharmacist is superior to telephone calls, since it reduces the possibility of misunderstanding.

Modems now link pharmacy computers through telephone or satellite transmission with computers in physicians' offices, third party program offices, or even patients' homes. Most pharmacies now have a modem connecting the pharmacy to a third party payer's computer, to check third-party payment eligibility of the patient prior to dispensing a prescription. For example, the Texas Department of Health (TDH) Vendor Drug Program began requiring pharmacies to electronically submit claims for payment. The TDH system checks for patient eligibility, reviews the patient's drug regimen for interactions and drug therapy duplication, as well as over- and under-utilization of their medications. If a problem is encountered, the system sends a message to the pharmacist alerting him/her to the problem. The limitation of this system is that it reviews only the drugs covered and dispensed through the Vendor Drug Program.

However, all too often, pharmacists only have access to a small portion of the information necessary to provide comprehensive pharmaceutical care. Technology which allows a pharmacy access to a patient's entire medical history would allow the pharmacist to review this history, check for drug interactions, and then evaluate the appropriateness of the drug therapy before dispensing the prescription.

Such systems allow prescription and patient information to be communicated directly between computers in the physician's office and the pharmacy. These systems are capable of transmitting new prescriptions, refill requests, refill authorizations, patient medical histories, and problems identified with a patient's drug regimen. This technology will provide rapid exchange of information necessary to practice pharmacy and medicine in a safer, more efficient manner. In March 1996, the agency promulgated rules to permit a prescription to be transmitted by a practitioner or practitioner's designated agent directly to a pharmacy or through the use of a data communication device, provided the prescription information is not altered during

communication and confidential patient information is not accessed or maintained by the operator of the data communication device (unless the operator is authorized to receive the confidential information).

This innovative agency rule recognizes the confidentiality issues that arise when technology allows pharmacies to share information with other health care providers and third party payers. Both the Texas Pharmacy Act and Board rules have safeguards to protect patient confidentiality. However, many drug manufacturers are entering into contracts with Pharmacy Benefit Managers (PBM) to monitor use of medications. Many times the drug manufacturer will use the patient information to market drug products directly to the patient. The question of patient confidentiality becomes confusing in these marketing programs, because when a patient agrees to participate in the third party plan, often the patient forfeits his/her rights to confidentially as a condition of participation in the third party plan.

However, it does not appear that this waiver of confidentiality would extend to a drug manufacturer. Since PBMs are not directly regulated by any governmental agency, enforcement of these confidentiality laws becomes difficult. States must take steps to determine appropriate regulatory measures to prevent unauthorized access to confidential health information. At least one of the comments to our review of this strategic plan suggested that PBMs need to be licensed or regulated by a state agency and specifically by the Board of Pharmacy. The Agency must be aware of and monitor initiatives to regulate PBMs.

Automated Dispensing Systems/Robotics

Automated dispensing systems are now available that range from those that simply count tablets to those which select the drug, count the appropriate quantity, then package and label the product for a prescription. Automated compounding systems able to measure and mix intravenous preparations, are also available and in use in hospital pharmacies and Class A pharmacies that compound sterile pharmaceuticals.

Currently, automated systems are used in large facilities with a high volume of prescription dispensing. However, as the technology develops, costs are expected to drop and these types of systems will be cost-effective for average volume pharmacies (hospital and community).

The perception of increased accessibility, accountability, and the desire to use these systems to their full potential, has prompted suggestions for their use in facilities not currently licensed to possess stock prescription drugs. Prefilled cabinets or carts could be placed in a non-licensed facility, such as a nursing home or residential treatment center, with access controlled by a pharmacist in a licensed pharmacy. Obviously, an appropriate level of regulatory control and accountability must be maintained as these systems develop.

Pharmacy Technicians

The use of pharmacy technicians in a hospital (inpatient) pharmacy setting has become a standard practice. These technicians perform many of the inpatient drug distribution functions under the direct supervision of a pharmacist who remains responsible for the accuracy of the distribution process. However, the use of pharmacy technicians in a community pharmacy setting, including outpatient dispensing from a hospital, continues to be a major issue in pharmacy practice.

In January 1993, the agency promulgated rules requiring pharmacists to perform a review of the patient's medical history, checking for such things as drug interactions, duplications, and contraindications, prior to dispensing any prescription. These rules also required pharmacists, on all new prescriptions, to verbally counsel patients concerning the proper use of their medications. As of September 1, 1993, pharmacists have been required to provide written information on all new prescriptions. Drug information is also required to be provided upon patient request and when deemed appropriate by the pharmacist. The agency clarified these rules in April 1997, requiring verbal and written drug information to be provided on transferred prescriptions [prescriptions previously taken by the patient but transferred to another ("new") pharmacy], as well as prescriptions issued for a drug previously taken by a patient, but in a different strength or dosage form than previously taken.

The new counseling rules compel the pharmacist to spend more time on clinical or patient care duties and less time on the technical, mechanical aspects of dispensing a prescription. To give the pharmacist more time to counsel patients, the agency promulgated rules in April 1997 to allow pharmacists to delegate the duty of labeling a prescription to a technician. Accordingly, the demand for qualified and trained pharmacy technicians is increasing.

Partly in response to this demand, both the Texas Pharmacy Association and the Texas Society of Health-System Pharmacists began offering an examination in 1993 to certify pharmacy technicians in Texas. More recently, the American Society of Health-System Pharmacists, the American Pharmaceutical Association, the Illinois Council of Hospital Pharmacists, and the Michigan Pharmacists Association organized the Pharmacy Technician Certification Board (PTCB).

The PTCB has established a standard examination to certify technicians from all practice settings nationwide. Currently, both the Texas Pharmacy Association and the Texas Society of Health-System Pharmacists actively support the PTCB's Pharmacy Technician Certification Examination. According to 1997 PTCB data, Texas has more certified pharmacy technicians than any other state. Of the approximate 22,000 certified pharmacy technicians in the nation, there are over 2,500 certified pharmacy technicians (11%) in Texas. Although this certification process partially addresses the *"competency"* issue for technicians, it does not address the potential need for regulation and control of these individuals.

The Board acknowledges the need for competent pharmacy technicians. To address this need, the Board recently passed a rule that all pharmacy technicians must pass the PTCB Pharmacy Technician Exam by January 1, 2001. In addition, upon the recommendation of a Board-appointed Task Force on Pharmacy Technicians, the Board adopted rules effective in March 1996 which strengthen the training and competency requirements for pharmacy technicians in both the hospital and community pharmacy setting. In addition, the 75th Legislature amended the Texas Pharmacy Act to give the Board the authority to determine and issue standards for recognition and approval of training programs for pharmacy technicians. In November 1997, TSBP established a Task Force to formulate recommendations to implement this legislation. The work of the Task Force is expected to be completed in FY98.

Unfortunately, as the use of pharmacy technicians increases, the agency is noticing an increase in the number of cases involving diversion of prescription drug products (controlled and non-controlled) by these individuals. Investigation of complaints over the past seven years revealed that forty-six non-licensed employees were responsible for theft of over 276,700 dosage units of controlled substances from pharmacies. However, the agency currently has no regulatory authority over pharmacy technicians. Since the Texas State Board of Pharmacy does not have the authority to register pharmacy technicians and discipline or revoke that registration, pharmacy technicians involved in diversion of drugs at one pharmacy are able to resign or be fired, only to go to work at another pharmacy and continue to divert prescription drugs.

According to the *NABP Survey of Pharmacy Law (1997-98)*, nineteen (19) states either certify, register, and/or license pharmacy technicians, as described below:

One (1) state certifies pharmacy technicians:

Louisiana

Fourteen (14) states register pharmacy technicians:

Alabama	Iowa	North Dakota
Arizona	Missouri	Oklahoma
Arkansas	Nevada	Rhode Island
California	New Mexico	West Virginia
Illinois	North Carolina	

Four (4) states issue licenses to pharmacy technicians:

Minnesota	Washington
Utah	Wyoming

The training and registration of pharmacy technicians is supported by the National Association of Boards of Pharmacy (NABP), who adopted the following resolution at its 1995 meeting:

> *WHEREAS, state boards of pharmacy regulate the practice of pharmacy and are responsible for protecting the public health and safety of the citizens of their state; and*
>
> *WHEREAS, pharmacists licensed by the state boards of pharmacy utilize pharmacy technicians to assist them in their practice in order to enable the pharmacist to focus on patient care; and*
>
> *WHEREAS, training programs are necessary for pharmacy technicians that are appropriate for the particular practice setting where they will be working; and*
>
> *WHEREAS, the training of pharmacy technicians is the responsibility of the employer and/or the supervising pharmacist; and*
>
> *WHEREAS, in 1993, when this issue was addressed by NABP, many resolutions addressing certification and licensure were rejected in favor of registration and site-specific training of technicians;*
>
> *THEREFORE BE IT RESOLVED, that NABP reaffirm the significant role of pharmacy technicians to assist in the practice of pharmacy; and*

BE IT FURTHER RESOLVED that NABP urge state boards of pharmacy to adopt regulations that register pharmacy technicians as outlined in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*; and*

BE IT FURTHER RESOLVED that NABP urge state boards of pharmacy to require initial and ongoing training that is site-specific for their particular practice setting as outlined in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*; and*

BE IT FURTHER RESOLVED that NABP establish a task force to review training programs and/or develop guidelines for training programs that can be adopted by the states; and

BE IT FURTHER RESOLVED that NABP develop a registration transfer program to facilitate the movement of technicians between states as presented in Resolution No. 89-20-93.

In addition, several state boards of pharmacy have expanded pharmacy technicians' duties to include accepting telephonic (called-in) prescriptions from the prescriber. For example, Iowa, Missouri, North Carolina, and South Carolina allow pharmacy technicians to accept telephonic prescriptions from prescribers. Kentucky allows pharmacy technicians to accept telephonic prescriptions only in hospital settings.

Manpower Shortage/Overage and Working Conditions

Two recent reports have conflicting results. A 1993 report to the Texas Higher Education Coordinating Board titled, *Meeting the Challenge: The Future of Pharmacy Education in Texas,* contained the following information regarding pharmacist manpower in Texas.

"According to data from the Texas Employment Commission (TEC), there were 11,400 pharmacists working in Texas in 1989. TEC projects an estimated 705 annual pharmacist job openings in Texas ... through the year 2000. However, the three Texas pharmacy schools presently graduate only 360 baccalaureate-trained pharmacists each year, resulting in a net shortage of 345 Texas-trained professional pharmacists.

"In part, this gap is being met by importing pharmacists from other states .... In the future ... fewer pharmacy graduates trained outside Texas will be available to import to Texas to fill this gap.

> *"Texas' ability to retain and import pharmacists may decrease because there is a national shortage of pharmacists, estimated to be 8 percent .... The shortage is expected to increase and may double to 16 percent with the change [from the entry level 5-year B.S. degree] to the [6-year] Pharm.D. degree."*

The second report comes from the Pew Health Professions Commission which is an organization created in 1989 to assist health care professionals, policy makers, and educational institutions in responding to the rapidly changing health care system. In November 1995, the Commission issued a report entitled "*Critical Challenges: Revitalizing the Health Professions for the Twenty-First Century.*" The Commission believes that a surplus of 40,000 pharmacists nationwide will develop as dispensing functions for drugs are automated and centralized. The report recommends that approximately 20 to 25% of the pharmacy schools should close by the year 2005.

Obviously, one of these scenarios will prove to be inaccurate. It is anticipated that Texas will continue to experience a shortage of pharmacists for the next five years because of its unique demographics and geography.

The driving forces behind the move to use automated technology and pharmacy technicians in pharmacy practice are:

- the demand for pharmacists to have more time to provide expanded *clinical services* to the patient; and
- the current and anticipated future shortage of pharmacists.

With automation or pharmacy technicians performing most of the manipulative tasks of dispensing a prescription, pharmacists will have more time to conduct drug regimen reviews, to counsel patients about their prescription drugs, and to provide other crucial patient care functions required by *"pharmaceutical care."*

A 1990 report from the United States Department of Health and Human Services, Office of the Inspector General (OIG), recognized the value of clinical pharmacy services and stated: *"there appears to be a correlation between pharmacists' patient counseling and better patient compliance ...."* However, this report, titled *The Clinical Role of Community Pharmacists* also stated that, *"clinical services are not usually provided in the community pharmacy setting."* The report made four recommendations for improving *clinical services* in community pharmacies, including one encouraging state governments to revise pharmacy practice acts to allow *"maximum use of technicians in community settings."*

The use of advanced technology and pharmacy technicians in the practice of pharmacy are closely related. Each, properly utilized, provides pharmacists with the assistance needed for them to deliver clinical pharmacy services to the patient. Regulations should allow pharmacists as much flexibility as possible to determine the best use of advanced technology and pharmacy technicians in their specific practice. The challenge to the agency will be to determine the appropriate level of regulation to ensure that the public's health is genuinely protected.

The shortage of manpower also has a significant impact on working conditions. Working conditions in pharmacies have become a leading issue in Texas, as well as the nation. Recently, TSBP has received an increased number of complaints from pharmacists and consumers regarding the working conditions in pharmacies. The complaints have ranged from inadequate staffing, increasing prescription volume (without adding personnel), lack of time to counsel patients, prescription "*quotas*," and no time for lunch or rest breaks. In November 1997, TSBP established a Task Force on Working Conditions and Their Impact on the Public Health. This issue is extremely complex because each practice setting is unique and the factors affecting the working conditions in each practice setting are different. It will be difficult and challenging to establish uniform standards for working conditions, given the various types of pharmacy operations. However, the Task Force will be seeking reasonable solutions to improve pharmacists' working conditions in order to better protect the public.

Impact on Agency

The agency must keep abreast of changes and advances in the uses of technology and pharmacy technicians in pharmacy practice. In addition, the agency must continually strive to be educated about, to understand, and to monitor technological innovations in pharmacy practice.

The marketplace will increasingly demand *less regulation* in order to provide less costly services to the health care consumer. Therefore, as the use of technology expands, the agency must determine the critical functions which must be controlled, supervised, or performed exclusively by pharmacists in order to promote, preserve, and protect the public health.

In addition, as the use of pharmacy technicians evolves, and as they are allowed to perform more technical and critical tasks, the need for trained and competent ancillary personnel will become even more critical. The agency will be challenged to set standards for education and training of pharmacy technicians, and to consider seeking legislative authority to register or license pharmacy technicians.

With the uncertainty regarding pharmacists' manpower, the agency will have to monitor the availability of pharmacist in the work force closely. If Texas continues to have a shortage of pharmacists, there will be an increase in the demand for pharmacists to use automated technology and pharmacy technicians to assist in the technical aspects of the practice of pharmacy.

Manpower and working conditions, as well as training and use of pharmacy technicians will be the focus of two different TSBP Task Forces appointed in FY98. The agency will be expending additional time and effort to staff these Task Forces, assist in the formulation of recommendations and prepare final reports.

Agency Strengths and Opportunities

- The Texas Pharmacy Act was amended during the 75th Legislative Session to give the Board the authority to determine and issue standards for recognition and approval of training programs for pharmacy technicians.
- The Texas Pharmacy Act gives the agency authority to adopt rules regarding pharmaceutical care (clinical) services, and the use of pharmacy technicians and technology in the practice of pharmacy.
- TSBP has continued to review, amend, and/or adopt rules for the expanded use of pharmacy technicians, and for the expanded use of automated technology, in the practice of pharmacy.
- The agency's Compliance Division is already in a position to observe the use of technology and pharmacy technicians in pharmacy practice, and to elicit grass-roots input from pharmacists.
- Texas has a wide variety of knowledgeable resource persons in pharmacy educational institutions and in the profession who can assist the Board in its decision-making about these issues.
- The national Pharmacy Technician Certification Board (PTCB) with local support from the Texas Pharmacy Association and the Texas Society of Health-System Pharmacists provides an opportunity for pharmacy technicians to become certified.
- Through the use of the Task Force on Pharmacists' Working Conditions and the Task Force on Technician Training, TSBP will examine these important issues and their impact on public health.

Agency Weaknesses and Constraints (Threats)

- Board members, agency staff, and pharmacists in general, have limited expertise in automated technology, while the technology is rapidly becoming more and more complex.
- Education and training programs for pharmacy technicians are limited.
- The agency does not have the authority to directly regulate pharmacy technicians through licensure or registration.
- Some pharmacists resist expanding the role of pharmacy technicians because they perceive it as a threat rather than an asset in their practice.
- The agency does not have the authority to directly regulate Pharmacy Benefit Managers (PBMs) and their ability to access confidential patient information.

POLICY ISSUE #4

The Agency's Leadership Role in Pharmacy Practice Regulation and Its Ability to Continue to Effectively Carry Out Its Mission

Issue Statement

The mission of the Texas State Board of Pharmacy is not only to protect the welfare of the people of Texas, but to *promote* it as well. The evolving role of the pharmacist as an integral, primary, part of the health care team is of great interest to the agency and to the profession. The future of the pharmacist's role will, in many ways, determine the future role of the agency. The Board of Pharmacy must be visionary in order to stay on the cutting edge of regulation. The agency's future will be determined by how the profession and the agency respond to increasingly complex demands and trends developing in the health care system.

The agency believes that innovative and proactive regulatory activities will not only protect the public health, but will enhance the quality of pharmacy practice experience for the practitioner, while improving care for the patient. In fact, the agency has demonstrated that it can serve as an agent of change through regulatory initiatives, by increasing the quality of pharmacy services to Texas consumers. In order for the agency to continue its leadership role and meet the increasing demand and complexity for agency services in the next five years, additional and highly qualified human resources must be made available, along with quality management practices and proper technology.

The increase in complexity and demand for information, enforcement, and other services has taxed the agency's ability to deliver excellence and thus, is hampering the optimum response to address the changing face of pharmacy practice and the health and safety needs of the public. Given continuing financial restraints in the State of Texas, budgetary restrictions on the agency may result in static (or worse, fewer) resources. The agency continues to seek ways to increase its efficiency; however, the impact of these increased efficiencies will be minimal, given the already exceptional level of agency services. Additional human and technical resources must be provided to the agency if the agency is to assure continuity of both the quality and quantity of agency services, allowing the agency to move forward in fulfilling its mission to the citizens of Texas.

Explanation of Issue

Expectations of Agency Services and Performance

However likely it is that budgetary constraints will continue, and funding to individual agencies may be reduced, there seems to be a continued expectation for agencies to provide quality services with ever-lessening resources. The Texas State Board of Pharmacy is committed to providing quality programs and services to its customers. However, with a documented, ever-increasing demand for services and no, or minimal, increases in human or technical resources, meeting these demands will be difficult, if not impossible for the agency.

The Texas State Board of Pharmacy's leadership role for pharmacy practice regulation is well-recognized among state and national organizations, in both public and private sectors. The Board believes that the agency's documented successes heretofore have been due to the following factors, and that these factors remain crucial to the agency's ability to operate responsively, efficiently, and effectively as a state regulatory agency:

- the Texas State Board of Pharmacy's position in state government as an independent agency;
- the proactive stance of the Texas State Board of Pharmacy Board members, as they set policy;
- highly qualified and dedicated management, professional, and line staff who consistently carry out policy with a quality customer service ethic;
- adequate technology necessary to support and enhance agency services; and
- adequate, self-generated funding of the agency in carrying out its responsibilities.

Available Agency Resources vs. Investments Needed

This issue, and the enforcement of pharmacy laws by state boards of pharmacy, was addressed in a 1990 study conducted by the Office of the Inspector General (OIG), U.S. Department of Health and Human Services (DHHS).

In the study titled, "*State Discipline of Pharmacists,*" the OIG indicates the following:

"The enforcement responsibilities of State pharmacy boards have become increasingly complex and challenging in recent years because of changes in pharmacy practice and the problem of drug diversion."

As background to this finding, the report stated:

"Pharmacy boards have, however, developed into entities which vary significantly from other health professional boards. Pharmacy boards do more than define the scope of professional practice and license and discipline the professionals. They also regulate pharmacies as the facilities in which the profession is practiced, and they regulate the distribution of the drug product itself. Thus, the purview of pharmacy boards is much broader and in some ways their task is more complex than that of other health professional boards.

"In addition to the dramatic changes occurring in pharmacy practice, the serious national problem of drug diversion has complicated the enforcement responsibilities of State pharmacy boards. For several years, the diversion of prescription drugs from legitimate distribution channels for illicit use has been most acute at the retail level — practitioners and pharmacies.

"More than 10 years ago, the General Accounting Office (GAO) estimated that over 200 million dosage units of prescription drugs were being diverted each year at the retail level. More recently, the Drug Enforcement Administration (DEA) has estimated that 80 to 90 percent of the prescription drugs diverted for non-medical use is occurring at the practitioner (i.e., physician, dentist, etc.) and pharmacy levels."

A second finding of the report is: *"The ability of many state pharmacy boards to protect the public is hampered by limitations in their legal authorities, administrative processes, and resources."* The report listed the following as *"Administrative Barriers,"* which hamper boards of pharmacy:

" ... Many pharmacy boards, for example, must share inspectors and investigators with other licensing boards or must rely on staff from offices of attorney general for their legal assistance ..."

" ... Finally, delays can occur after the hearing process is concluded . . . in those States with boards which are advisory, delays occur because of review of the advisory board decision and further deliberations by other State officials."

The background discussion of *"Inadequate Resources"* included these statements:

> *"Insufficient resources hinder the ability of pharmacy boards to enforce the laws and discipline pharmacists in several important ways. First, the number of staff available to do the job promptly and thoroughly may be insufficient.*
>
> *" . . . In many States, these inspectors are shared with other boards. In consequence, fewer and fewer pharmacy boards have been conducting routine inspections of pharmacies . . . a process important for educating pharmacists as well as for identifying violations."*

At the conclusion of this study, the Office of the Inspector General made several recommendations to state governments, including the following three:

- *"State governments should ensure that State pharmacy boards have adequate resources and authority for carrying out their enforcement responsibilities effectively."*

  The discussion of this recommendation included this statement:

  > *"If boards are to protect the public, they need adequate resources . . . . Resources available to the boards need not be limited by overall constraints on State budgets. States should ensure that the fees for pharmacy licenses and permits generate revenues sufficient for the boards' needs and that the revenues generated be available for use by the boards."*

- *"State governments should take steps to streamline the administrative process so that State pharmacy boards are able to process disciplinary cases more efficiently.*

  " . . . States should streamline their processes as much as possible and rid them of unnecessary reviews and other time-consuming procedures."

- *"State governments should take steps which enhance the capacity of pharmacy boards to deal with drug diversion and impairment of pharmacists."*

Included in the discussion of this recommendation is the following statement:

> *"By strengthening their overall efforts to address drug diversion and impairment, States can enhance the capacity of pharmacy boards, as well as other health professional boards, for dealing more effectively with these serious problems."*

As mentioned earlier, the mission of the Texas State Board of Pharmacy is not only to protect the welfare of the people of Texas, but to *promote* it. Such promotion requires investment.

Enforcement Services

The successful accomplishment of the agency's mission to promote, preserve, and protect the public health and safety, is primarily dependent on the enforcement services of the agency. The level of importance the agency attributes to these services is also reflected by the amount of agency appropriations budgeted in this area. Moreover, the agency's request for additional appropriations is based upon the increased demand in enforcement services.

For the past three bienniums, the agency has requested additional enforcement staff to respond to the increased number of complaints that the agency was receiving. These needs were not met, and in fact, the 75th Texas Legislature appropriated no additional funding to the agency. Accordingly, the time it takes the agency to resolve/close a complaint, as well as the backlog, has continued to increase. In response to this situation, the Board changed its policy with regard to the receipt of verbal (telephonic) complaints. As its meeting in August 1997, the Board received a report that all other health licensing agencies only accepted complaints in writing. In view of this fact, as well as the consideration of the complaint backlog and limited enforcement staff, the Board adopted the policy to require complainants to submit complaints in writing, but granted TSBP staff the discretion to accept verbal (telephonic) complaints in special situations.

Compliance Inspections

In 1982, the agency established a Compliance Division to routinely inspect pharmacies for compliance with the laws and rules affecting the practice of pharmacy. Experience during the last 16 years has indicated that an average compliance inspection takes about 1½ hours, a compliance officer can inspect approximately 400 to 500 pharmacies per year, and the optimum interval between compliance inspections is two years.

Currently, the agency licenses approximately 5,400 pharmacies and employees five compliance officers to inspect these pharmacies. With this staffing level, pharmacies are inspected approximately every 2½ to 3 years rather than every 2 years. The result is that pharmacies tend to have more problems and are less in compliance with the laws and rules when inspected. If the agency is to meet its goal of inspecting every pharmacy every two years, additional field compliance staff must be obtained.

Complaint Resolution

Due to phenomenal growth in the number of complaints received over the past five years, and the minimal growth in the number of personnel to handle the receipt/resolution of complaints, the agency began to experience a complaint backlog. The number of active/pending complaints was approximately 80% larger at year-end FY97 than it was at year-end FY95, and 150% larger than it was at year-end FY94. The number of complaints that the agency has received over the past five years is reflected in **Table 3** below.

Table 3

GROWTH IN NUMBERS OF COMPLAINTS AND TIME TO RESOLVE FY93 - FY97				
Fiscal Year	# Complaints Received	# Complaints Resolved	% Complaints Resolved	Average Resolution Time
FY93	940	900	95.74%	97 days
FY94	999	834	83.48%	113 days
FY95	1406	1236	87.90%	118 days
FY96	1842	1504	81.65%	132 days
FY97	1736	1698	97.81%	171 days
% increase from FY93 to FY97	**85%**	178%		76%

Budgetary constraints also continue to hamper the agency's ability to resolve complaints in a timely manner. The agency's average complaint resolution time was longer in FY97 than in any prior fiscal year, as depicted in Table 4 above.

Enforcement staff spent a considerable amount of time and effort communicating with complainants. Approximately 2,227 letters were mailed to complainants during FY97, regarding the receipt, status, and resolution of complaints. This increase is primarily due to the dramatic growth in the number of complaints received in the past five fiscal

years. FY97's performance represents a 218% increase over FY93's performance, as indicated in the following **Table 4.**

Table 4

Fiscal Year	Number of Letters Sent to Complainants	Cumulative Increase Since FY93
FY93	700	—
FY94	900	29%
FY95	1,380	97%
FY96	1,882	169%
FY97	2,227	218%

While "*raw numbers*" may be indicative of the quantitative workload, they do not address qualitative issues, such as complexity. For example, a complaint involving diversion of prescription drugs will generally take longer to resolve than other types of complaints. Examples of complex investigations include the following:

- TSBP and FDA investigators conducted a joint investigation into allegations of grey market diversion and illegal importation of drugs into Texas. Evidence of a scheme to distribute these illegal drugs resulted in the indictment and conviction, in federal court, of three individuals (non-pharmacists) in the Laredo area.

- A joint investigation between TSBP investigators and the Arlington Police Department narcotic officers produced evidence that an individual was passing forged prescriptions for Hydrocodone products in 18 different pharmacies in the Metroplex area. Board action resulted in one pharmacist losing his license, and another pharmacist's license being suspended for one year. Disciplinary action on several other licensees are still pending.

- A joint investigation between DEA, DPS and TSBP resulted in the revocation of a license of a pharmacist who diverted several thousand dosage units of Dilaudid, a Schedule II controlled substance of extemely high abuse potential. The pharmacist was arrested following the illegal delivery of Dilaudid to a DEA undercover agent and purchasing blank Triplicate Prescription Forms.

- One extremely labor intensive case which had the high potential for a negative impact on the public health and safety occurred in fiscal year 1994. On January 20, 1994, the Texas

State Board of Pharmacy received an anonymous letter alleging that students from the School of Pharmacy at Texas Southern University (TSU), in Houston, had access to questions on the NAPLEX examination. Enclosed with the letter were handwritten notes that contained material purported to be questions from a NAPLEX exam. The material was sent to the National Association of Boards of Pharmacy (NABP) and was verified as being NAPLEX exam material.

On January 25, 1994, TSBP discovered that one of the examinees, a graduate of TSU, who was taking the January NAPLEX examination had possession of confidential information that potentially compromised the January exam. The material recovered from the student consisted of a copy of the two-volume set of the 1992 set of the 1992 NAPLEX Review Book (composed of confidential "*test bank*" questions), as well as a set of typed exam questions which were copied from the books. An extensive investigation was conducted by the Texas State Board of Pharmacy in cooperation with the Harris County District Attorney's Public Integrity Unit and NABP. This investigation included appearances before a Harris County Grand Jury by several witnesses who had been identified during the investigation.

Due to the strong cooperative efforts with NABP and the Harris County District Attorney, the Texas State Board of Pharmacy was able to stop the leak of confidential information. Board action was instituted against two individuals who were alleged to be in possession of the material prior to and at the January 1994 exam.

The complexity of pharmacy practice dictates that the investigation and adjudication of licensees (pharmacists and pharmacies) will continue to be complex. In FY97, the Investigations Division completed investigations of 90 complaints involving alleged dispensing errors. Of that number, 48 complaints (53%) disclosed counseling as a secondary allegation or had a counseling violation revealed during the investigation. Many of these investigations require the agency to subpoena medical records and may require opinions from medical or drug experts.

As the agency receives more complaints regarding patient outcomes, the agency may need to retrain or redirect its enforcement personnel. In addition, the agency will fall behind in its ability to regulate practice and health care outcomes until it is able to attract and retain highly qualified pharmacists and other professionals to achieve its goals.

Monitoring Compliance with Disciplinary Orders

A majority of disciplinary orders entered by the Board each year requires agency staff to monitor the licensees' compliance with the terms of their Orders (e.g., 86% of Disciplinary Orders entered in FY97). For example, an Order may require the licensee to pay a fine, complete additional hours of continuing education, return a license that is suspended or revoked, and/or submit their written policies and procedures for recordkeeping, security, or other problem areas. In these cases, agency staff tracks if and when the licensee satisfies each of the requirements. If the licensee does not comply with the requirements, the Board initiates further disciplinary action. In addition to the in-house monitoring described above, Compliance Officers have conducted on-site inspections of pharmacies for the purpose of monitoring compliance with the terms of Orders, particularly individuals/facilities who were subject to a probated suspension.

In particular, monitoring of Orders entered against licenses of impaired pharmacists is very labor-intensive and complex. These types of Orders provide for initial suspension, which ends after sufficient documentation has been submitted stating that the pharmacist is no longer dependent and is able to return to practice. The license is then usually suspended for an additional five years, probated under numerous restrictions. Such monitoring involves random drug screenings and quarterly reports from as many as four persons, as follows:

- the recovering pharmacist (self reports);
- the supervising pharmacist (if applicable);
- the mental health professional (if under an MHP's care); and
- the pharmacist peer assistance program [Pharmacists' Recovery Network (PRN)].

One Order could result in as many as 16 reports being submitted to the agency each year of the five-year probation period. Each one of these reports must be reviewed, evaluated, and acknowledged by agency staff. **Table 5** indicates the increase in individuals being monitored by the agency over the past five-year period.

Table 5

Fiscal Year	Total Orders*	Total New Orders**	Total Being Monitored +
FY93	29	21	88
FY94	28	22	97
FY95	32	20	94
FY96	32	21	94
FY97	40	21	99

% Change from FY93 to FY97 = 13%

* All Orders entered by the Board involving an impaired pharmacist (including revocations, modifications, and "second orders" due to disciplinary action for violation of the terms of previously entered orders).

** An Order which resulted in 1 individual being added to the list of impaired pharmacists to be monitored by the agency. Since the agency monitors these pharmacists for a 5-year period, the cumulative effect of new Orders has a staggering impact on the workload of the agency staff who are monitoring the impaired pharmacist.

\+ Total # of pharmacists being monitored by the agency as of the last day of the fiscal year. The # represents the new orders entered by the agency during the fiscal year, minus the # of deletions made during the year (e.g., as a result of death, early termination of probation through the entry of an Order, and/or successful completion of probation).

Requests for Public Information on Enforcement Actions

The agency continues to spend significant amounts of time responding to the extremely large numbers of requests for public information concerning complaint and disciplinary actions. The agency experienced dramatic growth in the number of open records requests received and processed as indicated in the following **Table 6.**

Table 6

OPEN RECORDS REQUESTS HANDLED BY THE ADJUDICATION DIVISION										
Fiscal Year	Verbal Requests		Written Requests		Total # of Requests		Monthly Average		Cumulative Increase Since FY93	
	# of Requests	# of Licensees	# of Requests	# of Licensees	# of Requests	# of Licensees	# of Requests	# of Licensees	# of Requests	# of Licensees
FY93	106	132	127	295	233	427	19	36	-	-
FY94	244	279	192	472	436	751	36	63	87%	76%
FY95	296	398	241	795	537	1,193	44	99	130%	179%
FY96	748	1,037	246	451	994	1,488	83	124	327%	248%
FY97	935	1,321	299	1,277	1,234	2,598	103	217	453%	508%

Licensing Services

The licensee population continues to grow, directly resulting in increased workload in all areas of examination, internship, continuing education, pharmacists' changes of address/employment records, and licensure renewals, as well as all related telephone calls and correspondence. In order to partially address this increasing workload, the Board may consider initiatives such as the biennial renewal of licenses, the electronic submission of applications, and a voice response system to verify a limited amount of licensure information.

Table 7 shows how the agency's Licensing activities have increased, and are expected to increase over an 11-year period.

Table 7

PERFORMANCE OUTPUTS *FY92-97 (actual) FY98-2002 (projected)*						
Year	# Exams Administered	% Increase	# Pharmacists Licensed	% Increase	# Pharmacies Licensed	% Increase
FY92	1,436	-	16,883	-	4,938	-
FY93	1,394	<3%>	17,312	3%	4,963	2%
FY94	1,472	6%	17,681	2%	5,096	3%
FY95	1,381	<6%>	18,026	2%	5,107	1%
FY96	1,557	13%	18,450	2%	5,246	3%
FY97	1,698	9%	19,048	3%	5,404	3%
FY98	1,749	3%	19,429	2%	5,458	1%
FY99	1,801	3%	19,818	2%	5,513	1%
FY00	1,855	3%	20,214	2%	5,568	1%
FY01	1,911	3%	20,618	2%	5,623	1%
FY02	1,968	3%	21,030	2%	5,679	1%
Cumulative Increases FY1992-FY2002		37%		25%		15%

Impact on Pharmacists' Licensing

- **Pharmacy Technician Regulation**

The way patient safety and professional competence is ensured and how competence is measured will remain a prime focus of the agency's Licensing and Enforcement efforts. The emerging issue of registration or licensing of pharmacy technicians will play a key role in the overall patient care issue. Pharmacy technician training and regulation issues impact not only the agency, but educators and practitioners as well.

Although a voluntary certification program of pharmacy technicians currently exists, voluntary certification does not address the issue of disciplinary authority. Regulation of pharmacy technicians is needed to ensure that individuals possess the skills and knowledge sufficient to safeguard public safety and allow the Board to discipline those individuals who violate the law. Registration would identify how many, the identity of, and where pharmacy technicians are employed, and would help identify, and give authority to the agency to remove from the profession, any pharmacy technicians deemed incompetent or dangerous to the public.

Licensure on the other hand, would encompass registration requirements, but would also require that competency areas are met and would address education issues.

Approximately *40,000* pharmacy technicians currently practice in Texas, largely unrecognized in their significance to the public. The impact of this population as registrants or licensees, would more than double the agency's current population of licensees *(19,000 pharmacists and 5,000 pharmacies).* A dramatic and substantial amount of resources would be required to implement a registration, certification, or licensure program. The Licensing Division would be immediately impacted, followed closely by an unprecedented escalation of services required in the Enforcement areas of the agency both at initial certification, addressing continued competency of pharmacy technicians, and most importantly, ensuring that the public health and safety are not compromised.

- **The Demand for Pharmacists**

  As noted in Policy Issue #3, a report entitled "*Critical Challenges: Revitalizing the Health Professions for the Twenty-First Century,*" released by the Pew Health Professions Commission, projects that there will be a *national* surplus of 40,000 pharmacists due to the automation and centralization of the dispensing function for drugs. However, projections for the state of Texas seem to indicate that there will be a shortage of pharmacists, as evidenced by a report entitled *"Meeting the Challenge: The Future of Pharmacy Education in Texas"*. This report concluded *"that there will be a need for 750 to 800 new pharmacists annually to meet the projected and ongoing needs in Texas, to overcome the current shortage, and to fill new positions that will become available. Texas will continue to be dependent on imported pharmacists to meet the gap between Texas' pharmacist production and vacant pharmacist positions. In the future however, fewer pharmacy graduates trained outside Texas will be available to import to Texas to fill this gap."*

  This demand takes on even greater significance when coupled with the aging of the Texas population.

- **Assuring Competency**

  An article published by the National Council of State Boards of Nursing, Inc. 1966 notes: "*As the pace of technological and scientific development accelerates, one of the greatest challenges to health care professionals is the attainment, maintenance and advancement of professional competence in an evolving health care environment. Licensing boards have a role in assuring the public of the competence of licensees, but what should that role be? . . . What is the standard to which a licensee is to be held for continued competence?*

  The Pew publication, *Reforming Health Care Workforce Regulation: Policy Considerations for the 21st Century,* clearly articulates several recommendations regarding competence. These recommendations are:

  - States should standardize entry-to-practice requirements and limit them to competence assessments for health professionals . . .;

- States should base their practice acts on demonstrated initial and continued competence . . . ;

- States should require each regulatory board to develop, implement, and evaluate continuing competence requirements to assure the continuing competence of regulated health care professionals . . . ; and

- States should maintain a fair, cost-effective, and uniform disciplinary process to exclude incompetent practitioners to protect and promote the public's health . . . .

The Board has a role in assuring that health professionals meet minimum standards of competence throughout their professional lives. These emerging issues of continued competence will most certainly impact the Licensing and Enforcement activities of the agency.

Impact on Pharmacy (Facility) Licensing

While the number of pharmacies has remained relatively stable, quantity issues do not reflect the complexity of regulating pharmacies. The agency licensed four different Classes of Pharmacy during FY88-91, increasing to five Classes of Pharmacy in FY92.

The complexity of regulation is due, in part, to Rules (standards) which have been established for each Class of Pharmacy, in addition to Rules (standards) for four specific *"sub-classes"* of pharmacies. As mechanisms for providing pharmacy services to patients continue to diversify, the agency fully expects that the number of pharmacies (and possibly the Classes of Pharmacy) will continue to increase over the next five years. The agency has standards for the following types of pharmacy practice:

- Class A (Community) Pharmacies;
- Class A Pharmacies Compounding Sterile Pharmaceuticals;
- Class B (Nuclear) Pharmacies;
- Class C (Institutional) Pharmacies;
- Class C Pharmacies in Ambulatory Surgical Centers;
- Class D (Clinic) Pharmacies;

- Class D (Clinic) Pharmacies with Alternative Pharmacist Visitation Schedules;
- Class D (Clinic) Pharmacies with Expanded Formularies; and
- Class E (Non-Resident) Pharmacies

The ability of the agency to *prepare for and respond to* Information and Licensing issues and demands will depend on its continued leadership role in the public arena and pharmacy profession, and on having adequate resources to carry out its mission.

Information and Education Services

The Board of Pharmacy sees itself in a leadership role in terms of developing and implementing an innovative and proactive approach to enhance pharmacy consumer education, ultimately increasing the quality of patient care and decreasing health care costs. Statistics show that more than 125,000 people a year in the United States are dying from medication mismanagement (non-compliance with cardiovascular drugs alone). Even more an impact to health care costs is that number of elderly individuals who are hospitalized or placed in nursing homes, mainly because of their inability to manage their medications. The cost of illness associated with prescribed medication in the United States has been estimated to be between $7 billion and $30 billion annually. Much of this cost is due to medications made ineffective because of their underuse, overuse, or misuse.

Another emerging consumer education issue is the proliferation of over-the-counter drugs (those drugs that do not require a prescription). Statistics show that in 1995 the number of prescription drugs that became available over the counter increased *fivefold* from 1994. Health care experts contend that the proper use of these drugs should not pose any real problem; however, the public needs to be better educated as more drugs become available that do not require a prescription. For example, cross reactions between alcohol and drugs are believed to contribute to 2,500 deaths and 47,000 emergency-room visits each year, according to a report in the journal *Geriatrics*. These alarming statistics again point to the importance of medication compliance and the public's need to know certain information about their medications.

The power of consumer education cannot be overemphasized. As quoted in *Drug Topics, January 5, 1998, "North Carolina is adding consumer education to the mix. The Board of Pharmacy spent $35,000 on high-visibility television and newspaper advertising in the state's top markets late last year. "We know patient counseling saves lives,"* explained the Pharmacy Board's Executive Director David Work. *"Counseling is a public health and safety issue. If the public is aware of what they're entitled to, they will demand more of pharmacists. We're telling the public just what their expectations of pharmacists should be. . . . We can show conclusively that counseling saves lives."*

In keeping with the agency's mission statement, and in order to provide a comprehensive, cost-effective statewide information program, a major emphasis must be placed on a *"coalition"* approach between the Texas State Board of Pharmacy, other government entities, professional organizations, and consumer advocacy groups. This *"coalition"* approach is key to the potential success of this program. A pioneering approach of the agency to enhance consumer information and education during 1992-93 was built on this *"coalition"* strategy. Using various consumer advocacy, professional pharmacy, other medical professional, private sector (both profit and non-profit), state, local, and federal groups' specialties, resources, and networks, the agency addressed consumer education needs, particularly those of elderly residents of Travis County, in a pilot program. Although the pilot program was a success, the agency was unable to continue this effort due to a lack of resources.

The agency has continually addressed this critical issue in the agency's Strategic Plans for 1995-99, 1997-2001, and again in 1999-2003. Although the agency Strategic Plan contains a strategy entitled "*Education and Information*," this strategy was not addressed in the 1995-96 or 1997-98 biennial budget requests due to the legislative mandates imposed to limit requests for additional appropriations.

It is indeed unfortunate that given these legislative mandates, the agency has been unable to continue to devote any significant resources to this important area. The agency's achievement of its strategic goals and the improved health care of the people of Texas are dependent on the provision of proactive preventive education and information to the citizens of Texas and not only on the provision of reactive enforcement activities of the agency.

Telecommunication System Services

Information services, and the demand for such, arise partly out of constant and complex changes occurring in pharmacy practice and partly due to the continued rise in the population of licensed pharmacists in Texas. However, the primary demand for information services is due to the increased awareness of the public, both pharmacists and consumers, of the role of the agency. From FY90 through FY96, the agency experienced a total increase of 57% in the number of telephone calls received. The agency anticipates that this increase will continue to grow dramatically. The majority of the increase is related to Enforcement and Licensing activities. For example, from FY90 - FY96, the Enforcement area of Compliance, Investigation, and Adjudication telephone calls increased from 16,600 to 22,574 (36%) and the Licensing Division's telephone calls increased from 14,913 to 23,732 (60%).

In today's environment, every agency and division is expected to do more with less. In order to address the number of inquiries coming into the agency, and particulary the licensing and enforcement divisions, the agency will be reviewing options that integrate a voice response system and/or internet capability to automate public access to a limited amount of licensure information. Although this solution may address part of this workload issue, it is certain that progress cannot be made unless additional staffing is also seriously considered. Projected growth, coupled with a lack of funding, will most certainly affect the agency's ability to maintain its current (much less its desired) level of services. **Table 8** shows the increase in telephone calls received by the agency from FY90-96.

Table 8

TELEPHONE CALLS	FY90	FY91	FY92	FY93	FY94	FY95	FY96
Enforcement Staff							
Number of Calls Received	16,000	18,384	18,629	19,350	20,290	21,662	22,574
Cumulative Increase 36% (FY90-FY96)							
Licensing Staff							
Number of Calls Received	14,193	22,508	21,414	22,950	21,800	24,272	23,732
Cumulative Increase 60% (FY90-FY96)							
Agency							
Number of Calls Received	36,925	45,817	44,264	45,000	50,563	56,474	57,884
Cumulative Increase 57% (FY90-FY96)							

The agency's achievement of its Strategic Goals is dependent on the provision of comprehensive and reliable information in all areas. Constant and complex changes occurring in pharmacy practice, as well as ever-increasing demands and quantities of information services required, have tapped the human resources of the agency to their limits.

Administrative Services

An increasing area of demand for the agency is that of "Administrative Services." One key factor that is gaining an ever-increasing importance to the agency's ability to accomplish its primary mission is the increasing amount of staff time required to implement and monitor the many legislative mandates imposed during legislative sessions. A partial list of the mandates that have been imposed on all agencies in the last two bienniums is as follows:

- The state-paid portion towards employee-paid FICA Taxes (5.85%) was eliminated with the result that new employees hired receive a lesser compensation.

- A review of the agency's affirmative action plan was required by the Texas Human Rights Commission.

- The reimbursement rate for meals and lodging for board members' travel within the State of Texas was increased from $75 to $80 per day, with no increase in agency appropriations. Board members who travel outside the State of Texas, within the continental U.S., were reimbursed for their actual expenses (within Comptroller guidelines). This increased expense was not compensated with a like increase to the agency's appropriations.

- Mileage reimbursement rate for all travel was increased to 28 cents per mile, with no increase in agency appropriations.

- Employee in-state travel was raised from $55 to $70 per day for lodging and remained $25 per day for meals. There was no additional appropriation to the agency for the increase in the lodging rate.

- Appropriations for all travel expenditures (Board and Staff) are capped at 90% of the total FY97 expenditures for travel. Additional restrictions require a certification that in cases where more than one individual has submitted a travel voucher or claim for reimbursement of expenses for the same or similar travel occurrence the number of individuals on travel status was necessary to execute the state business conducted.

- A cap on the number of full-time equivalent positions (FTE) in each year. Sec. 34 of Article IX reads in part: "A state agency shall not have on its payroll, without written approval of the Governor and the Legislative Budget Board, a number of employees which would cause the number of full-time equivalent employees (FTEs) employed by the agency for a fiscal quarter to exceed the "Number of Full-time Equivalent Positions (FTE)" figure indicated by this Act for that agency."

- Merit Increases
  - allows for any percentage or step increase in same salary group.
  - 12 months must lapse between merit increases.
  - there is a cap on the total agency amount used for merit increases, based on a percentage of the agency's total salaries in FY97.
- Review of Agency Rules. None of the funds appropriated by this Act shall be expended by a state agency for the purpose of developing, promulgating, or adopting rules unless the state agency reviews and considers for readoption, each rule adopted by that agency pursuant to the Administrative Procedures Act . . . for a rule which became final prior to September 1, 1997, a review described by this section shall be conducted no later than August 31, 2001.
- Paperwork Reduction. Agencies must reduce by January 1, 1998, the amount of information that is required to be submitted, whether on paper or electronic medium, by its customers. "Customer" includes benefit recipients, clients, licensees, regulated entities, and students.

Agencies are faced with allocating *existing staff resources* to implement and monitor not only the above legislative initiatives, but the various rules and procedures that are created, revised, or deleted by many of the oversight agencies each fiscal year. As additional staff time is demanded by these administrative functions, less and less staff time is spent on the agency's primary mission — that of protecting the public health and safety.

In addition, many of these initiatives are a result of the mistakes of a few agencies. It appears the Legislature assumes that problems in a few agencies indicate widespread abuse of the system and, thus, create legislation that requires this kind of oversight for *all state agencies.* These oversight functions may more appropriately belong to the individual boards, commissions, and executive directors of these agencies that are abusing the system.

Reporting Requirements

A final area of increased demand for service from the agency is responding to Legislative and Executive Branch report requirements, many of which contain duplicate information. This *"information service"* constitutes a significant amount of the agency's administrative and information services workload. Between September 1995 and August 1996, the agency was required to submit over 65 reports, surveys, and the like. The volume of these reports compares to FY91-96 in the following manner, showing an *increase* of *110%* in these reporting requirements since FY91.

FY91 — 31 reports and 7 fiscal notes submitted
FY92 — 27 reports submitted
FY93 — 54 reports and 10 fiscal notes submitted
FY94 — 63 reports submitted
FY95 — 51 reports and 13 fiscal notes submitted
FY96 — 65 reports submitted

These reports require significant time and efforts of managerial and professional staff. The agency does not foresee any decline in demand for any agency services within the next five years. In fact, the agency expects current trends to continue, and to increase at a minimum of 10% per year for the next five years, based on historical experience.

Impact on Agency

Given the growth and increase in complexity of pharmacy practice and health care and the continued increase in demand for services, the agency's ability to function efficiently and effectively in the public interest is in jeopardy.

At the current level of operation, there is no *"slack"* in terms of agency workload. In fact, staff in several Divisions work significant amounts of overtime in order to maintain the current level of services. Any increase in the demand for agency services without additional human resources and updated technology will require a reassessment of the organization, its systems, and personnel. This may require a shift in resources and, consequently, a reassessment of agency priorities and initiatives. The net result could decrease the quality and quantity of agency services vital to its mission.

Agency personnel continue to look for efficiencies to save time and money. However, in response to the increasing demands placed on agency personnel, agency staff has begun to look for services that can be eliminated or modified. For example, in August 1997, the Board changed its policy with regard to the receipt of verbal (telephonic) complaints. The Board determined that all other health

licensing agencies accepted only written complaints. In view of this fact, as well as the consideration of the complaint backlog and limited enforcement staff, the Board adopted the policy to require complainants to submit complaints to the agency in writing, but did grant agency staff discretion to accept verbal (telephonic) complaints in special situations.

Agency Strengths and Opportunities

- Organizational structure, leadership, and management provide the mechanisms necessary to carry out the agency's mission and to accomplish its strategic and operational objectives.

- The agency's position as an independent agency, along with its statutory authority, gives it the authority and flexibility needed to function as the "*lead agency*" for pharmacy regulation in Texas.

- The agency generates its own *"tax"* revenue primarily through licensure fees from pharmacists and pharmacies. The agency does not use general tax revenues and is not directly subject to the problems of fluctuation in state revenue due to economic or political factors. Further, the regulated community fully supports this method of funding agency operations.

- The Board members are dedicated to their role as policy-makers, and the staff to its role as implementers of this policy. Through their complementary roles, the Board and staff form an efficient team, achieving consistently high level agency performance in a customer-service oriented manner.

- The agency has involved itself in Strategic Planning for the past twelve years. As one of the first efforts in Texas state government to institute this important process, the agency published its first Strategic Plan in 1986. Updated Strategic Plans were published in 1990, 1992, 1994, and 1996.

- The agency has an approved Strategic Plan for Information Management that addresses its technology needs for the next five years.

- The agency is serving in a leading role within the newly-formed Health Professions Council and is in a position to share the agency's successful operational strategies with the other regulatory agencies.

- The agency is highly regarded by its customers, including consumers, legislators, and the regulated profession, as well as local communities throughout Texas.

Agency Weaknesses and Constraints (Threats)

- Demand for all agency services and the increased complexity of regulation and enforcement are growing at a dramatic rate and, unless additional human and technical resources are provided, both quality and quantity of services provided to agency customers will decline, posing a danger to the public health of the citizens of Texas.

- Even though the agency generates its own revenue and receives no tax dollars from the General Revenue Fund, it is subject to constraints imposed by general economic and political conditions of state government.

- Compensation for executive, managerial, and professional staff is significantly lower than comparable positions in the private sector. *State executives and employees must be adequately compensated in order to attract and retain quality personnel.* These personnel are the backbone for the effective operation of state government.

- Increasing reporting requirements of Legislative and Executive agencies require significant amounts of time from managerial and professional staff, which reduces the agency's ability to deliver needed services.

- Establishment of the Office of Administrative Hearings and the requirement that the agency use this office for administrative disciplinary hearings delays the agency's ability to take swift disciplinary action against licensees who violate pharmacy and drug laws.

- Despite the resounding national and state need for preventive patient care information, the agency continues to be placed in the position of having vital information which would improve the health and safety of the citizens of Texas, but not able to effectively disseminate this information through a comprehensive Public Information Service. Countless agencies have similar efforts, sometimes quite extensive, to disseminate public information about parks, recreation, land usage, environmental issues, immunization concerns for children, and child and adult protective issues.

  Medication misuse not only costs the citizens of Texas billions of dollars, it seriously impacts their recovery from illness, their management of chronic illness, their independent lifestyles, and even their lives. The possibilities exist for receiving grant monies, both private and public, and for forming effective, dynamic coalition-based efforts across Texas; however, the agency's hands are tied due to lack of program and human resource funding. This is an area where a small investment of time and money could grow exponentially and reach the entire state.

AGENCY GOALS

- We will establish and implement reasonable standards for pharmacist education and practice, and for the operations of pharmacies to assure that safe and effective pharmaceutical care is delivered to the citizens of Texas [Texas Pharmacy Act (Article 4542a-1, V.T.C.S.), Sections 17, 20-22, 24, 24A, 29-31, and 40].

- We will assertively and swiftly enforce all laws relating to the practice of pharmacy to ensure that the public health and safety are protected from unprofessional conduct, fraud, and misrepresentation, and to prevent the misuse, abuse, and diversion of prescription drugs from pharmacies [Texas Pharmacy Act (Article 4542a-1, V.T.C.S.), Sections 6, 16-19, 26, 26A, 26B, 28, and 33-37, and Health and Safety Code, Chapter 483, Dangerous Drugs, Subchapters B, C, and D].

- We will provide information and education services to the profession of pharmacy to promote compliance with laws and rules and to consumers and other agency customers to enhance and promote the public health [Texas Pharmacy Act (Article 4542a-1, V.T.C.S.), Sections 4, 17, 40, and 40A].

- We will establish and carry out policies governing purchasing and public works contracting that foster meaningful and substantive inclusion of historically underutilized businesses.

AGENCY OBJECTIVES AND OUTCOME MEASURES

OBJECTIVE Through each year of the strategic plan, to operate a licensure system for pharmacists and pharmacies that will assure that 100% of pharmacists and 100% of pharmacies meet minimum licensing standards.

Outcome Measure

- Percent of Licensees with No Recent Violations

OBJECTIVE In each year of the strategic plan: to deter and reduce the incidence of violations of the law through compliance inspections of 50% of the licensed pharmacies in Texas and through technical assistance to licensees; to educate and increase licensee access to information by contacting 100% of licensees; to resolve/close complaints received within 250 days of receipt.

Outcome Measures

- Percent of Complaints Resolved Resulting in Disciplinary Action
- Recidivism Rate of Those Receiving Disciplinary Action
- Percent of Documented Complaints Resolved Within 6 Months
- Recidivism Rate for Peer Assistance Program

- One Year Completion Rate for Peer Assistance Programs

- Percent of Non-Board Peer Assistance Program Referrals Reported to the Board

OBJECTIVE By 2001, to educate and to increase consumer awareness of: TSBP's regulatory role, the need for Texas citizens to be informed about their prescription drugs and the questions they should ask, and the requirements for pharmacies/pharmacists to provide consumers with information about their prescription drugs.

Outcome Measures

- Percent of Consumers of Pharmacy Services Aware of TSBP Role and the Need to be Informed about Their Prescription Drugs

OBJECTIVE To include historically underutilized businesses (HUBs) in at least 20% of professional service contracts, 33% of other services contracts, and 11.5% of commodities contracts of the total value of contracts and subcontracts awarded by the agency in purchasing and public works contracting by fiscal year 2003.

Outcome Measure

- Percent of Total Dollar Value of Purchasing and Public Works Contracts and Subcontracts Awarded to HUBs

AGENCY STRATEGIES AND OUTPUT, EFFICIENCY, AND EXPLANATORY MEASURES

STRATEGY 01.01.01

Operate a timely, cost-effective application and renewal licensure system for pharmacies and pharmacists.

Output Measures

- Number of Individuals Examined
- Number of New Licenses Issued to Individuals
- Number of Licenses Renewed (Individuals)

Efficiency Measures

- Average Cost of Examination
- Average Licensing Cost per Individual License Issued
- Average Licensing Cost per Facility License Issued

Explanatory Measures

- Total Number of Individuals Licensed
- Total Number of Business Facilities Licensed
- Pass Rate

STRATEGY 01.01.02

Purchase and Grading of National Exam

STRATEGY 02.01.01

Emphasize preventive enforcement by conducting compliance inspections of pharmacies, providing technical assistance, licensee information, and education programs; receiving, investigating, and resolving complaints; and monitoring compliance with disciplinary orders resulting from Board adjudication.

Output Measures

- Number of Inspections
- Complaints Resolved

Efficiency Measures

- Average Time for Complaint Resolution
- Average Cost per Complaint Resolved

Explanatory Measures

- Jurisdictional Complaints Received

STRATEGY 02.01.02

Operate a Peer Assistance Program by monitoring the growth, development, and compliance of a program to aid pharmacists and eligible pharmacy students impaired by chemical abuse or mental or physical illness, and monitor the success of individuals in the program.

Output Measure

- Number of Individuals Participating in Peer Assistance Program
- Number of Licensed Individuals Participating in Peer Assistance Program
- Number of Peer Assistance Participation Months

STRATEGY

Respond to consumer information and education requests and promote consumer education.

Output Measures

- Number of Public Service Spots
- Number of Consumer Brochures and Other Printed Information Distributed
- Number of Contacts Made through Speeches, Presentations, and Exhibits

STRATEGY

Develop and implement a plan for increasing the use of historically underutilized businesses through purchasing and public works contracts and subcontracts.

Output Measures

- Number of HUB Contractors and Subcontractors Contacted for Bid Proposals
- Number of HUB Contracts and Subcontracts Awarded
- Dollar Value of HUB Contracts and Subcontracts Awarded

APPENDIX A

Description of Agency Planning Process

Internal/External Assessment and Issue Identification

In developing its Strategic Plan, Board and agency staff needed to identify and analyze those trends and resulting issues expected to have the most significant impact on the profession and regulation of pharmacy over the next six years. In 1986 and 1990, the agency conducted research into these areas utilizing a contracted consultant-facilitator, working with the Board's Committee on Strategic Planning and agency staff.

The Board subsequently updated the identified issues in 1991, 1992, 1994, 1996, and 1998 as a result of the requirements of H.B. 2009.

The 1998 Strategic Plan has been the product of:

- overall review of the 1996 Strategic Plan by the Board members and agency staff (Internal Assessment) with a significant amount of input provided as to changes, issues, and updates that need to be addressed; and

- comments received from a mailing (External Assessment) of the 1996 agency Strategic Plan, along with a letter inviting comments, sent to:

    - the Deans of the Texas colleges of pharmacy;

    - the Executive Directors of the Texas pharmacy professional organizations;

    - the Executive Directors of four of the largest national pharmacy professional organizations;

- the Executive Director of the National Association of Boards of Pharmacy;
- the Executive Directors of five Texas consumer advocacy groups;
- the Texas Commissioner of Health; and
- agency Board members.

A list of the individuals receiving an invitation for input and whether they responded is found in this Appendix.

The questions asked in the External Assessment were the following:

- As the agency updates its Strategic Plan, what are the issues in general, but specifically in health care, which will affect the practice of Pharmacy and the regulation of the practice, about which the agency should be concerned?
- How will any of these issues affect the agency's ability to carry out its mission?
- Which of these issues poses the greatest challenge for the agency in its ability to respond, and why?
- How should the agency attempt to respond to these issues and challenges?
- What should be the future of the agency's Enforcement Efforts?
- What should be the future of the agency's Public Information and Education efforts?

- What do you see as the greatest area of opportunity for the agency?

Resulting issues to be addressed by the 1998 Strategic Plan were identified as:

- The Crucial Role of Pharmacists in Improving Patient Health through Pharmaceutical Care.

- Traditional and Non-Traditional Pharmacy Practice Settings and the Delivery of Full-Access Patient Care.

- The Effects on Pharmacy Practice and Patient Care of Technology, Pharmacy Technicians, Pharmacist Manpower and Working Conditions.

- The Agency's Leadership Role in Pharmacy Practice Regulation and Its Ability to Continue to Effectively Carry Out Its Mission.

The Board's Committee on Strategic Planning met on March 27, 1998, to review the draft compiled by agency staff in response to those comments as well as those from the Internal Assessment.

The Board members met and approved the Strategic Plan on May 5-6, 1998.

Request List for Comments on the Agency Strategic Plan	
Name/Address	**Response Received**
COLLEGES OF PHARMACY	
Dr. Mustafa F. Lokhandwala, Dean College of Pharmacy, The University of Houston 4800 Calhoun, SR-2.141 Houston, TX 77204	No
Dr. Pedro J. Lecca, Dean College of Pharmacy and Allied Health Sciences Texas Southern University 3100 Cleburne Street Houston, TX 77004	No
Dr. James T. Doluisio, Dean College of Pharmacy, The University of Texas at Austin Austin, TX 78712	Yes
Dr. Arthur Nelson, Dean School of Pharmacy, Texas Tech University Health Science Center 1400 Wallace Blvd. Amarillo, TX 79106	Yes
CONSUMER GROUPS	
Reggie James, Director Texas Consumers Union 1300 Guadalupe, Suite 100 Austin, TX 78701	No
J. Patrick Luby, Area Director American Association of Retired Persons, Area VII 8144 Walnut Hill Lane, Suite 700, LB-39 Dallas, TX 75231	No
Suzy Woodford, Executive Director Common Cause Texas 1615 Guadalupe, Suite 204 Austin, TX 78701	No
Tom "Smitty" Smith, Director Public Citizen Texas 1800 Rio Grande Austin, TX 78701	No
Madeline Unterberg, President National Council of Jewish Women, Greater Dallas Section 219 Preston Royal Village, Suite 9 Dallas, TX 75230-3832	Yes

Request List for Comments on the Agency Strategic Plan	
Name/Address	**Response Received**
NATIONAL PHARMACY ORGANIZATIONS	
John A. Gans, Pharm.D., Executive Vice President American Pharmaceutical Association 2215 Constitution Avenue, NW Washington, DC 20037	No
Henri Manasse, Jr.,P.D., Executive Vice President American Society of Health-System Pharmacists 7272 Wisconsin Avenue Bethesda, MD 20814	Yes
Ronald L. Ziegler, President and CEO National Association of Chain Drug Stores P.O. Box 147-D49 Alexandria, VA 22313-1417	No
Carmen A. Catizone, R.Ph. National Association of Boards of Pharmacy 700 Busse Highway Park Ridge, IL 60068	No
Calvin Anthony, Executive Vice President National Community Pharmacists Association 205 Daingerfield Road Alexandria, VA 22314	Yes
TEXAS PHARMACY ORGANIZATIONS	
Paul Davis, Executive Director Texas Pharmacy Association P.O. Box 14709 Austin, TX 78761-4709	Yes
Terri Bair, President Texas Society of Health-System Pharmacists PO Box 140046 Austin, TX 78714	Yes
Chuck Courtney, Director of Public Affairs Texas Federation of Drug Stores 504 West 12th St. Austin, TX 78701	Yes
STATE PUBLIC HEALTH OFFICIALS	
William R. Archer, M.D., Commissioner Texas Department of Health 1100 West 49th Street Austin, TX 78756	Yes

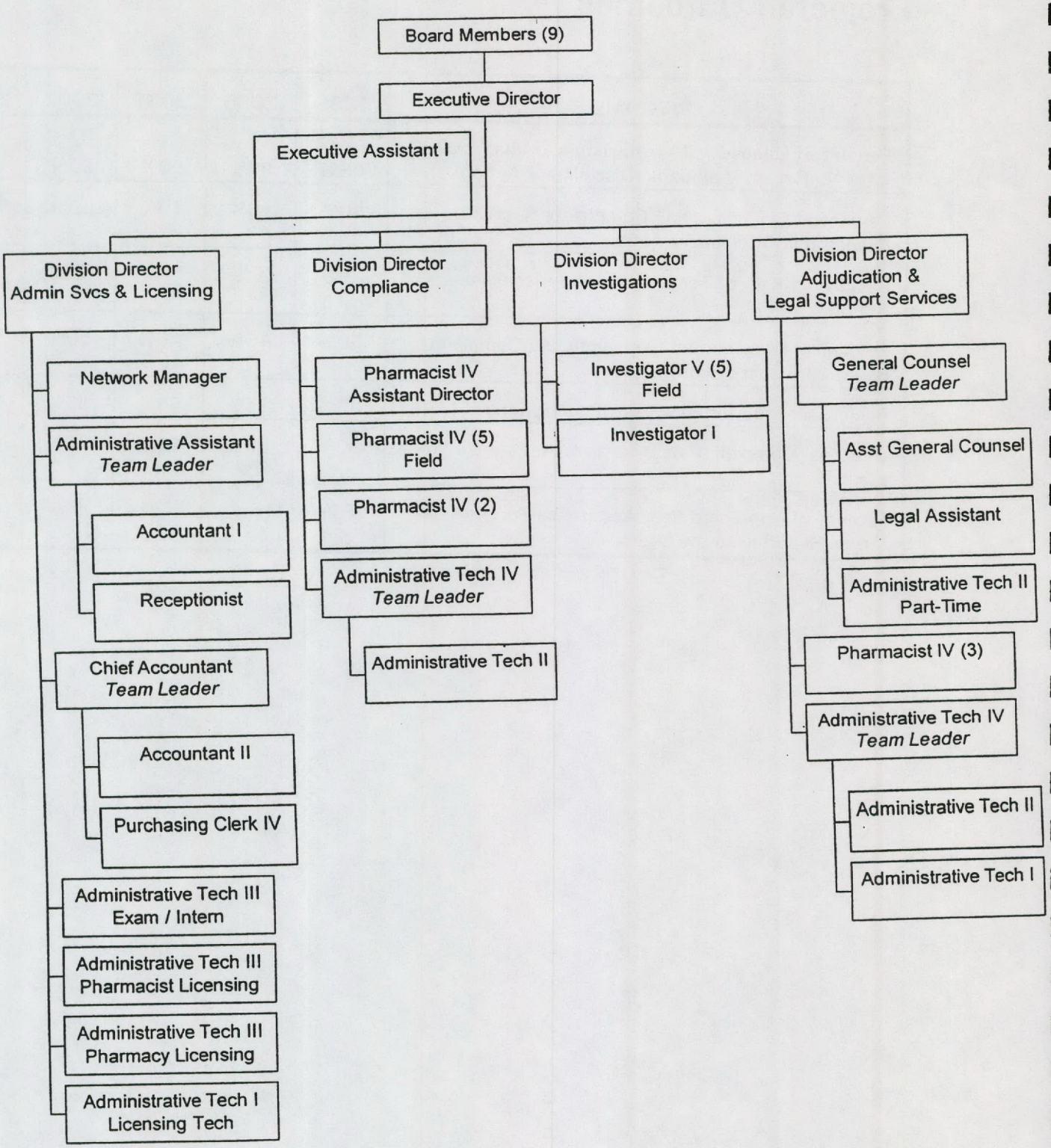
APPENDIX B

Fiscal Years 1999-2003
Projected Outcomes

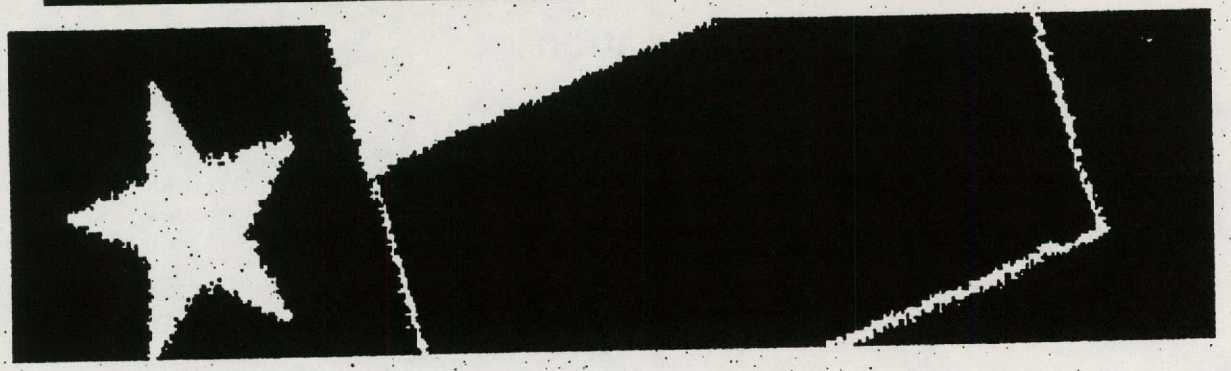
OUTCOME	1999	2000	2001	2002	2003
Percent of Licensees (Pharmacists and Pharmacies) With No Recent Violations (Disciplinary Action)	99%	99%	99%	99%	99%
Percent of (Jurisdictional) Complaints Resolved Resulting in Disciplinary Action	10%	10%	10%	10%	10%
Recidivism Rate of Those Receiving Disciplinary Action	3%	5%	5%	5%	5%
Percent of Documented (Jurisdictional) Complaints Resolved within 6 months	50%	45%	45%	50%	50%
Recidivism Rate for Peer Assistance Program	30%	35%	35%	30%	30%
One Year Completion Rate for Peer Assistance Programs	80%	80%	80%	80%	80%
Percent of Non-board Peer Assistance Program Referrals Reported to the Board	5%	5%	5%	5%	5%

APPENDIX C

TEXAS STATE BOARD OF PHARMACY
FISCAL YEAR 1998



APPENDIX D



The 1998-99 Survey of Organizational Excellence

for the

Board of Pharmacy

Center for Social Work Research
The University of Texas at Austin

Survey Respondent Information

Total Respondents: 26
Response Rate: 70%

	Number of Survey Respondents	Percent of Survey Respondents	Statewide Results
Gender			
Male:	9	35%	45%
Female:	17	65%	53%
Race/Ethnic Identification			
African-American:	Not Available	Not Available	11%
Hispanic-American:	5	19%	16%
Anglo-American:	19	73%	64%
Asian-American or Pacific Islander or Native American Indian:	Not Available	Not Available	2%
Other:	Not Available	Not Available	4%
Age			
Under 20 years old:	Not Available	Not Available	0.2%
20 to 29 years old:	5	19%	11%
30 to 39 years old:	5	19%	26%
40 to 49 years old:	7	27%	34%
50 to 59 years old:	5	19%	22%
60 years and older:	Not Available	Not Available	4%
Education			
Did not finish high school:	Not Available	Not Available	1%
High school diploma (or GED):	Not Available	Not Available	17%
Some college:	6	23%	30%
Associate degree:	Not Available	Not Available	9%
Bachelor's degree:	12	46%	28%
Graduate degree:	Not Available	Not Available	12%
I am currently in a supervisory role:			
Yes:	7	27%	30%
No:	18	69%	66%

Survey Respondent Information

Total Respondents: 26
Response Rate: 70%

	Number of Survey Respondents	Percent of Survey Respondents	Statewide Results
My employment status in the organization is:			
Regular:	25	96%	98%
Temporary:	Not Available	Not Available	1%
Hours per week employed:			
40 or more hours:	24	92%	95%
21 to 39 hours:	Not Available	Not Available	1%
Less than 21 hours:	Not Available	Not Available	1%
I received a promotion during the last two years:			
Yes:	13	50%	29%
No:	12	46%	66%
I received a merit increase during the last two years:			
Yes:	22	85%	29%
No:	Not Available	Not Available	69%
I plan to be working for this organization in two years:			
Yes:	19	73%	83%
No:	6	23%	12%
My length of service with this organization is:			
Under 1 year:	Not Available	Not Available	7%
1 to 2 years:	Not Available	Not Available	12%
3 to 5 years:	7	27%	21%
6 to 10 years:	Not Available	Not Available	23%
11 to 15 years:	Not Available	Not Available	13%
Over 15 years:	7	27%	21%
I am the primary wage earner in my household:			
Yes:	17	65%	65%
No:	8	31%	30%
There is more than one wage earner in my household:			
Yes:	17	65%	61%
No:	9	35%	37%

Survey Respondent Information

Total Respondents: 26
Response Rate: 70%

	Number of Survey Respondents	Percent of Survey Respondents	Statewide Results
The number of persons in my household is:			
1 person:	6	23%	16%
2 persons:	9	35%	32%
3 persons:	Not Available	Not Available	21%
4 persons:	6	23%	20%
5 persons:	Not Available	Not Available	7%
6 persons:	Not Available	Not Available	2%
7 persons or more:	Not Available	Not Available	1%
My annual gross (before taxes) salary is:			
Less than $11,000:	Not Available	Not Available	1%
$11,001 to 15,000:	Not Available	Not Available	5%
$15,001 to 19,000:	Not Available	Not Available	12%
$19,001 to 23,000:	5	19%	14%
$23,001 to 27,000:	Not Available	Not Available	21%
$27,001 to 31,000:	Not Available	Not Available	13%
$31,001 to 35,000:	Not Available	Not Available	9%
$35,001 to 39,000:	Not Available	Not Available	7%
$39,001 to 43,000:	Not Available	Not Available	6%
$43,001 to 47,000:	5	19%	3%
$47,001 to 51,000:	Not Available	Not Available	2%
$51,001 to 55,000:	Not Available	Not Available	2%
$55,001 to 59,000:	Not Available	Not Available	1%
$59,001 to 63,000:	Not Available	Not Available	1%
$63,001 to 67,000:	Not Available	Not Available	0.4%
Over $67,000:	Not Available	Not Available	1%
I have lived in Texas:			
Less than 2 years:	Not Available	Not Available	1%
2 to 10 years:	Not Available	Not Available	7%
Over 10 years:	25	96%	91%

Survey Constructs

The Survey assessment is a framework which, at its highest level, consists of five Workplace Dimensions. Taken together these five dimensions, including Team Perceptions, Physical Work Setting/Accommodations, General Organizational Features, Communication Patterns and Personal Demands, capture the total work environment.

Each Workplace Dimension consists of several Survey Constructs. The Survey Constructs are designed to broadly profile organizational strengths and weaknesses so that interventions may be targeted appropriately. Survey Constructs are developed from the Primary Questions series and scores for the Constructs range from a low of 100 to a high of 500.

The survey questions included in each construct are as follows:

Supervisor Effectiveness
21. Work groups receive adequate feedback that helps improve their performance.
26. Employees have an opportunity to participate in the process of strategic planning and goal setting.
29. Employees seem to be working toward the same goals.
31. Each employee is given the opportunity to be a leader.
40. Employees are given accurate feedback about their performance.
45. Management knows whether an individual employee's life goals are compatible with organizational goals.
54. People who challenge the status quo are valued.
55. Promotion recommendations are made by a team of evaluators.
56. Raises and promotions ensure that workers are rewarded solely for their performance.

Fairness
7. Average work is rewarded the same as excellent work.
30. There is a basic trust among employees and management.
41. Alternative work schedules (flex-time, compressed work weeks, job sharing) are offered to employees.
56. Raises and promotions ensure that workers are rewarded solely for their performance.

Team Effectiveness
21. Work groups receive adequate feedback that helps improve their performance.
28. Decision-making and control are given to employees doing the actual work.
30. There is a basic trust among employees and management.
35. Employee productivity is high.
36. We "walk our talk."

Job Satisfaction
39. Employees have adequate resources to do their jobs.
49. The environment supports a balance between work and personal life.
50. The pace of work in this organization enables employees to enjoy their work.

Diversity
8. My close contacts and co-workers are a lot different from people elsewhere in the organization.*
9. Every employee is valued.
10. Managers are committed to incorporating cultural diversity.
20. Work groups (that group of people with whom you have daily contact) are trained to incorporate the opinions of each member.

Fair Pay
57. Salaries are competitive with similar jobs in the community.
60. Benefits are comparable to those offered in other jobs.

Adequacy of Physical Environment
11. Employees have adequate computer resources (hardware and software).
46. Employees feel safe working in this organization.
47. Employees feel that they work in pleasant surroundings.
48. There is a feeling of community within this organization.

Benefits
58. Benefits can be selected to meet individual needs.
60. Benefits are comparable to those offered in other jobs.
61. The overall benefits and compensation packages offered by my employer were a consideration for me to take this position.

Employment Development
20. Work groups (that group of people with whom you have daily contact) are trained to incorporate the opinions of each member.
43. Training is made available to employees so that they can do their jobs better.
44. Employees have access to information about job opportunities, conferences and training.
45. Management knows whether an individual employee's life goals are compatible with organizational goals.

Change Oriented
16. This organization integrates information and acts intelligently upon that information.
19. We routinely use different people from different parts of the organization to solve problems.
26. Employees have an opportunity to participate in the process of strategic planning and goal setting.
51. New ideas suggested by employees are seriously considered for implementation.
53. Creativity and innovation in work are encouraged.

Goal Oriented
3. Our goals are consistently met or exceeded.
16. This organization integrates information and acts intelligently upon that information.
26. Employees have an opportunity to participate in the process of strategic planning and goal setting.
34. We are efficient.
35. Employee productivity is high.
36. We "walk our talk."

Holographic (Consistency)
8. My close contacts and co-workers are a lot different from people elsewhere in the organization.*
15. Information and knowledge are shared openly in this organization.
17. The work atmosphere encourages open and honest communication.
19. We routinely use different people from different parts of the organization to solve problems.
27. Employees know how their work impacts others in the organization.
28. Decision-making and control are given to employees doing the actual work.
32. Employees feel a sense of pride when they tell people that they work for this organization.
33. Work in this organization feels like it is "coming together."
37. Employees feel that their efforts count.
38. The "buck stops here" describes how employees accept personal accountability.
48. There is a feeling of community within this organization.

Strategic Orientation
1. We are known for our customer service.
5. We know who our customers are.
22. We work well with other organizations.
23. We work well with our governing bodies (the legislature, the board, etc.).
24. We work well with the public.
25. We understand the state, local, national, and global economic issues that impact the organization.

Quality
1. We are known for our customer service.
2. We are constantly improving our services.
4. We produce high quality work that has a low rate of error.
5. We know who our customers are.
6. We develop services to match our customers' needs.

Quality (continued)
7. Average work is rewarded the same as excellent work.*
33. Work in this organization feels like it is "coming together."
39. Employees have adequate resources to do their jobs.

Internal Communication
12. Computerized information is easily shared among divisions in this organization.
14. The right information gets to the right people at the right time.
15. Information and knowledge are shared openly in this organization.
17. The work atmosphere encourages open and honest communication.
21. Work groups receive adequate feedback that helps improve their performance.
40. Employees are given accurate feedback about their performance.

Availability of Information
12. Computerized information is easily shared among divisions in this organization.
14. The right information gets to the right people at the right time.
18. Employees feel that they must always go through channels to get their work done.*
25. We understand the state, local, national and global economic issues that impact this organization.
27. Employees know how their work impacts other employees in the organization.

External Communication
13. Computerized information is shared as appropriate with other organizations.
17. The work atmosphere encourages open and honest communication.
24. We work well with the public.
25. We understand the state, local, national and global economic issues that impact this organization.
44. Employees have access to information about job opportunities, conferences and training.

Time and Stress Management
41. Alternative work schedules (flex-time, compressed work weeks, job sharing) are offered to employees.
49. The environment supports a balance between work and personal life.
52. Employees balance their focus on both the long range and short term.

Burnout
33. Work in this organization feels like it is "coming together."
36. We "walk our talk."
37. Employees feel that their efforts count.
38. The "buck stops here" describes how employees accept personal accountability.
53. Creativity and innovation in work are encouraged.

Empowerment
18. Employees feel that they must always go through channels to get their work done.*
27. Employees know how their work impacts other employees in the organization.
29. Employees seem to be working toward the same goals.
30. There is a basic trust among employees and management.
31. Each employee is given the opportunity to be a leader.
32. Employees feel a sense of pride when they tell people that they work for this organization.
54. People who challenge the status quo are valued.

Survey Constructs

Board of Pharmacy 515

Team Perceptions

This dimension relates to employees' activities with others in their immediate work vicinity. They include factors that concern how employees interact with peers, supervisors and all of the persons involved in day-to-day work activity. This is the immediate work environment of the employee.

Supervisor Effectiveness

Supervisor Effectiveness provides insight into the nature of supervisory relationships in the organization, including the quality of communication, leadership and fairness that employees perceive exist between supervisors and themselves.

1998-99 BENCHMARKS

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	359	347	323	7.21%

Statewide	258
FTE Category	313
Mission	287

Fairness

Fairness measures the extent to which employees believe that equal opportunity exists for all members of the organization.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	365	355	333	6.43%

Statewide	254
FTE Category	321
Mission	298

Team Effectiveness

Team Effectiveness captures employees' perceptions of the effectiveness of their work group and the extent to which the organizational environment supports teamwork among employees.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	391	384	358	6.51%

Statewide	282
FTE Category	342
Mission	315

Job Satisfaction

Job Satisfaction addresses employees' satisfaction with their overall work situation. Weighed heavily in this construct are issues concerning employees' evaluation of the availability of time and resources needed to perform jobs effectively.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	359	355	333	5.13%

Statewide	292
FTE Category	350
Mission	325

Diversity

Diversity addresses the extent to which employees feel that individual differences, including ethnicity or lifestyle, may result in alienation and/or missed opportunities for learning or advancement. (This construct was formerly entitled "Affirmative Action.")

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	357	331	332	4.93%

Statewide	296
FTE Category	338
Mission	316

Survey Constructs

Physical Work Setting/Accommodations

This dimension looks at the physical work setting and the factors associated with compensation, work technology and tools. It is the "total benefit package" provided to employees by the organization.

Fair Pay

Fair Pay is an evaluation from the viewpoint of employees of the competitiveness of the total compensation package. It addresses how well the package "holds up" when employees compare it to similar jobs in their own communities.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	283	306	299	-3.34%

1998-99 BENCHMARKS

Statewide	296
FTE Category	300
Mission	291

Adequacy of Physical Environment

Adequacy of Physical Environment captures employees' perceptions of the work setting and the degree to which employees believe that a safe and pleasant working environment exists.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	416	391	397	3.88%

Statewide	296
FTE Category	378
Mission	338

Benefits

Benefits provides an indication of the role that the employment benefit package plays in attracting and retaining employees.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	377	377	355	4.38%

Statewide	366
FTE Category	380
Mission	369

Employment Development

Employment Development captures perceptions of the priority given to the career and personal development of employees by the organization.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	388	388	362	5.32%

Statewide	304
FTE Category	338
Mission	326

Survey Constructs

Board of Pharmacy 515

General Organizational Features

This dimension addresses the organization's interface with external influences. It is an internal evaluation of the organization's ability to assess changes in the environment and make needed changes. Also included are employees' assessments of the quality of relations the organization shares with the public. In essence, this dimension captures the "corporate" culture.

Change Oriented

1998-99 BENCHMARKS

Change Oriented secures employees' perceptions of the organization's capability and readiness to change based on new information and ideas.

	1998-99	1996-97	1994-95	Change In Score Since 1994-95
Average Score:	382	394	384	-0.27%

Statewide	284
FTE Category	348
Mission	324

Goal Oriented

Goal Oriented addresses the organization's ability to include all its members in focusing resources towards goal accomplishment.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	422	422	404	3.59%

Statewide	302
FTE Category	362
Mission	340

Holographic (Consistency)

Holographic refers to the degree to which all actions of the organization "hang together" and are understood by all. It concerns employees' perceptions of the consistency of decision-making and activity within the organization.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	374	367	352	4.34%

Statewide	282
FTE Category	338
Mission	310

Strategic Orientation

Strategic Orientation secures employees' thinking about how the organization responds to external influences, including those which play a role in defining the mission, services and products provided by the organization. This construct includes an assessment of the organization's ability to seek out and work with relevant external entities.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	448	460	455	-1.47%

Statewide	367
FTE Category	413
Mission	393

Quality

Quality focuses upon the degree to which quality principles, such as customer service and continuous improvement, are a part of the organizational culture. This construct also addresses extent to which employees feel that they have the resources needed to deliver quality services.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	421	427	414	1.20%

Statewide	334
FTE Category	378
Mission	363

Survey Constructs

Board of Pharmacy 515

Communication Patterns

This dimension refers to how consistent and structured communication flow is within the organization and to outside groups. It examines the degree to which communication is directed towards work concerns. How focused and effective it is, as well as, how accessible information is to employees.

Internal Communication

Internal Communication captures the nature of communication exchanges within the organization. It addresses the extent to which employees view information exchanges as open and productive and the degree to which computerized information is efficiently exchanged across the entire organization.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	387	391	361	5.22%

1998-99 BENCHMARKS

Statewide	277
FTE Category	330
Mission	309

Availability of Information

Availability of Information provides insight into whether or not employees feel that the information they need to perform their jobs is accessible to them- employees know where to get needed information and they have the ability to access it in a timely manner.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	393	392	388	0.90%

Statewide	289
FTE Category	334
Mission	315

External Communication

External Communication looks at how information flows in and out of the organization. It captures the ability of the organization to synthesize and apply external information to work performed by the organization.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	421	418	408	2.49%

Statewide	328
FTE Category	378
Mission	354

Survey Constructs

Personal Demands

This dimension reports on how much internalization of stress is occurring and the extent to which debilitating social and psychological conditions appear to be developing at the level of the individual employee. It addresses the important interface between employees' home and work lives, and how this relationship may impact job performance and organizational efficiency.

Time and Stress Management

Time and Stress Management looks at the extent to which employees feel that job demands are realistic given time and resource constraints. This construct also captures employees' feelings about their ability to balance home and work demands.

(Standard scoring methodology is maintained for this construct; therefore, the higher the score the less likely that employees perceive time and stress management to be problematic.)

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	379	371	345	6.93%

1998-99 BENCHMARKS

Statewide	306
FTE Category	367
Mission	346

Burnout

Burnout is a feeling of extreme mental exhaustion that can negatively impact employees' physical health and job performance, leading to lost resources and opportunities in the organization.

(Standard scoring methodology is maintained for this construct; therefore, the higher the score the less likely that employees perceive that burnout exists in the organization.)

	1998-99	1996-97	1994-95	Change In Score Since 1994-95
Average Score:	392	386	371	4.34%

Statewide	285
FTE Category	350
Mission	318

Empowerment

Empowerment measures the degree to which employees feel that they have some control over their jobs and the outcome of their efforts.

	1998-99	1996-97	1994-95	Change in Score Since 1994-95
Average Score:	368	364	344	4.79%

Statewide	270
FTE Category	327
Mission	293

APPENDIX E

AGENCY STAFF

Office of the Executive Director

Executive Director
Gay Dodson, R.Ph.

Executive Assistant
Kay Wilson, C.P.S.

Administrative Services & Licensing Division

Division Director
Cathy Stella, PHR

Purchaser
Patricia Maldonado

Administrative Assistant
Robbi Polanco

Administrative Technician
Misty Whitcomb

Information Systems Manager
vacant

Exam-Intern Specialist
Nicki Green

Chief Accountant
Jane Bennett

Pharmacist Licensing Specialist
Kristen Williams

Accountant
Sandra Morton

Pharmacy Licensing Specialist
René Howard

Accountant
Todd Hayek

Licensing Specialist
Angela Hicks

Compliance Division

Division Director
Steve Morse, R.Ph.

Senior Compliance Officer - Dallas
Cy Weich, R.Ph.

Assistant Director
Iona Grant, R.Ph.

Compliance Officer - San Antonio
Mike Ethridge, R.Ph.

Senior Compliance Staff Officer
Roger Hernandez, R.Ph.

Compliance Officer - Houston
vacant

Senior Compliance Secretary
Retta Stanford-Cole

Compliance Officer - West Texa
vacant

Administrative Assistant
Rebecca Humphrey

Compliance Officer - East Texas
vacant

Investigations Division

Division Director
James Moore

In-House Investigator
Pat Dobbs

Senior Investigator
Don Green

Senior Investigator
Joe B. Lewis

Senior Investigator
Bebe Jones

Senior Investigator
Johnny Martin

Senior Investigator
H. C. Wallace

Adjudication and Legal Support Services Division

Division Director
Carol Fisher, R.Ph., M.P.A.

General Counsel
Cynthia Villarreal-Reyna, J.D.

Assistant General Counsel
Mark Connelly, J.D.

Enforcement Officer
Allison Benz, R.Ph.

Enforcement Officer
Milton Jez, R.Ph.

Enforcement Officer
Marilyn Pearce, R.Ph.

Senior Administrative Assistant
Sherry Stevenson, C.P.S.

Legal Assistant
Janelle Nastri

Administrative Technician
Patricia Galan

Administrative Technician
Maria Renteria