AGENCY STRATEGIC PLAN

For the 1995-99 Period

by

TEXAS STATE BOARD OF PHARMACY

Board Member	Dates of Term	Hometown
Gilbert Acuna, R.Ph.	03-22-94 to 08-31-99	Kingsville
Thomas A. Aday, R.Ph.	08-24-89 to 08-31-95	Plainview
Charlie Bellinger Bethea, R.Ph.	12-20-91 to 08-31-97	Houston
Jeanette H. Coffield	12-20-91 to 08-31-97	Jasper
David L. Franklin, R.Ph.	12-13-89 to 08-31-95	Dallas
Susan H. Jacobson	03-22-94 to 08-31-99	El Paso
Ann H. Peden, R.Ph.	08-24-89 to 08-31-95	Hondo
Marina P. Sifuentes, R.Ph.	12-20-91 to 08-31-97	Austin
Susan Williams	03-22-94 to 08-31-95	McAllen

JUNE 30, 1994

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JUNE 30, 1994

Signed: Fred S. Brinkley, Jr.

Fred S. Brinkley, Jr., R.Ph., M.B.A.
Executive Director/Secretary

Approved: Ann H. Peden

Ann H. Peden, R.Ph.
TSBP President

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VISION

WE ENVISION A TEXAS WHERE ALL PEOPLE HAVE THE SKILLS AND OPPORTUNITIES THEY NEED TO ACHIEVE THEIR INDIVIDUAL DREAMS; A TEXAS WHERE PEOPLE ENJOY GOOD HEALTH, ARE SAFE AND SECURE FROM HARM, AND SHARE A QUALITY STANDARD OF LIVING; AND A TEXAS WHERE WE AND FUTURE GENERATIONS CAN ENJOY OUR BOUNTIFUL NATURAL BEAUTY AND RESOURCES.

FUNCTIONAL GOALS

TO BUILD A SOLID FOUNDATION FOR SOCIAL AND ECONOMIC PROSPERITY

STATE GOVERNMENT WILL OPERATE EFFECTIVELY AND EFFICIENTLY AND WILL MAXIMIZE OUR RETURN OF FEDERAL DOLLARS.

TO PROTECT AND ENHANCE THE HEALTH, WELL-BEING AND PRODUCTIVITY OF ALL TEXANS

ALL TEXANS WILL BE HEALTHY.

ALL TEXANS WILL BE AS PRODUCTIVE, RESPONSIBLE AND SELF-SUFFICIENT AS POSSIBLE.

ALL TEXANS WILL HAVE ACCESS TO A SYSTEM OF PROMPT, COMPREHENSIVE, EFFECTIVE AND EFFICIENT HEALTH AND HUMAN SERVICES.

TO ENSURE THE SAFETY OF OUR COMMUNITIES

OUR CITIZENS WILL BE PROTECTED FROM CRIME.

THOSE WHO COMMIT CRIMES WILL PAY THEIR DEBT TO SOCIETY.

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.

AGENCY EXTERNAL - INTERNAL ASSESSMENT: A MEASURED OVERVIEW OF THE AGENCY BY PERSPECTIVE

I. AGENCY STATUTORY BASES & THE HISTORICAL PERSPECTIVE: OUR ORIGIN & EVOLUTION.

The Texas State Board of Pharmacy (TSBP) 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 & 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 that, "*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.*"

The 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 the Association 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.

With a 1981 amendment to the Act, there appeared a definition of the Practice of Pharmacy that read, *"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."*

In 1993, the Texas Pharmacy Act was again amended. Between the passage of the 1981 and 1993 Pharmacy Acts, several major events occurred that had a substantive impact upon the Agency. These events are recounted in Section IV. Organizational Perspective, under Key Agency Events/Areas of Change & Impact. **One key area of significant change in the 1993 Pharmacy Act was the inclusion of the updating of the definition of pharmacy practice, the inclusion of the concept of pharmaceutical care, and the following definitions, which established the legal basis for pharmacists' increased involvement in patient care:**

(38) "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; and*
- *(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.

(33) "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.

(31) "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.

(24) *"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.

(43) "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 the 1993 amendment to the Act, the Agency's existence was extended for another 12 years.

II. THE KEY SERVICE POPULATION PERSPECTIVE: WHO ARE THEY NOW, WHO WILL THEY BE IN THE FUTURE, AND HOW DO THEY PERCEIVE THE AGENCY?

In consideration of the Agency's Mission Statement, and through the Agency Internal and External Assessment, we have the consensus that our key service populations are, in priority order:

- The Citizens of Texas (directly and through service to Texas Legislators, representing their constituents);
- Licensees (pharmacists & pharmacy owners; pharmacy students & interns);
- Executive & 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, our reference data comes from Forces of Change, Volume II, Part I, published in November 1993 by the Texas Comptroller of Public Accounts:

"Improved health care has benefited all age groups, from newborns to the elderly, but the most pronounced effects have been for the older population. The over-59 population grew by almost twice the state average since 1900, at an average annual rate of 3.3 percent per year, and increased from just 4 percent of state population to 14 percent.

"Texas has been following the national aging trend. The difference is Texas' demographic factors, and perhaps its traditions, which result in higher birth rates, lower death rates, and relatively high net migration.

"As the large baby boom generation moves into middle and old age over the next 30 years, the aging . . . will accelerate . . . . The large bulge appearing in the middle of Texas' 1990 age distribution, from around age 26 to 44, indicates the baby boom. One can imagine that bulge aging through time, in what demographer Philip Hauser has described as the 'shape of a thin snake digesting a mouse.'

"Early in the next century, the boomers' leading edge will begin entering retirement, placing unprecedented demands on public and private goods and services important to an older population. For example, health services, especially long-term care, will become an even more important segment of the nation's economy in that period.

"This will translate into calls for a greater share of government resources dedicated to programs for the elderly, such as . . . health care assistance.

"The forecast points to major changes in population by . . . race and ethnicity . . . .

"In 2026, whites will no longer be the majority racial/ethnic group in Texas, with their share dropping from 61 percent in 1990 to 47 percent in 2026 . . . .

"The Hispanic population will almost double in size to 8.5 million, and its population share will increase from about 26 percent to 38 percent. While the black population will grow by almost 450,000 to 2.4 million, its population share will drop to 11 percent. The other race groups will more than double in size to more than 900,000, almost doubling in population share to more than 4 percent."

Add to these figures the undocumented numbers of immigrants and their dependents. Together 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.

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 seems 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, or they realize that we can serve as advocates 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. In Appendices A & B, there appears a list of the organizations whose comments we solicited, and a list of those responding to our invitation to comment.

III. THE MAIN FUNCTIONAL PERSPECTIVE: WHAT WE DO & THE APPROACH WE TAKE.

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** on pharmacies, pharmacists, & related laws and rules; information on consumer issues such as generic drugs, patient counseling requirements; and the concept & implementation of Pharmaceutical Care;

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

- **Compliance** of licensees in promoting and monitoring pharmacy laws and rules, including specialized requirements regarding the handling, safeguarding, and distribution of prescription drugs and devices;

- **Investigation** of alleged violations of pharmacy laws and rules; and

- **Adjudication/Legal Support** in monitoring the complaint process and prosecuting those found in violation of pharmacy laws and rules.

~ THE AGENCY APPROACH: EFFICIENT AUTONOMY/STRONG COALITIONS

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 (TDH), the Department of Public Safety (DPS), the Federal Food & Drug Administration (FDA), the Drug Enforcement Administration (DEA), 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 established itself as the *lead agency* responsible for coordinating all relevant regulatory efforts as they relate to the practice of pharmacy in Texas.

By keeping the lines of communication open between the related health regulatory and law enforcement agencies, by coordinating investigations involving pharmacies and pharmacists, and by providing technical assistance to regulatory & law enforcement officials and state and federal prosecutors, the Agency has developed a close and effective working relationship with each of them. This has fostered (and continues to promote) a cooperative regulatory environment. The bottom-line result is cost-effective enforcement and virtual elimination of duplication of efforts. Even so, the Agency's reputation and the ability to operate as an independent agency has been the key to the Agency's success in assuming the leadership role with regard to the regulation of pharmacies and pharmacists.

With the Legislature's recent creation of the Health Professions Council, the Agency entered into a new phase of coordination and coalition-building with other state health regulatory agencies. The Council, made up of representatives of all health regulatory agencies in Texas, has been mandated to address certain common areas of coverage, such as administrative, budgeting, board member training, and the administration of complaints. The Council is also serving to facilitate the exchange of valuable information and ideas -- just as important and valuable as the possible sharing of actual functions.

Even before the creation of the Health Professions Council, however, the Texas State Board of Pharmacy realized the importance of coalition building, and of interaction with other agencies and consumer groups. An effort now known as Texas SMART (the Texas Seniors' Medication Awareness Resource Team), was founded and chaired by Agency staff, and membership in the alliance continues to be a multi-faceted representation of Texas communities interested in the health of elderly Texans. Member organizations include the Travis County Retired Senior Volunteer Program (RSVP), the Austin Area Society of Hospital Pharmacists, the University of Texas, the Capital Area Agency on Aging, the federal agency ACTION, the Section of Retired Pharmacists of Texas Pharmaceutical Association, the Texas State Board of Pharmacy, and the Capital Area Pharmaceutical Association. Individuals who represent these organizations, or who otherwise participate in the planning and facilitating of the group's activities, include retail pharmacists, hospital pharmacists, home health care pharmacists, retired pharmacists, retired consumers, retired individuals representing other healthcare fields, community activists, social workers, and governmental representatives.

As other private and public sector organizations and agencies have heard about Texas SMART's activities, they have contacted the Agency to see what part they might play in addressing consumer needs. As a direct result of this type of contact, the Agency participated in the first co-exhibit between the Texas State Board of Pharmacy and the Texas State Board of Medical Examiners. The event was a consumer-focused healthfair in Sherman, Texas in early 1993. Vials of Life, Consumer Brochures, and Medication Profile Cards were distributed free of charge to consumers, as TSBP Compliance (Pharmacist) and TSBME Investigative staff were on hand to speak with consumers about medications, proper medication usage, and their consumer rights.

As a result of the success of this co-exhibit, the Agency was then invited to present an

exhibit on issues surrounding the concept of pharmaceutical care to the annual conventions of the Texas Medical Association and the Texas Osteopathic Medical Association -- **a first for the Agency, and an important step in building bridges between the professionals on the patient's healthcare team.**

The Agency has further demonstrated leadership in collaborative efforts through its involvement with the Texas Pharmacy Congress (made up of the seven major pharmacy-related organizations in the state), addressing educational and professional issues, and with Texas Pharmacists United in Patient Care (a task force of the Texas Pharmacy Congress addressing itself exclusively to patient care issues).

While this section addresses the Agency's general approach to cooperative activities and service, the Agency's particular management and operation methods are covered in Section IV. The Organizational Perspective. In addition, the outlook on interactions and coalition-building with other agencies is further explored under Policy Issue #5.

IV. THE ORGANIZATIONAL PERSPECTIVE: HOW WE POSITION THE AGENCY TO DO WHAT WE DO.

~ 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, must be in good standing with the Board, and must 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 utilization 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 & STAFF MANAGEMENT STYLE/STRUCTURE ~

The Agency's office headquarters is located at 8505 Cross Park Drive, Suite 110, Austin, Texas, in the Northeast quadrant of the city. The Agency staff totals 40 persons, consisting of five management staff, 21 professionals, and 14 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.

Since the issues surrounding Pharmacy practice regulation are unique (it being the only professional area to regulate individuals [pharmacists], facilities [pharmacies], and products [prescription drugs]), the interaction and coordination between the Divisions of the Agency and their staff members are crucial and integral parts of the effectiveness of our efforts. Further, the Agency licenses approximately 17,000 pharmacists and 5,000 pharmacies over a land area of approximately 270,000 square miles. Travel distances for limited Compliance and Investigative staff present a real challenge in the regular monitoring of these licensees. In addition, Medically Underserved areas present specific challenges for comprehensive inspection/investigative efforts. These areas are defined as locales where medical care -- and specifically pharmaceutical care -- may be inaccessible due to distance & 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 by the Board, and are directly tied to the Agency's Strategic Plan. The Executive Director manages the staff to accomplish the adopted objectives.

Regarding management structure, the Director of Operations and Administrative Services is responsible for overall supervision of the Licensing and General Services programs. The Directors of Compliance, Investigation, and Adjudication and 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 state 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, and all Agency staff are encouraged to participate in professional development activities as time and financial resources provide.

Human resource investments, such as provision of state of the art technology and continued training for Agency staff, help position the Agency as public and private sector employers compete for the same workforce pool. The Agency has 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 -- is definitely an asset when recruiting staff. 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.

Meanwhile, the impact of Texas' continued fiscal crisis, as it relates to salaries and funding for staff development, 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.

~ STAFFING PATTERN & PROFILE ~

Agency employee turnover increased from 3% in FY88 to 15.2% in FY92, and dropped slightly in FY93 to 9%. Although the Field Compliance Officer turnover rate has remained stable in FY93, an alarming 40% turnover occurred in FY92. The reason for this turnover rate may be directly attributed to salary dissatisfaction and uncertainty 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 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.

Exhibit #1 shows a comparison of race distribution among the overall Texas population, the Texas pharmacist population, and the TSBP non-manager pharmacist positions for FY93.

EXHIBIT 1

Race	Texas Population Race Distribution	Texas Pharmacists Population Race Distribution	TSBP Non-Manager Pharmacists Population Race Distribution
Anglo	60.59%	75.73%	78%
Hispanic	25.55%	8.83%	11%
Black	11.63%	8.53%	11%
Other	2.23%	6.91%	0%

The Agency's overall workforce profile, as shown in **Exhibit #2**, indicates that the Agency

needs to increase its efforts to recruit and retain qualified minority applicants at all levels of job categories.

EXHIBIT 2
EQUAL EMPLOYMENT DATA
Staff Analysis
2/28/94

Total Agency Employees	Anglo		Hispanic		Black		Other		Total	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Officials/Admin	1	0	0	0	0	0	0	0	1	0
Professionals	11	11	1	0	0	1	0	0	12	12
Admin Support	0	11	0	0	0	2	0	0	0	13
Totals	12	22	1	0	0	3	0	0	13	25

~ HISTORICALLY UNDERUTILIZED BUSINESSES ~

It is the intent of the Legislature that each state agency receiving appropriations in this Act, shall, in acquiring, constructing, or equipping new or existing facilities, and in the operational implementation of each strategy funded in this Act, make a good-faith effort to include historically underutilized businesses (HUB) in at least 30 percent of the total value of contracts awarded.

The Agency attempts to use every HUB listing in bidding for delegated services. The Agency must also satisfy the requirements listed in the overall bid process for delegated services, which states that the award for bids must go to the lowest qualified bid. Other constraints in implementing the overall goal of awarding 30% of the Agency's contracts to HUB certified vendors are the following:

- Expenditures that are proprietary in nature and must be awarded to a single vendor. For example, the Agency contracts with the Department of Information Resources for its cash, licensing and complaint computer programs, and the National Association of Boards of Pharmacy for the development of its national licensing exam. These expenditures constitute approximately 51% of the total amount awarded to contractors, and these vendors are not HUB-certified.

- Expenditures that are processed through the open-market process through the General Services Commission. The award of these expenditures are beyond the Agency's control, and comprise approximately 11% of the Agency's award to contractors, which may or may not be HUB-certified.

The Agency has made a reasonable and good-faith 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 utilizing an Agency HUB Policy as the basis for obtaining the HUB participation goal of 30 percent.

~ CAPITAL IMPROVEMENT NEEDS ~

Assuming capital improvement needs are defined to include expenditures for assets with a project cost or unit cost in excess of $25,000 within the catagories defined in Sec. 106 of the General Appropriations Act, 73rd Legislature, the Agency will require expenditures in two categories: Technology and Transportation.

The Agency Strategic Plan for Information Resources outlines any additional or updated information resources necessary to continue to regulate effectively in the coming years. Section VI, The Technological Perspective, contained in this document, outlines the Information Resource Goals and the major initiatives requiring resources to accomplish these goals.

The second category, Transportation, is an ongoing expenditure each biennium relating to the purchase of Agency vehicles for field enforcement staff. The enforcement efforts are highly dependent on Agency-owned automobiles which are used by the field compliance officers and investigators. The Agency routinely replaces one half (approximately 6) of its vehicles each biennium after they reach approximately 70,000 miles. Experience indicates that high mileage automobiles incur higher maintenance costs and have more frequent breakdowns.

To summarize, Information Resource initiatives as outlined in this document and the Agency Information Strategic Plan, and Transportation needs are the two primary capital improvement areas the Agency will address in the coming biennium.

~ KEY AGENCY EVENTS/AREAS OF CHANGE & IMPACT SINCE LAST STRATEGIC PLAN ~

Since the publication of the 1992 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 implication to the Agency -- the increase in demand for Agency services, from licensing and enforcement to consumer awareness and emphasis by the public and the profession on the issues surrounding the delivery of pharmaceutical care -- and its meaning to the citizens of Texas (fully discussed in Policy Issues 1 and 5).

- The implementation of the 1992 Agency Strategic Plan.

- The implementation of OBRA '90 and the federal mandate for pharmacists to perform Drug Use Review (DUR) and counseling for Medicaid patients.

- The Board rules which mandate that pharmacists provide DUR and counseling on new prescriptions for <u>all</u> Texans.

- The Agency's 1993 Sunset Review, specifically recognizing:
  - the favorable evaluation given to the Agency by the Commission; and
  - the implementation of across-the-board recommendations of the Sunset Commission, including:
    - establishment of a "1-800" phone line for consumer complaint use, with no operational funding for such an operation;
    - the requirements in notification and follow-up information to complainants;
    - the increase in the number of public members of the Board (from two to three);
    - increases in fine amounts for violations of the Pharmacy Act and Rules; and
    - increased disciplinary authority in Section 26, to summarily suspend a pharmacy or pharmacist license when an imminent threat is posed to the public health.
- The passing of the 1993 Pharmacy Act, specifically as the new Act relates to its provisions for:
  - the newly clarified and expanded definition of The Practice of Pharmacy;
  - the recognition of the concept of Pharmaceutical Care;
  - changes in sanctioning and adjudicative processes for licensees;
  - the provision for a limit on the number of times a pharmacist applicant may sit for the Board examinations; and
  - the re-creation of the Agency.
- The Legislative creation of the Health Professions Council with no operational funding (further discussed in Policy Issue 5).
- The President's initiative on Healthcare Reform.

V. THE FISCAL PERSPECTIVE: PAYING THE BILLS

~ CURRENT FUNDING ~

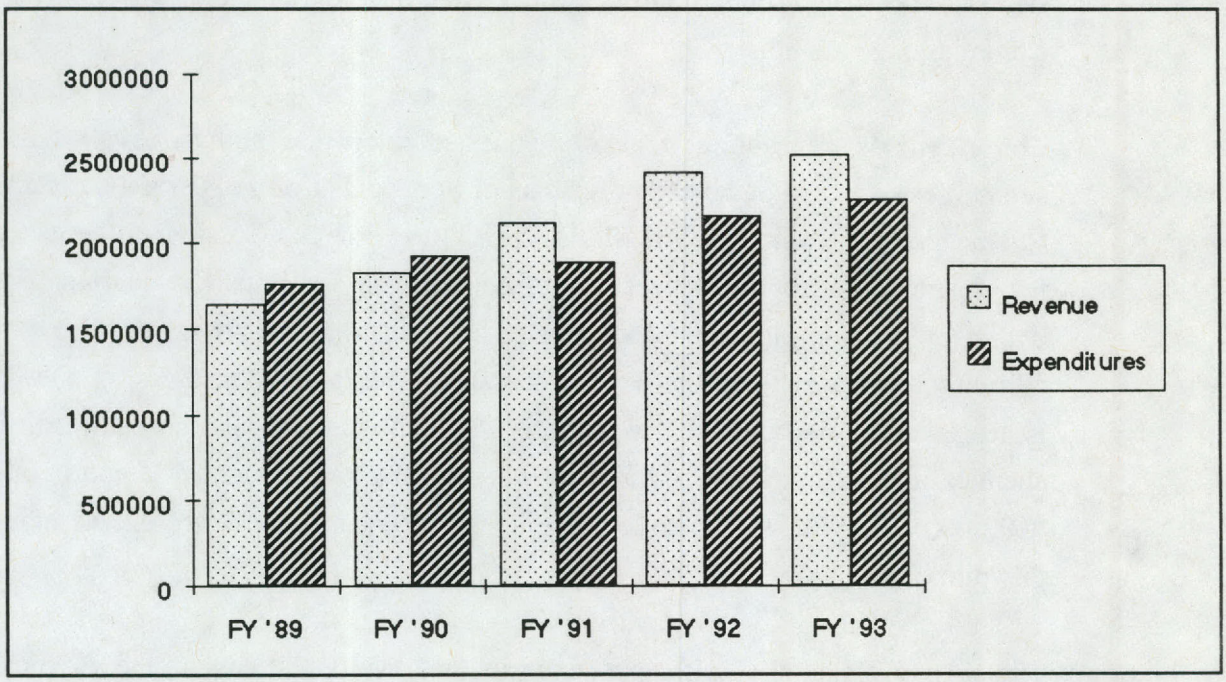
The Agency's operating budget for fiscal year 1992 was approximately $2 million. This includes Legislative appropriations of $1.8 million, and unappropriated expenditures of approximately $400,000. These unappropriated expenditures include such items as the Agency's employee matching benefits and operating transfers to the General Revenue Fund for administrative services provided by other state agencies such as the Comptroller's Office, State Auditor's Office, and General Services Commission.

The Agency's appropriation also includes a rider that authorizes all fees and surcharges collected under the provisions of Section 27a of the Texas Pharmacy Act as amended by House Bill 333, 72nd Legislature, Regular Session, to be expended for financing an approved peer assistance program for impaired pharmacists and pharmacy students, including the costs of administering the program. The Agency currently contracts with the Peer Assistance Program, sponsored by the Texas Pharmaceutical Association, the purpose of which is to aid pharmacists impaired by chemical abuse or mental or physical illness. It is anticipated that approximately $100,000 each year will be collected and appropriated to the Board of Pharmacy for this purpose.

The Agency is totally self-supporting, in that the operations of the Agency are supported primarily from statutory fees related to licensing, reciprocity, examinations, and interest earned on savings and NOW checking accounts and certificates of deposit. The general operating fund of the Board is considered a special revenue fund which is used to account for the proceeds of specific revenue sources legally restricted to expenditures for specified purposes. In accordance with Senate Bill 3, 72nd Legislature, the Pharmacy Board Operating Fund was consolidated into the General Revenue Fund on August 31, 1993. The cash transfer from the Board's local bank to the State Treasury will occur on August 31, 1994, and it is the Agency's understanding that this special account within the State Treasury will retain its current properties; i.e., its ability to retain earned interest.

Exhibit #3 analyzes the Agency's revenues and expenditures for a five-year period (FY89-FY93). As shown in Exhibit #3, Agency expenditures occasionally may exceed Agency revenues (1989 and 1990). The Agency maintains two to three months of *"operating capital"* as a reserve for such contingencies.

Exhibit 3
Texas State Board of Pharmacy
Revenue and Expenditures FY89-FY93



The Agency also maintains a Fines Account for fines collected by the Agency and deposited in the State's General Revenue Fund. In the last biennium, the Agency collected and deposited $68,155 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.

A significant portion of the increased demand for Agency services is a direct result of federal mandates, including the following:

- The Omnibus Budget Reconciliation Act of 1990 (OBRA)

  This federal act requires pharmacists to obtain patient histories, perform drug use reviews and offer counseling to Medicaid patients. Approximately 95% of the pharmacies in Texas deliver prescription services to Medicaid patients. The Agency, in cooperation with the Department of Human Services, must ensure that pharmacists are complying with these requirements. The impact of OBRA upon the Agency and the public is more fully discussed in Policy Issue #1.

- The Prescription Drug Marketing Act (PDMA)

  This federal act prohibits pharmacies and pharmacists from selling, buying, trading, bartering, or exchanging the following types of drugs, except in certain very limited situations: prescription drug samples, prescription drugs sold for export use only, prescription drugs donated or supplied at reduced prices to charitable institutions in the U.S. or abroad, expired prescription drugs, and pharmaceuticals purchased by hospitals, clinics, or other health facilities for the exclusive use of those institutions and not intended for resale. These kind of activities result in prescription drugs being diverted outside the normal distribution chain ("grey-market" diversion). The Agency has received an increased number of consumer complaints alleging that pharmacists have not only dispensed sample drugs, but have charged the consumer a fee for the samples.

  In FY94, following an undercover investigation conducted by the Agency in which a pharmacist dispensed sample drugs for a fee on five separate occasions, the pharmacist closed the pharmacy and the Board revoked the pharmacist's license.

- The Health Care Quality Improvement Act (HCIA)

  This federal act establishes the National Health Practitioner Data Bank. In accordance with this Act, regulatory actions and other types of adverse reports involving health care professionals will be reported to the Data Bank. As a result of this Act, the Agency is required to report disciplinary action to the HHS and DHS and, in the future, will be required to report disciplinary actions to the Data Bank. In addition, insurance companies are required to report malpractice payment reports to the Data Bank and send a copy of the report to the applicable state licensing board. The Agency expects to receive an increasing number of malpractice reports on pharmacists. When these reports are received, a complaint is opened and an investigation is conducted. The requirements of the HCIA have and will continue to increase the demands on the Agency's enforcement services.

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, Legislative appropriations have, in the past, represented a level of funding that, if continued, will inflict serious consequences on the Agency's ability to maintain an acceptable level of performance.

If the Agency is to accomplish its mission and be in a *proactive* rather than a *reactive* position, it must be funded at an adequate level. Failure to receive this funding will severely impact 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, cannot 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 reduce the quality and quantity

of its services, and will continue to leave unmet the public's need for education/information services. Further discussion on the need for public information is found in Policy Issue 5.

Meanwhile, within each Policy Issue segment, there is a detailed discussion of relative budgetary needs & constraints. Additionally, in Policy Issue 5, there is a discussion on the opportunities the Agency sees to increase our own revenue, as well as to take full advantage of available grant monies, partially funding Public Information efforts.

VI. THE TECHNOLOGICAL PERSPECTIVE: HOW WE'RE KEEPING UP.

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, and secure the necessary resources. To achieve this overall plan, the Agency will pursue three ***Information Resource Goals***:

- To provide all TSBP 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 Board customers, as well as the provision of open access to other appropriate entities and State Agencies.

- To provide additional means of information dissemination and education methods. This will include, but will not be limited to, posting or distribution of proposed law changes and adoption of rules which impact the practice of pharmacy through the use of automation and technology.

- 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 Board customers. This initiative will include, but will not be limited to:

- investigation and research of client/server database technology;
- reviewing available imaging systems for records management;
- considering a bulletin board system for an additional and efficient method of information dissemination and education;
- provision of laptop personal computers for Compliance and Investigations field staff; and
- investigation of remote access technologies to Local Area Network (LAN) facilities.

The Agency's current information resources environment includes an office automation system comprised of a Local Area Network, 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, networking 25 personal computer workstations with word processing, electronic mail and other application needs.

Even though the Agency's computer technology has recently been improved, there remains a major need for improvement of the Agency's telephone system. The dramatic increase in telephone calls received by the Agency from FY88 through FY93 is of such magnitude, it alone could stall the overall progress of the Agency. Discussion of this problem is fully covered in Policy Issue 5.

Meanwhile, 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.

VII. THE "INTROSPECTIVE" PERSPECTIVE: AGENCY SELF-EVALUATION, PROGRESS, AND OPPORTUNITIES FOR IMPROVEMENT.

~ AGENCY SELF-EVALUATION ~

As covered in Section IV. 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, as is every Division, as is every employee. This process always ties into the Agency Goals & Objectives, which tie into the Strategic Plan. In addition to this continuous process, and in preparation for this Strategic Plan, we have sought the input of Board Members, TSBP staff, officials of national and state pharmacy organizations, pharmacy academicians, and officials of state consumer advocacy groups. The list of the recipients of our survey letters is included in Appendix A, and is followed in Appendix B by a list of the questions we asked all these "interested parties."

~ AGENCY PROGRESS IN MEETING LEGAL REQUIREMENTS, AND IN ESTABLISHING CREDIBILITY AND RECOGNITION ~

The Texas State Board of Pharmacy has an excellent state and national reputation for its stature and effectiveness as a state health regulatory agency. This reputation has been reinforced within Texas and throughout the nation, as evidenced by the following:

- a 1991 award from the Federal Drug Enforcement Administration (DEA) for **"the Agency's Outstanding Efforts in Drug Law Enforcement in Texas."**

- the **1988 Program Award** from the Council of State Governments, Clearinghouse on Licensure, Enforcement and Regulation (CLEAR). This national award is presented annually to the one regulatory program or agency in the United States which has provided the most outstanding and innovative service to the regulatory community.

- a 1986 award from the Federal Drug Enforcement Administration (DEA) for "**Outstanding Contributions in the Field of Drug Law Enforcement, Specifically with Regard to the Practice of Pharmacy in Texas.**"

The Board of Pharmacy has also been recognized for its efficiency and effectiveness within Texas through:

- three consecutive exception-free financial audits by the State Auditor;

- 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 1991 Legislative Budget Board (LBB) 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...";

- a recent citation by the Director of the Sunset Advisory Commission that the Agency is "**one of the most consumer-oriented health regulatory agencies;**"

- the receipt of an award in 1991 for "Agency Participation in the State Employee Incentive Program" from the Texas Incentive and Productivity Commission (TIPC). The Texas State Board of Pharmacy had the best record of suggestions awarded as a percentage of suggestions submitted of any state agency in Texas. The Agency continued in this effort by submitting two additional employee suggestions that were approved and certified in FY92. These two employee suggestions constituted 6% of the total number of suggestions resulting in cash

awards and, in fact, TSBP was one of only 11 agencies who were able to certify savings in FY92;

- its submitted and certified savings in FY92 for the Agency Productivity Bonus Plan; and

- its pre-Strategic Plan assessment, in which comments from external customer organizations, both national and statewide, were solicited. The feedback comments we received were not only instructive, but extremely positive, and complimentary to the 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:

- utilize ad hoc task forces in its pre-rule-making process;

- publish a Newsletter which is distributed to all licensees and other interested customers (The Newsletter 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;

- develop and implement a Strategic Plan; 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.

~ AGENCY CHARACTERISTICS REQUIRING IMPROVEMENT ~

The Texas State Board of Pharmacy is in a unique position to be able to impact the delivery of pharmaceutical patient 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:

- minority hiring at all staff levels;
- meeting the challenges, and the goals, of the Americans with Disabilities Act, while continuing to ensure competency of licensees;
- acquiring legislation that would allow the Agency to receive and expend grant monies; and
- expand and enhance our capabilities of encouraging the delivery of pharmaceutical care, to improve the quality of life for Texas consumers.

~ KEY OBSTACLES: STATUTORY, FISCAL, HUMAN RESOURCE, GEOGRAPHIC, TECHNOLOGICAL, CULTURAL, SOCIAL ~

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. However, the following obstacles are roadblocks to meeting customer needs:

- Fiscal, in that the Agency has not been adequately funded to achieve even its current goals, and has been left without additional funding to address future initiatives.

- Human Resource, in that the Agency has not been adequately funded to hire the staff needed to maintain and enhance services to Agency customers.

- Statutory, in that the Agency does not currently have the authority to receive or expend grant monies for any operations or special initiatives; and also in that the Agency cannot currently authorize or monitor demonstration projects to fully utilize pharmacists' expertise in providing pharmaceutical patient care.

- Cultural, in that the Agency faces the challenge of minority hiring into specialized fields.

- Social, in that the Agency has not been given resources to respond to increased demand for improved services, and in that our ability to respond is steadily deteriorating.

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

~ OPPORTUNITIES: HUMAN RESOURCES, STATUTORY CHANGES, COMMUNITY/BUSINESS RESOURCES, TECHNOLOGY, SOCIAL ~

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 healthcare 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 resources to do so.**

~ HOW SHALL WE WORK WITH LOCAL, STATE, AND FEDERAL ENTITIES TO ACHIEVE SUCCESS? ~

The Agency 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* existing between TSBP, the Texas Department of Health, and the Texas Department of Mental Health and Mental Retardation; and a formal *Memorandum of Agreement* existing between TSBP, and the Texas Department of Human Services and the U.S. Consumer Product Safety Commission.

Additionally, TSBP has developed excellent working relationships with the Texas State Board of Medical Examiners (TSBME), The Texas State Board of Nurse Examiners, and other state health profession regulatory agencies. These relationships will be enhanced and improved with the new Health Professions Council. In several cases, TSBP and TSBME have coordinated Investigative activities involving conspiracies or questionable "*arrangements*" between pharmacists and physicians. This particular approach implements the section of the Texas Pharmacy Act which states, in Section 6: *"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."*

As mentioned earlier, although these agencies have specific jurisdiction over various aspects of the practice of pharmacy in Texas, their jurisdictions do not usurp or preclude the authority of TSBP in carrying out its responsibility. In fact, licensure of pharmacists and pharmacies by TSBP is a prerequisite to other agencies' jurisdiction and regulation. As a result of the above, and in line with the Agency's statutory responsibility, the Board has established itself as the *lead agency* in Texas responsible for coordinating all regulatory efforts as they relate to the practice of pharmacy.

Again, mention must be made here about the coalition-building efforts of the Agency in regard to pharmaceutical care issues and direct public information (see Section III. The Main Functional Perspective, under the heading, "The Agency Approach: Efficient Autonomy/Strong Coalitions").

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 following Policy Issues.

POLICY ISSUE #1: *The Crucial Role of Pharmacists: Improving Patient Outcomes Through Pharmaceutical Care.*

ISSUE STATEMENT

The aging of Texas' population, advances in medical technology, Health Care Reform, and economics -- these forces are all forging rapid change in our healthcare system. In fact, these forces themselves are being driven, both by new governmental strategies and by marketplace issues. Altogether, these forces are directly causing an evolution in the practice of pharmacy, causing less emphasis to be placed on the "traditional" pharmacist responsibilities of dispensing drugs and more emphasis to be concentrated on those responsibilities that relate to direct patient care, with improved patient outcomes being the result. In order to serve the public health and to survive as a profession, pharmacists must respond (both to the consumer and to other members of the healthcare team) by expanding their communication and informational skills and responsibilities, in addition to performing "traditional" delivery of medication to the patient.

Pharmacists need to be aware of, and committed to, the patient's interest and the direct outcomes of their individual drug therapies. During the Pharmacy in the 21st Century Strategic Planning Conference in October 1989, Dr. C. Douglas Hepler defined such a role as "pharmaceutical care." In this role, pharmacists form working relationships with their patients, and provide both medication management and follow-up services. Such follow-up, or monitoring, services include the identifying, preventing and/or resolving of drug-related problems -- before and after a medication is dispensed. Progressing toward a more patient-oriented practice, pharmacists must provide not only the product, but ongoing information to meet the varying needs of individual patients in order to improve -- or maintain -- each patient's quality of life.

Pharmaceutical care is a crucial component of comprehensive patient care -- and is a vital part of solving the cost, access and quality concerns about health care. Pharmacists have the knowledge and opportunity to achieve better patient outcomes along with a significant savings to Texas' healthcare system. The cost of this pharmaceutical care can be recovered from the savings it generates, but only if an environment is created by healthcare 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 healthcare system -- and the changing ways in which health care is delivered -- have similarly changed the way pharmacists practice. Within the next six years, factors such as the aging of Texas' population, medical technology advances, and healthcare reform will continue to change the practice of pharmacy. This will necessitate the viewing of pharmacy by professionals and patients in a way different than 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 supportive personnel (pharmacy technicians) and/or technological advances to replace any pharmacists who dedicate themselves solely to the dispensing and sale of medications and other products. Policy-makers, the public -- and pharmacists -- need to be continually reminded that prescription drugs, if taken improperly, or without proper professional guidance, often lose their effectiveness, resulting (at the least) in treatment failure, in damage to the patient's health, and in added treatment costs. Alone, the failure to fill -- or refill -- prescriptions results in an estimated national annual cost of $8.6 billion -- due to increased hospital admissions and physician office visits.

As mentioned before, the term pharmaceutical care recognizes both aspects of pharmacy practice -- the delivery of a product and the delivery of clinical services (counseling patients and monitoring patient outcomes). 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 study stemmed from an earlier OIG report identifying weaknesses in the healthcare delivery system, which accounted for a high incidence of mismedication among elderly adults.

In this report, the OIG 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 in a hospital (institutional) setting include:

(1) the operation of drug information centers;
(2) the performance of pharmacokinetic consultations;
(3) the routine practice of drug use reviews;
(4) under protocol of a physician:
    (a) initiating and adjusting the drug regimen of a patient;
    (b) ordering drug therapy-related tests;
    (c) ordering or performing routine drug therapy-related patient assessment procedures; and
    (d) administering drugs and biologicals by injection; and
(5) the education of physicians about Total Parenteral Nutrition (TPN) solutions and other new drugs, drug therapies, and/or delivery systems.

As a result of amendments made by the 73rd Texas Legislature to the Texas Pharmacy Act, pharmacists who are conducting clinical consultations in any healthcare setting must be licensed by the Texas State Board of Pharmacy, effective September 1, 1993. In the next two years, the Agency will be engaging in education and licensing efforts to bring previously unlicensed (and therefore unregulated) pharmacists under the Agency's jurisdiction.

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.

The OIG report recommended that the National Association of Boards of Pharmacy 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.

The use of voluntary systems (through professional organizations) is one approach that could be utilized to ensure that pharmacists continue to be competent. However, because not all pharmacists participate in voluntary programs, the Agency must continue to regulate this important area. Unless there is a cost benefit or a marketplace pressure for the pharmacist to prove continuing competence, this competence may not be attained voluntarily by all practicing pharmacists. To protect the public health and welfare, the Agency must address the issue of assessing continued competence.

As important as competency is the pharmacists' need to access their patients' medical information in order to properly and effectively monitor their drug use. Access to information could be provided through direct contact with the prescriber, a personalized patient ID card *(smart card)*, a centralized health information & 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 73rd Texas Legislature, and resulted in positive changes. For example, the Texas Pharmacy Act was amended to provide confidentiality to any health-related record maintained by a pharmacy or pharmacist, such as a patient medication record, a prescription drug order, or a medication order. In addition, amendments made to the Texas Controlled Substances Act and Texas Dangerous Drug Act now require prescribers to indicate the "intended use" on all written prescriptions issued on or after September 1, 1993, unless the prescriber determines that the furnishing of this information is not in the best interest of the patient. If prescribers comply with this requirement, the information will be used by pharmacists when counseling patients about their medications, specifically because most drugs have more than one indication for use. This information may also be typed on the patient's prescription label, which should increase the patient's understanding of the drug and promote drug compliance. In the next two years, the Agency will be engaged in educating pharmacists and prescribers about these important measures.

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. Mismedication 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.

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 several 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, with non-pharmacists (corporate managers, managed care officials, etc.) making many policy decisions about how pharmacy will be practiced, the delivery of true pharmaceutical care may be threatened unless healthcare policy-makers objectively determine that pharmaceutical care is cost effective.

Several studies indicate that the public would benefit from receiving adequate information about proper use of the prescription and non-prescription drugs they take. In 1982, a national coalition of 250 groups involved in health care was organized to improve the dialogue between patients and healthcare providers about prescription medicines. This coalition, called the National Council on Patient Information and Education (NCPIE), has reported the following alarming statistics concerning patient non-compliance with prescription drug therapy:

- 30 to 50% of all prescriptions fail to produce the desired results because they are used improperly;
- 25 to 90% of patients make errors in administering their medicines;
- an estimated 125,000 deaths -- and about 300,000 hospitalizations -- occur annually because of non-compliance with cardiovascular drugs alone;
- nearly one-fourth of all nursing home admissions result, exclusively, from older people failing -- or being unable -- to take their medications properly; and
- up to 500,000 hospital admissions per year are each the result of an adverse drug reaction.

In response to this awareness of non-compliance, the Food and Drug Administration (FDA) conducted a survey to determine if patients were asking and/or receiving information about their prescription drugs. The FDA survey indicated, that of the people surveyed, up to:

- 96% do not ask questions about their prescription medication; and
- 70% received no counseling about drug precautions or possible side effects.

In addition, a study in 1990 indicated that Texas patients desire to be counseled by their pharmacists. Although this study was conducted prior to the implementation by the Board of mandated patient counseling (as explained in the next paragraph), the findings of the study specifically pointed out that:

- patients need and want counseling and clinical services, but are not receiving them;
- non-compliance results in poor quality of patient outcomes; and
- misuse of medication is an increasing threat to the elderly.

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.

IMPACT ON AGENCY

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. In the future, there is likely to be a trend for the courts to find the pharmacist responsible for patient counseling, due to enactment of the Omnibus Budget Reconciliation Act (OBRA '90), requiring pharmacists to obtain patient histories, perform drug utilization reviews (DURs), and offer counseling to Medicaid patients. Using the OBRA '90 as a springboard, the Board adopted rules which required pharmacists to perform these functions. However, the Agency's rules are more stringent than the federal 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.

Trends indicate that the pharmacist does not have control over his/her pharmacy practice environment. Corporate control exists in virtually all practice settings. With non-pharmacists making decisions about how pharmacy is to be practiced, and with third-party payors making decisions about which pharmacy services will be paid for, 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, and given President Clinton's proposed package for healthcare reform, which includes quality assurance programs. The goals of healthcare 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. Assuming Congress passes a bill including the major components of pharmaceutical care, the Agency will be at the forefront in the regulation of these services, assuring that the Texas public is receiving quality care.

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:

(1) drug utilization review;
(2) monitoring their patients for drug abuse;
(3) providing effective counseling; and
(4) directly monitoring drug use in certain settings.

Such efforts may require the addition or retraining of investigators and compliance officers for clinical enforcement, and retaining the services of practicing "clinical consultants." For example, Agency staff will need to be able to assess patient outcomes and whether clinical services provided to the patient by the pharmacist helped -- or harmed -- the patient. As pharmacy practice moves to incorporate the concept of pharmaceutical care, regulatory and enforcement activities must be based on quality assurance standards, not just performance of process-oriented tasks.

Compliance inspections of pharmacies will 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).

AGENCY STRENGTHS AND OPPORTUNITIES

(1) The Texas Pharmacy Act was amended effective September 1, 1993 to include within the definition of "practice of pharmacy" the "provision of those acts or services necessary to provide pharmaceutical care." Pharmaceutical care was also defined as "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 a patient symptoms, or arresting or slowing of a disease process."

(2) Various organizations are promoting pharmaceutical care to the public and to the profession, including the following organizations:

(a) A Texas Pharmacy Congress' Task Force -- Texas Pharmacists United in Patient Care -- has implemented an organized effort to:

(i) increase patients' awareness of their need for drug information and of the pharmacist's ability to provide this information; and
(ii) educate pharmacists about the need to provide patient counseling and about the best methods by which to counsel patients.

Designated Board Members and Agency staff are appointed to serve on the Congress and the Task Force.

(b) The National Council on Patient Information and Education (NCPIE) 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.*" A designated Board representative works with the NCPIE

organization.

(c) 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:

(i) pharmaceutical products and pharmaceutical care should be included as a core benefit in a reformed healthcare system;
(ii) pharmacists' services and proper management of medications can generate significant savings to a reformed healthcare system;
(iii) quality assurance programs administered by pharmacists can significantly improve the effectiveness of medications in achieving positive patient outcomes; and
(iv) integrated information systems that include pharmacists offer the potential for cost savings and better patient outcomes.

(3) Quality Assurance programs, such as drug utilization review, are mentioned in President Clinton's Health Security Act. These provide a base for the advocacy of a broader array of pharmaceutical care services.

(4) A precedent exists for expanded roles for Texas pharmacists, because:

(a) the federal government, through the DHHS' Office of the Inspector General, has supported the clinical role of community (retail) pharmacists;
(b) the Texas Pharmacy Act now recognizes administration of drugs as a role of the pharmacist, under certain conditions; and
(c) 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.

(5) Current Board rules require patient counseling, 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.

(6) Current Board rules require patient outcome monitoring, under certain circumstances, in some practice settings.

(7) 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.

(8) All pharmacy schools will be implementing six-year curricula, conferring the Doctor of Pharmacy degree upon successful graduates. The new curricula will provide a knowledge base on which pharmacists can expand their current and future roles, such as those in education/training in patient assessment skills.

AGENCY WEAKNESSES AND CONSTRAINTS (THREATS)

(1) Expanded pharmacy services may not be compensated. 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? Policymakers 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 policymakers to recognize the value of pharmaceutical care and its benefit to the public.

(2) In spite of the need for health care to be based on a multi-disciplined healthcare delivery system, expanded roles for pharmacists may be perceived as threatening the "*turf*" of other health professionals such as physicians and nurses.

(3) 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 the patient's medical records (*e.g.*, pharmacists may not know the patient's diagnosis, or the outcome sought by the physician).

(4) If pharmacists are not permitted to fully utilize the assistance of technology and/or supportive personnel (pharmacy technicians), but are required to provide "*pharmaceutical care,*" the cost of prescriptions could rise significantly.

(5) 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.

(6) There is a need for appropriate Board 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).

POLICY ISSUE #2: *"Traditional" and "Non-Traditional" Pharmacy Practice Settings: 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 healthcare 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.

Managed-care networks and third-party payors are recognizing the value of pharmaceutical care. For example, one program entitled, "Coordinated Care Network," has implemented programs to support and compensate pharmacists in their role in patient monitoring and counseling. These programs are described in further detail in the next section,"Explanation of Issue."

EXPLANATION OF ISSUE

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

(1) The "Blurring" of Retail (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 (retail) pharmacies are now providing "home health care" services.

(2) The Rapid Growth of Pharmacy "Specialization."

(a) Health Maintenance Organizations (HMOs) -- Pharmacists in a "closed" system, often with formularies and increased routine **interaction/teamwork** with physicians and the nursing staff of the HMO;

(b) Hospice and Home Health Care -- Pharmacists using more technical expertise in the preparation of IV 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.

(c) 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 (technicians) may be handling customer complaints about prescription drugs and prescription errors; and
- Patients of mail-order pharmacies may ask their local pharmacists questions about the mail-order medications, since local pharmacists are more accessible.

(d) "Closed" Pharmacies -- Pharmacies that are serving nursing home patients only; as a result, the pharmacies are not open to the general public, and represent an "institutional" pharmacy not located in an "institution;" and

(e) "Compounding" Pharmacies -- Pharmacies that dispense a large number of compounded medications directly to patients. These pharmacies include the following:

- Hospice and Home Health Care pharmacies, in which pharmacists compound sterile pharmaceuticals. (Pharmacists who work in these settings are required by Board rules to obtain additional education and training.);

- Non-institutional-based pharmacies in which pharmacists compound nuclear pharmaceuticals. ("Nuclear" pharmacists are required by Board rules to obtain additional education and training.); and
- Retail pharmacies, in which pharmacists compound specialized topical, oral, and inhalation medications.

(3) 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 with a "special" pharmacy license (Class D and Class F), 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.

(4) The Increased Demand for "Clinical" Pharmacists.

As pharmacists become more recognized as drug experts -- as "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.

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. These concerns should be reduced as pharmacists are recognized for providing patient counseling and monitoring services. Another example of the response to increased demand for pharmacy services is the plan of "Coordinated Care Network," administered by PAID Prescriptions, Inc., to

begin implementing several programs in the Spring of 1994, to include:

- The Seniors Counseling Program -- this program will compensate pharmacists for providing personalized drug regimen counseling to participating elderly patients taking multiple medications;
- The Prescription Screening Program -- this program will recognize and compensate pharmacists for their expertise and time in reviewing a patient's profile to avoid potential drug-to-drug interactions; and
- The Disease Management Program -- this program will compensate pharmacists for their enhanced role in educating, counseling and managing medication compliance for high-risk patients through disease-specific patient support programs (such as respiratory disease management, smoking cessation, diabetes and osteoporosis).

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.

Possibly one of the most innovative -- and pragmatic -- examples of pharmaceutical care in action, and an example of reimbursement for cognitive services, has been started in Waco, Texas by Pharmcare, a pharmaceutical care system that can work in any pharmacy. Maximizing pharmacists' time with patients, monitoring medications and providing counseling; maximizing technicians' time and abilities in administrative, clerical and dispensing functions; and also providing maximum followup with patients all make Pharmcare work. Particularly impressive is the practice of the pharmacy providing quarterly reports to each patient's physician on each patient's drug regimens.

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 pharmaceutical care; and
- 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; the consumer being unable to afford even the reduced "co-payments" for care; the consumer being under-insured or non-insured; and even by way of the consumer's mobility, transportation, and family support limitations.

Further, being "employees," these consumers' 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 ten years (1983 to 1993), the number of community (retail) chain pharmacies has increased by 29%, while the number of community (retail) independent pharmacies has decreased by 17%. 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.

Further, 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 and, in fact, may be more restrictive or expansive in scope. 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 types of mechanisms for delivery of pharmacy and healthcare services will need to address the healthcare 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. 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 healthcare delivery systems, other economic factors will continue to affect the delivery of pharmaceutical services over the next six years. These economic factors include "*multi-tiered*" pricing by drug manufacturers, predatory pricing, 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. These new locations will create additional settings and a challenge for the Agency to regulate them.

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.

The Agency will also continue to receive an increased number of complaints regarding how pharmaceutical services are delivered, as there are:

(1) increased numbers of complaints alleging that pharmacists have failed to provide patient counseling or drug use reviews, or have provided improper patient counseling/drug use reviews;

(2) increased numbers of complaints involving dispensing errors (this type of complaint represents the largest number of complaints received by the Agency);

(3) increased numbers of complaints about mail-order pharmacies (in- and out-of-state), compounding pharmacies, and other types of "non-traditional" practice settings, multiplying as these types of settings increase;

(4) increased numbers of complaints from third-party payors alleging fraud (as third-party auditors detect fraud and abuse in their respective programs);

(5) increased numbers of 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);

(6) increased numbers of complaints alleging that a pharmacist is impaired (including complaints about pharmacists who are fired at one pharmacy because of impairment and, before the Board is able to take disciplinary action against the pharmacist, he/she becomes employed at another pharmacy, only to again be fired because of impairment);

(7) increased numbers and types of settings where drugs are provided will increase the potential for, and thus the number of complaints alleging diversion of controlled substances (drugs of abuse/addiction) to the public, as well as diversion of Stadol, Nubain and Soma (The Board recently placed additional controls on these abusable drugs.);

(8) increased types of prescribers, and/or individuals (such as optometrists, physician assistants and nurses) who are able to possess prescription drugs and/or drug samples, will increase the potential for (and thus the number of) complaints alleging diversion of prescription drugs to the public;

(9) 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; and

(10) increased numbers of malpractice reports filed by insurance companies, as required by the Health Care Quality Improvement Act.

The anticipated increases in complaints will place resource demands on the Agency that will be difficult, if not impossible, to meet. Additional demands have already been placed on the Agency's complaint process by recommendations of the Sunset Advisory Commission, incorporated into the Texas Pharmacy Act during the 73rd Texas Legislative Session. For example, the Act now requires pharmacies to notify consumers of the name, address and telephone number of the Agency, so they can direct complaints to the Agency. In addition, the Agency will be required to implement a 1-800-number for consumers' use in filing complaints, although adequate funding was not provided for this program.

The Texas Pharmacy Act was also amended, effective September 1, 1993, to address some of the topics mentioned in this Policy Issue, including:

(1) authority granted to the Board to summarily suspend a license, so that the Agency can prohibit an impaired pharmacist from continuing to practice until he/she has received treatment;

(2) authority granted to the Agency to release information about restrictions placed on an impaired pharmacist's license, when these restrictions affect the person's practice of pharmacy;

(3) a clear definition added to the Pharmacy Act to distinguish "manufacturing" from "compounding" in the practice of pharmacy; and

(4) a new class of pharmacy license (Class F) established, giving the Agency the authority to regulate certain dangerous drugs possessed by home health care agencies.

An issue remaining unaddressed, however, is the **Agency's inability to inspect financial records.** Without this authority, the Agency is unable to investigate complaints relating

to (1) **"kickback"** arrangements between pharmacists and other health care providers, (2) **"grey market diversion"** (previously defined), and (3) **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 during the 73rd Texas Legislative Session were unsuccessful.

As a result of the emergence of Positron Emission Tomography (PET), and other new practice considerations in "nuclear" pharmacies, the Board will be adopting rules to require pharmacists in these facilities to obtain additional education and training. In addition, the Board will be adopting rules to establish additional standards for pharmacies compounding non-sterile products but not registered as manufacturers. The rules will require additional education, inspection and regulation efforts by the Agency. The Board may also be required to adopt additional standards for other new types of pharmacy services that emerge.

AGENCY STRENGTHS AND OPPORTUNITIES

(1) The Agency has the statutory authority to regulate the majority of practice settings through the six classes of pharmacy licenses.

(2) Through its current rulemaking authority, the Agency has already established different types of 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.

(3) 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 has also resulted in effective coordination of activities with other agencies that impact the practice of pharmacy (*e.g.*, Department of Health, Department of Public Safety). 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.

(4) 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)

(1) 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.

(2) Without appropriate regulation of unfair economic practices, such as predatory pricing, multi-tiered pricing, and inadequate reimbursement of pharmacists by third-party payors, **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, and Pharmacist Manpower.*

ISSUE STATEMENT

Use of computers, robotics, and other forms of automation -- as well as increased use of pharmacy supportive personnel (technicians) -- will increase in pharmacy practice over the next six years. Meanwhile, Texas is 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.

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 supportive personnel in caring for increasing patient needs.

EXPLANATION OF ISSUE

I. 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 shows 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.

These technologies can be separated into three general areas: Information Storage Technology; Information Transfer (Communication) Technology; and Automated Dispensing Devices (Robotics).

A. Information Storage Technology

The improvements in storage technology over the past ten years have been significant. Current storage technologies, such as optical memory, CD-Rom, and microprocessors are capable of storing large amounts of information in a very small space. 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 healthcare 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 of the current proposals to the U.S. Congress for healthcare reform include 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 -- information necessary if pharmacists are to realize their potential as *clinical pharmacists*, providing the patient with comprehensive pharmaceutical care.

B. 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. Modems now link pharmacy computers through telephone or satellite transmission with computers in physicians' offices, third party program offices, or even patients' homes. In fact, most pharmacies now have a modem connecting the pharmacy to a third party payor's computer, to check third-party payment eligibility of the patient prior to dispensing a prescription.

The use of these systems is increasing. During the last year 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 by the Vendor Drug Program.

If the pharmacy could access the patient's entire medical history, this technology would allow the pharmacist to review history, check for drug interactions and then evaluate the appropriateness of the drug therapy before dispensing the prescription.

Facsimile (*FAX*) communication technology is now affordable for small businesses and can be used to transmit patient information between physician and pharmacy. Many believe that *FAX* communication between physician and pharmacist is superior to telephone calls, since *FAX* reduces the possibility of misunderstanding.

Bar coding is another communication technology that rapidly and accurately inputs data into computer systems. Bar codes placed on drug products and then scanned prior to dispensing are now used to ensure accuracy.

C. Automated Dispensing Systems/Robotics

Now available are automated dispensing systems ranging from those machines which 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 now available and in use in hospital pharmacies and pharmacies that prepare sterile products.

Automated systems are currently being 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 retail).

II. Pharmacy Technicians (Supportive Personnel)

Over the past five years, the use of pharmacy technicians in a community (retail) pharmacy setting has become a major issue in pharmacy practice. Many states, including Texas, have appointed advisory committees to study the issue, and have subsequently promulgated rules increasing the duties pharmacy technicians may perform -- in all pharmacy settings.

This last year, the Agency enacted rules requiring pharmacists to perform a review of the patient's medical history against all prescriptions, checking for such things as drug interactions, duplications, and contraindications, prior to dispensing the prescription. For each new prescription, the pharmacist is now required to counsel the patient concerning the proper use of the medication, and to provide written information about the drug.

These new requirements compel the pharmacist to spend more of his/her time on clinical -- or patient care -- duties and less time on the technical, mechanical aspects of dispensing a prescription. As a result, many pharmacists are demanding that pharmacy technicians be allowed to perform tasks previously required to be performed by pharmacists. Thus, the demand for qualified and trained pharmacy technicians is increasing.

Partly in response to this demand, both the Texas Pharmaceutical Association and the Texas Society of Hospital Pharmacists began last year to offer an examination to certify pharmacy technicians in Texas. In addition, the American Society of Hospital Pharmacists, the American Pharmaceutical Association, the Illinois Council of Hospital Pharmacists and the Michigan Pharmacists Association are exploring the feasibility of establishing a standard examination that could be used to certify technicians from all practice settings nationwide. 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.

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; however, the Agency currently has no

regulatory authority over pharmacy technicians. Lack of control by a regulatory agency means that a pharmacy technician involved in diversion of drugs at one pharmacy resigns or is fired, only to go to work at another pharmacy. This appears to be a national trend and, as a result, the National Association of Boards of Pharmacy adopted the following resolution at its 1993 meeting:

WHEREAS, there is a need to recognize the accountability of pharmacy technicians assisting pharmacists in the practice of pharmacy; and

WHEREAS, the state boards of pharmacy are the bodies responsible for the regulation of the practice of pharmacy and the sites where pharmacy is practiced;

THEREFORE BE IT RESOLVED that pharmacy technicians be required to work under the personal and direct supervision of a licensed pharmacist; and

BE IT FURTHER RESOLVED that pharmacy technicians be required to register with the state boards of pharmacy by completing a form from the applicable state board.

Pharmacy technicians are crucial to effective pharmacy practice. Over the next few years the Agency will need to examine the feasibility of, and need for, state regulation of these individuals.

III. Manpower Shortage

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."

During 1993, all three of the Texas colleges of pharmacy announced that they are converting their curricula to a six-year, entry-level Doctor of Pharmacy (Pharm.D.) degree, from the five-year Bachelor of Science (B.S.) degree. This conversion should be completed in all of the colleges by the Fall of 1996. All the colleges announced that they will have to reduce class size in order to offer the six-year Pharm. D. degree if they don't receive additional funding needed to effect the conversion and add faculty. If this class reduction occurs, the pharmacy manpower shortage in Texas will worsen.

Two additional Texas universities, one public and one private (Texas Tech and Baylor), are considering the addition of colleges of pharmacy to their curricula. If both of these universities open colleges of pharmacy, their first classes will not graduate until four years after opening; therefore, it will be a minimum of four years before these graduates will fill job openings in Texas. The schools' programs will consist of two years of pre-pharmacy, and four years of professional pharmacy courses - this scenario is based upon entry to the professional courses. These added schools would improve the shortage problem in Texas, but the impact would not be felt until after the year 2000.

The continuing shortage of pharmacists will increase the demand for pharmacists to use automated technology and pharmacy technicians to assist in the technical aspects of the practice of pharmacy.

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 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."*

During the last year, several Texas pharmacies have expanded services in their facilities to include pharmaceutical care services, including drug therapy monitoring, counseling, routine checks of patients' compliance with therapy, and regular feedback to physicians regarding the effectiveness of each patient's medication therapy. This has proven to be a profitable service that physicians have welcomed, and that patients appreciate and are willing to pay for. In addition, third-party carriers are recognizing the value of such patient care services and are developing plans to reimburse pharmacists for these services. These successes will encourage more and more pharmacies to shift the emphasis in their practice to the provision of these clinical services. As this shift occurs, the Agency will need to review its regulations to determine if changes need to be made to allow the best use of pharmacists' time and expertise.

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.

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 healthcare consumer. As a result, the Agency will be in a position of determining if its policies and rules are in the best interests of the public. More specifically, the Agency must determine which functions 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.

AGENCY STRENGTHS AND OPPORTUNITIES

(1) The Texas Pharmacy Act gives the Agency authority to adopt rules defining the use of pharmacy technicians and technology in the practice of pharmacy.

(2) The Texas State Board of Pharmacy has recently adopted rules for the expanded use of pharmacy technicians, and for the expanded use of automated technology, in the practice of pharmacy.

(3) 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.

(4) 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.

(5) The Texas Pharmacy Act was amended, during the 73rd Legislative Session, to include the provision of pharmaceutical care (clinical) services in the definition of the practice of pharmacy.

(6) The Texas Pharmaceutical Association and the Texas Society of Hospital Pharmacists have implemented processes whereby pharmacy technicians now have the opportunity to become certified.

AGENCY WEAKNESSES AND CONSTRAINTS (THREATS)

(1) Board members and Agency staff have limited expertise in automated technology, while the technology is rapidly becoming more and more complex.

(2) In general, pharmacists have limited expertise in the use of automated technology, as well as limited knowledge of Agency requirements for the legal use of such technology.

(3) Education and training programs for pharmacy technicians are limited.

(4) The Agency does not have authority to directly regulate pharmacy technicians through licensure or registration.

(5) Some pharmacists persist in the notion that pharmacy technicians pose a threat rather than an asset to them in practice. As a result, there is resistance by some pharmacists to the expanding of the role of pharmacy technicians in community (retail) pharmacy.

POLICY ISSUE #4: *The Evolution of Drugs, Devices, and Dosage Forms.*

ISSUE STATEMENT

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 (pharmacology) of all new drugs, devices, and administration forms in order to properly 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.

EXPLANATION OF ISSUE

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.

In addition, an entirely new type of therapeutic agent will emerge. Natural products, such as peptides and proteins, based on substances secreted by the body, will be developed and produced through the use of genetic engineering. Some new drug classes being studied now include immunomodulators, neurotransmitters, neurotrophic hormones, mood-altering drugs, monoclonal antibodies, and prostaglandins. The delivery systems designed for these drugs will provide safer, more successful therapies and better patient compliance. The resulting compliance will empower patients to assume more responsibility for their own recovery and overall wellness.

Many new devices and delivery systems (some of which are already available) will employ controlled-release technology, such as transmucosal, transdermal, osmotic pressure, iontophoresis, and magnetic systems; and implanted pumps, respiratory (inhalation) delivery, biodegradable implants, matrixes, ion exchange and microencapsulation. These controlled-release technologies deliver drugs at constant rates; however, some drugs, such as anti-cancer drugs, are best when given in "pulses." Erodible polymers, and an enzyme-responsive release system, are systems being studied that will deliver drugs in such timed pulses.

Still other delivery systems may be structured to deliver medications to specifically targeted tissues and cells, using liposomes, microspheres, chemical carriers, monoclonal antibodies and hormones. Some researchers even predict that doses of medication will be individualized and tailored to the individual patient, taking into consideration the patient's personal biochemistry.

New drugs and delivery systems will have advantages of fewer side effects and thus be safer for the patient; however, higher potency of medications, along with complexity of delivery systems used for them, also increases potential danger to the patient if these medications are not used properly.

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 study and education essential for any pharmacist dealing with these products.

In addition, the pharmacist will 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, 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.

IMPACT ON AGENCY

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.

Additionally, the Board will be faced with determining if additional education, certification or specialization will be necessary for a pharmacist to safely and effectively *dispense/administer* these medications and to be qualified to advise patients and/or other health practitioners on the use of these medications, devices and delivery systems.

AGENCY STRENGTHS AND OPPORTUNITIES

(1) The Agency has the authority to establish task forces composed of pharmacists and other professionals who have special expertise, to advise the Board in those areas.

(2) There is a vast pool of knowledgeable resource persons in Texas' pharmacy educational institutions and in its health professions, available to the Agency.

(3) The Agency has recognized and anticipates the potential for difficulties in regulating new medications, devices, dosage forms, and delivery systems in the public interest.

(4) The Texas Dangerous Drug Act gives the Agency the authority to regulate prescription drugs and devices.

(5) The current definition of the *practice of pharmacy* in the Texas Pharmacy Act 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.

AGENCY WEAKNESSES AND CONSTRAINTS (THREATS)

(1) 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.

(2) 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.

(3) The Agency has no direct authority to mandate certification, and the pharmacy profession has only limited mechanisms for voluntary certification, of pharmacists who specialize in advanced technological drugs and dosage forms.

(4) The current definition of dangerous drugs includes "devices which require a prescription," but does not include other types of devices.

(5) 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.

POLICY ISSUE #5: *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 healthcare team is of great interest to the Board and to the profession. The future of the pharmacist's role will, in many ways, determine the future role of our Agency. The Board of Pharmacy must be visionary in order to stay on the cutting edge of regulation. Our future will be determined by how the profession -- and the Agency -- respond to increasingly complex demands and trends developing in the healthcare system.

The Board 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, increasing the quality of pharmacy services to Texas consumers. In order for the Agency to continue its leadership role and meet the demand for Agency services in the next five years, however, additional and highly qualified human resources must be made available, along with quality management practices and proper technology.

The increase in demand for information, enforcement, and other services has taxed the Agency's ability to deliver excellence and thus, is hampering our optimum response to the future of Pharmacy and to the safety needs of the public. Given continuing financial crises 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 operations. Additional human and technical resources must be provided to the Agency if we are 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

I. 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. TSBP 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, we believe that the State's (and TSBP's) goal to provide *"legendary customer service"* may become illusory.

TSBP'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:

(A) TSBP's position in state government as an independent Agency;

(B) The proactive stance of our Board members, as they set policy;

(C) Highly qualified and dedicated management, professional, and line staff who consistently carry out policy with a quality customer service ethic;

(D) Adequate technology necessary to support and enhance Agency services; and

(E) Adequate, self-generated funding of the Agency in carrying out its responsibilities.

II. The Consolidation Issue

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 to 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.*"

Comparing efficiency measures with the other similar-size state boards of pharmacy, in California and Florida, TSBP has documented superior performance in such areas as licensing and enforcement. Both the California and Florida boards are under the control of "*umbrella agencies.*"

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*. 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:

1. the Board of Chiropractic Examiners;
2. the Board of Dental Examiners;
3. the Texas Optometry Board;
4. the Board of Pharmacy;
5. the Board of Podiatry Examiners;
6. the Board of Veterinary Medical Examiners;
7. the Board of Medical Examiners;
8. the Board of Nurse Examiners;
9. the Board of Examiners of Psychologists;

10. the Board of Vocational Nurse Examiners;
11. the entity that regulates the practice of physical therapy;
12. the entity that regulates the practice of occupational therapy;
13. the Health Licensing Division of the Department of Public Health; and
14. the Governor's office.

The Council has since had its organizational meeting and will carefully review and make recommendations to the 74th Legislature regarding various aspects of coordination vs. consolidation. Ideally, this Council will provide a valuable oversight function and a forum for health licensing agencies' discussion and consensus on major licensing goals and statewide regulatory policies, without sacrificing the independent efficiency and effectiveness of each agency. However, an initial and primary problem with the creation of the council centers on its own lack of resources. The Council is mandated to be funded by a pro-rata share of each affected agency's appropriation; however, each agency's appropriation was not increased by any amount to compensate for this pro-rata share. In keeping with legislative intent, it appears at this writing that the Governor's Office will provide emergency and/or deficiency grants to fund the Council for this biennium. Recommendations to include a funding rider to each agency appropriation will be considered in the next legislative session.

III. 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 & 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:

1. *"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."*

2. *"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."

3. *"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.

Meanwhile, the following items (A-E) illustrate trends toward increasing demand for innovative Agency services, and serve as a "snapshot" of issues on the cutting edge of regulation practices. As such, these items represent crucial areas of investment for the Agency, the certain return from which will be reaped by the citizens of Texas.

A. Enforcement Services

From FY89 through FY93, the Agency experienced an increased demand for Enforcement services. The most significant increases are indicated by the following data:

1. **The number of complaints** that the Agency has received: In FY89, the Agency received 492 complaints, as compared to FY93, when the Agency received 940 complaints (an increase of 91% over the past five years).

2. **The number of impaired pharmacists** being monitored by the Agency: At year-end FY89, the Agency was monitoring 47 individuals, as compared to year-end FY93, when the Agency was monitoring 88 individuals (an increase of 87% over the past five years).

3. **The requirement that the Agency contract with the State Office of Administrative Hearings (SOAH)**: Since April 1992, the Agency has been required to use the State Office of Administrative Hearings (SOAH) to conduct formal disciplinary hearings. This change has increased the Agency's average adjudicative costs by approximately $1,000 per disciplinary licensee. The increased costs notwithstanding, it is extremely difficult to project the funds necessary for services rendered by SOAH. The Agency has no control over these costs, other

than not scheduling hearings or reducing the number of hearings, in cases where SOAH costs exceed estimates. Neither of these alternatives is desirable, and either would actually have an adverse effect on the public health, safety and welfare of Texas' citizens.

Beside the adverse economic effects of SOAH, the Agency's resolution time for complaints referred to SOAH is longer (average of 4 months), due to processing time involved, including time for each of the opposing counsels to prepare and file proposed Findings of Fact/Conclusions of Law, time for the Administrative Law Judge (ALJ) to prepare the Proposal for Decision (PFD), time for the ALJ to distribute the PFD to opposing counsels, wait for their responses/exceptions, and then to wait until a regularly scheduled meeting of the Board to present to them the PFD.

4. **The number of cases involving misuse of Hydrocodone products.** This issue is discussed at length at the end of this section.

When the number of complaints increase, other enforcement services are affected, such as: the number of investigations; the number of complaints resolved; and the number of disciplinary orders entered. The impact of the increased workload -- with no increased human resources to meet the demand for services -- results in the Agency taking a longer time in resolving complaints. This, in turn, has a direct effect upon the public health, safety, and welfare.

The following chart illustrates the growth in the number of complaints received and resolved over this five-year period.

Year	Complaints Received	% Increase	Complaints Resolved	Average Resolution
FY88	482	--	529	--
FY89	492	2%	491	79 days
FY90	595	21%	556	85 days
FY91	648	9%	636	100 days
FY92	598	-8%	561	111 days
FY93	940	57%	900	97 days

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.

Complexity issues are also evident in the adjudication of licensees (pharmacists and pharmacies). Because of the complexity of pharmacy practice, enforcement has, and will continue to, become complex. Cases involving such areas as professional judgement, malpractice, and computer fraud generally require the Agency to consult and use expert witnesses.

Serious cases result in the revocation of a license. Examples of serious complaints resulting in the revocation of licenses between FY 91-93 include:

- A case resulting in the revocation of three licenses occurred after simultaneous audits were conducted in four Austin pharmacies under the same ownership. The result of the four audits showed total shortages of over 60,000 dosage units of Schedule II controlled substances (drugs of extremely high abuse potential) and having an estimated street value of $1.2 million.

- A case resulted in the revocation of a license, when the licensee diverted 156,556 dosage units of controlled substances during a three-month period.

- A case resulting in revocation of two licenses involved a 14-month joint investigation between TSBP and the El Paso Narcotics Task Force, and produced evidence of illegal delivery, on eight different occasions, of dangerous drugs and controlled substances, including anabolic steroids. An audit showed that the pharmacy could not account for 5,000 tablets of anabolic steroids and 230 ml. of injectable anabolic steroids.

- A case resulted in the revocation of one license and forced closing of a pharmacy engaged in grey-market diversion and the selling of drug samples to consumers.

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. 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 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 five persons, as follows:

1. the recovering pharmacist (self reports);
2. the supervising pharmacist (if applicable);
3. the mental health professional (if under an MHP's care);
4. the probation officer, (if applicable); and
5. the pharmacist peer assistance program (TPA's Pharmacists' Recovery Network [PRN]).

One Order can require up to 20 reports annually. Each one of these reports must be reviewed, evaluated, and acknowledged by Agency staff. The following chart indicates the increase in individuals being monitored by the Agency over the past seven-year period:

Fiscal Year	Total Orders*	Total New Orders**	Total Being Monitored +	Cumulative Increase
FY87	26	17	n/a	-
FY88	17	9	n/a	-
FY89	28	20	47	-
FY90	19	13	58	-
FY91	37	23	72	53%
FY92	21	14	73	55%
FY93	29	21	88	87%

n/a Data not available

* 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).

One of the most disturbing trends challenging the Agency's Enforcement effort is the skyrocketing abuse of a group of drugs containing Hydrocodone. A drug routinely used in pain management or as a cough suppressant, it is commonly known in tablet or capsule form as: Vicodin, Hydrocodone w/APAP, Tussend, Hycomine, Anexsia, Tussionex, Lortab, or Hydrocet. In liquid form, Hydrocodone products include: Hydrocodone, Tussionex, Hycodan, Hycotuss, Endal-HD, Tussend, and Rutuss.

Texas is facing a critical situation due to increasing amounts of Hydrocodone products being illegally prescribed, bought, sold, stolen -- and ultimately misused -- by its citizens. Hydrocodone is safe and effective when taken properly. Actually, most individuals abusing Hydrocodone state that they didn't start out to abuse the drug, but were taking it for legitimate purposes, built up a tolerance for the drug, increased their own dosages, and then became addicted. At this point, addicted or unscrupulous pharmacists and/or consumers will do anything to obtain Hydrocodone products -- either for personal use or for street sale, where the drug is extremely popular and relatively cheap.

The Agency requested, in April 1992, that the Commissioner of the Texas Department of Health reclassify Hydrocodone products as Schedule II drugs, rather than their present Schedule III status, therefore putting increased safeguards and controls in place. However, the Agency's plea was denied due to "lack of scientific data," and this drug continues to be classified as a Schedule III drug -- inadequately restricted, in the opinion of the Agency, considering its abuse factor.

The most concise way to illustrate the Agency's concerns is to list the following facts surrounding Hydrocodone abuse and its impact on consumers, pharmacists, and the Agency:

-- Between 9/1/86 and 8/31/90, the Agency entered Board Orders against pharmacies/pharmacists involving a total of 90,732 dosage units of abused Hydrocodone in its tablet/capsule forms alone (not including those involving the abuse of hundreds of gallons in its liquid forms).

This figure, 90,732 tablets/capsules, is represented in 32 Board Orders. This means that, among the cases brought to completion in Board Orders, the average amount of non-liquid Hydrocodone abused per instance is 2,835 unit doses -- one pharmacist, or one pharmacy, allegedly diverting an average of 2,835 individual doses of an addictive drug! One case involved two pharmacists, employed in the same pharmacy, allegedly diverting or not maintaining purchase/disposal records on over 19,000 dosage units of various Hydrocodone products. On the other end of the spectrum, one case involved charges against a pharmacist who was videotaped "pocketing" 16 Hydrocodone doses.

In addition to the above figures, the amounts of abused liquid Hydrocodone products (reflected in Agency Board Orders) totalled 147.90 GALLONS for the period FY 86 to FY 94. This amount represents roughly 56,834 average individual dosage units (based on an average dosage of 5mg/ml. strength, two teaspoons). Together with the total for solid-form Hydrocodone, the number of diverted individual dosage units comes to approximately 147,566 doses of Hydrocodone products.

Of course, these are the figures for those instances of abuse which were reported, investigated, apprehended, and successfully adjudicated by the

Agency, and do not address the undiscovered abuse under Agency jurisdiction, or diversion traffic outside Agency jurisdiction.

-- Most Hydrocodone is obtained illegally through forged prescriptions, unauthorized refills, and theft. Agency investigators report that related inventories of the drug are often falsified or "missing."

-- The Agency has documented that the amounts of misused Hydrocodone jumped dramatically for the first time in 1987. An even more dramatic jump in its misuse has been observed since 1992. In fact, virtually every major case of drug diversion seen by the Agency's Enforcement division involves Hydrocodone products. This also includes practically every case the Agency handles involving a drug-impaired pharmacist.

-- The National Institute on Drug Abuse (NIDA) reports, through its Drug Abuse Warning Network (DAWN), that Hydrocodone is showing up in hospital emergency rooms as a frequent source of overdose, citing 359 such cases from January 1989 - September 1991 in the Dallas area alone. These reports are based on estimates from a representative sample of non-federal short-stay hospitals, with 24-hour emergency rooms.

-- The Agency's Fall/Winter 1993-1994 Newsletter included a cover article written by Sam T. Searcy, a police officer in the Narcotics Division, Diversion Squad of the Houston Police Department. Officer Searcy's article is entitled, "It's Everywhere, It's Everywhere!: A View From the Field." The article reports that, in Houston alone, Hydrocodone products account for 98% of all forged prescription cases filed with the District Attorney's office, and that these cases are third degree felonies. The article continues on to advise pharmacists across the state to watch for Hydrocodone abuse and forgeries in their practices, and to refuse to fill any prescription they suspect

is for illegitimate purposes. In his article, Officer Searcy states, "For many people who are given the medication for a legitimate medical purpose, it quickly becomes their drug of choice, and nothing else will do. Once the prescriptions from their doctor stop, the theft of prescription blanks, copies of blanks, and fictitious telephone prescriptions begin. During this time, the tolerance level increases. With a wide range of people, this drug takes over. It is not uncommon to see a person who ingests 30 or more tablets a day."

The overall impact on the Agency -- and on the citizens of Texas -- of this escalating problem is a combination of increased time and cost of investigation by the Agency and by federal, state and local law enforcement agencies, and more importantly, an increased danger to our professionals and consumers posed by this effective, but too-accessible/addictive substance. This substance needs to be regulated at a higher level to reduce its diversion into the illicit market. The first step toward increased safety and efficiency would be the reclassification of Hydrocodone to a Schedule II drug.

B. 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. The following table shows how the Agency's Licensing activities have increased, and are expected to increase over an 11 year period:

PERFORMANCE OUTPUTS

FY89-94 (actual)

FY95-99 (projected)

YEAR	INDIVIDUALS EXAMINED	% INCREASE	# OF PHARMACISTS LICENSED	% INCREASE	# OF PHARMACIES LICENSED	% INCREASE
FY89	1,185	—	15,265	—	4,714	—
FY90	1,344	13%	15,885	4.0%	4,856	3.0%
FY91	1,397	5%	16,302	3.0%	4,888	1.0%
FY92	1,436	3%	16,883	4.0%	4,938	1.0%
FY93	1,394	<3%>	17,312	3.0%	4,963	2.0%
FY94	1,415	1.5%	17,658	2.0%	5,673	14.0%
FY95	1,443	2%	18,099	2.5%	5,773	2.0%
FY96	1,457	1%	18,551	2.5%	5,830	1.0%
FY97	1,486	2%	19,014	2.5%	5,888	1.0%
FY98	1,516	2%	19,489	2.5%	5,947	1.0%
FY99	1,546	2%	19,976	2.5%	6,006	1.0%
CUMULATIVE INCREASE FOR FY89-99		**30%**		**31%**		**27%**

(1) Impacts on Pharmacist Licensing:

(a) 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 the 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. 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. Although there exists now a laudible voluntary certification program of Pharmacy Technicians through state pharmacy associations, its impact to the public health remains to be seen.

Approximately *20,000* Pharmacy Technicians currently practice in Texas, largely unrecognized in their significance to the public. The impact of this population as registrants, or licensees, most certainly would require additional resources in the Licensing Division of the Agency -- both at initial certification and in addressing continued competency of Pharmacy Technicians.

(b) The Demand for Pharmacists

As noted in earlier policy statements, the demand for pharmacists -- and quality patient services -- is increasing as a direct result of the changes in the overall healthcare marketplace. This demand takes on even greater significance when coupled with the aging of the Texas population. As the Texas population continues to grow **and** age, Texas, as well as the nation, is experiencing a shortage of professional pharmacists. In addition, a national change in the entry-level degree from the B.S. to the Pharm.D. is already significantly affecting pharmacy education and could affect the number of professional pharmacists in Texas.

In a report to the Texas Higher Education Coordinating Board, one possible long-term solution to help meet this challenge in Texas was the creation of a new school of pharmacy. Thus, in 1994, we have seen the creation of a new school of pharmacy, to be part of Texas Tech University, and to be located in Amarillo. An additional Texas university (Baylor University) is considering the addition of a college of pharmacy to their curricula. The creation of new schools of pharmacy will most certainly impact Licensing services of the Agency -- in areas of examination, reciprocity, internship, information services, and certification of preceptors, not to mention the related Compliance and other Enforcement activities involved in regulating another academic program, and its students, under our authority.

(c) The Americans with Disabilities Act

Another area of Agency focus for coming years will be the responsibilities and concerns related to the Americans with Disabilities Act (ADA) of 1990. The Agency endorses the ADA; however, its

adoption has raised both legal and psychometric concerns with regard to the licensing of pharmacists. Generally, the ADA prohibits discrimination against "otherwise qualified," disabled individuals, particularly those individuals who have substantiated disabilities as defined in the law and who can otherwise meet the essential requirements of practice.

The National Association of Boards of Pharmacy (NABP) has appointed a special Task Force to:

(i) Review the impact of the ADA legislation on NABP's exam programs and on the administration of such exams by the states;
(ii) Discuss the responsibilities of NABP and the states in responding to the requests of qualified individuals seeking accommodations in accordance with ADA;
(iii) Develop a process for states to use in requesting testing accommodations for qualified, disabled candidates from NABP, and
(iv) Evaluate the need, in the interest of the public health, to provide for restricted licensure.

To quote an excerpt of a statement from NABP:

"Evaluating individual disabilities and whether their accommodations mask an applicant's ability to perform the essential functions of a profession's responsibilities without endangering the public health and safety is a serious concern of licensing agencies. Test administrators and health care licensing boards are now confronting the dilemma of complying with the ADA's mandate prohibiting discrimination against qualified disabled candidates for licensure, while also meeting their

statutory responsibilities of protecting the public from unqualified practitioners by denying licensure in legitimate circumstances.

"Although psychometricians generally believe that accommodating disabled candidates through extended testing times, and other such minor modifications as may be reasonably available in practice, do help to "level the playing field," the possibility exists that significant accommodations could actually change the nature of what is being tested. In their extreme, significant accommodations may alter test results to such an extent that the examiner is unable to accurately assess the competence of candidates."

In the meantime, the Agency will continue to monitor these developments as well as any decisions deferred to the judicial system interpreting the legislation and defining the responsibilities of those involved. The Agency believes in the importance of complying with the ADA's provisions for qualified, disabled individuals to be offered the opportunity to meet requirements for licensure, without compromising examinations or statutory requirements so as to endanger the public health.

(2) Impacts 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.

In FY94, implementing legislation passed by the 73rd Legislature, the Agency is licensing a 6th Class of Pharmacy -- The Class F Pharmacy License. This Class of license will be issued to pharmacies "located in

facility licensed under Chapter 142, Health and Safety Code, for the purpose of dispensing, distributing, or administering to their patients under physicians' orders, certain dangerous drugs." The new Class F mandate may result in an increase of up to ***1,400*** new pharmacies licensed by this Agency.

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 two 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 six years. The Agency has, or will soon have, Rules for the following types of pharmacy practice:

- Class A (Community) Pharmacies;
- Class A Pharmacies Dispensing 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 Expanded Formularies;
- Class E (Non-Resident) Pharmacies; and
- Class F (Home and Community Support Support Services Agency) 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.

C. 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 healthcare 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 healthcare 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.

In keeping with the Board'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 Board to enhance consumer information and education during the past two years has been built on this "coalition" strategy. Utilizing 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 is addressing consumer education needs -- particularly those of elderly residents of Travis County -- in a pilot program. This effort, the Texas Seniors' Medication Awareness Resource Team (TX S.M.A.R.T.), features education of individual consumers and consumer groups on issues regarding prescription and non-prescription medicines, the importance of medication compliance,

citizens' rights to know certain information about their medications, how they should choose a pharmacist and/or pharmacy, and the pharmacist's vital, coordinating, role on their health care team.

The Agency has already taken a major step in the promotion of consumers' rights to information and education, by addressing this critical issue in the Agency's Strategic Plan, as well as in the Agency's FY94-95 Legislative Appropriation Request. This plan provides for:

(1) television and radio public service announcements, informing the general public of vital issues related to the use and misuse of prescription and over-the-counter medications;

(2) general and specific written information for mailouts, regarding urgent consumer health and pharmaceutical care issues;

(3) the continuation and expansion of the Agency's statutorily mandated Consumer Information Brochure;

(4) speeches, presentations, and exhibits to local communities and professional groups; and

(5) surveys to indicate consumer attitudes and perceptions regarding care needs, as well as perceptions of the pharmaceutical care they now receive in their communities.

Although the 73rd Legislature did not fund this program, the Agency will again address this issue in the 74th Legislative Session. The Agency would not be left alone to fund this type of effort. There are documented resources of grant monies available for medication-related consumer information programs, both

through public and private grant sources. The Agency's achievement of its strategic goals, and the improved health care of the people of Texas, is ABSOLUTELY 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.

D. Telecommunication System Services

Information services, and the demand for such, arise partly out of constant and complex changes occurring in pharmacy practice. From FY88 through FY93, the Agency experienced a total increase of 58% in the number of telephone calls. In FY94, the cumulative increase for FY88 through FY94 is anticipated to be *81%*. The majority of the increase is related to Enforcement and Licensing activities. For example, the Compliance Division's telephone calls increased from 8,574 to 14,870 (73%) and the Licensing Division's telephone calls increased from 10,996 to 23,500 (114%).

While we applaud the concept of a telephone number for consumers' use in reporting complaints, we anticipate that the Agency will experience a resulting significant fiscal and human resource impact. The new -- and current -- requirement that a sign be posted in each facility, bearing the Agency's phone number, is expected to impact frontline staff workload -- significantly and immediately. Further, with the implementation of a 1-800 phone number, we anticipate a potential 25% increase in the number of complaints received, an increase in the number of Open Records requests (for complaint information), and the number of disciplinary actions taken -- all resulting in a need for additional staff. Again, the Agency submitted this Fiscal and Agency impact to the 73rd Legislature, but the effort was not funded. 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.

The following table shows the increase in telephone calls, specifically in Compliance and Licensing, from FY88-94. Although the number of calls decreased from 45,817 in FY91 to 42,264 in FY92, we believe this decrease is due to an inadequate telephone system (many calls were turned away due to overloaded phone lines). Several studies substantiate this statement. First, in 1991, a Southwestern Bell telephone traffic study showed that, during the two-week study period, 253 calls were rejected from the Agency switchboard (in other words, these callers received a *"busy"* signal). A second study was conducted during a two-week period in 1992, and we found that 284 calls were rejected -- an increase of *11%*. If the number of rejected telephone calls continues at this rate, we can expect that in one year, over 7,000 callers will be rejected. Again, the Agency projected the costs of this activity in its FY94-95 Legislative Appropriation Request. Again, this improvement was also not funded. Meanwhile, we strongly believe that there has been (and will continue to be) a significant loss of service to Agency customers.

Year	**Calls Received by Compliance Staff**	% Increase	Compliance Staff	% Increase
FY88	8,574	--	2	--
FY89	10,041	17%	2	-0-
FY90	10,825	8%	2	-0-
FY91	13,706	27%	2	-0-
FY92	14,095	3%	2	-0-
FY93	14,850	5%	2	-0-
FY94 project	14,870	--	2	-0-

Year	Calls Received by Licensing Staff	% Increase	Licensing Staff	% Increase
FY88	10,996	--	3	--
FY89	13,250	20%	3	-0-
FY90	14,913	13%	4	25%
FY91	22,508	51%	4	-0-
FY92	21,414	<5%>	4	-0-
FY93	22,950	7%	4	-0-
FY94	23,550	2%	5	25%

Year	Calls Received by Agency Staff	% Increase	Agency Staff	% Increase
FY88	28,548	--	32	--
FY89	33,430	17%	32	-0-
FY90	36,925	10%	34	6%
FY91	45,817	24%	34	-0-
FY92	44,264	<8%>	34	-0-
FY93	45,000	7%	35	3%
FY94 Project	52,222	16%	38	9%

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.

E. Administrative Services

An increasing area of demand for the Agency is that of "Administrative Services." The results of the 72nd and 73rd Legislative Sessions were brought on in large part by the fiscal crises and reorganization of state government, and have significantly taxed, and diverted, our human resources and their ability to carry out the Agency's primary mission of protecting the public health.

These demands are addressed as follows:

(1) Budgetary Demands

The 72nd and 73rd Legislative Sessions produced an Appropriations Bill that contains many unknowns regarding specific Agency appropriations. Although the Agency was granted a specific appropriation amount, this amount is dependent on several reduction riders to the General Appropriations Act. These riders must be evaluated and monitored constantly throughout the biennium, involving a significant amount of staff time, in order to ensure that the Agency maintains the adequate appropriation level to meet its expenditures. Approximately 19 such riders were contained in the General Appropriations Acts of 1991 and 1993. Many times the effects of the reduction amounts are simply not known until well into the biennium, making strategic planning of the Agency's operational needs extremely difficult.

(2) New Systems

Recent Legislative Sessions have created many new and significant systems, affecting all areas of the Agency, but primarily affecting the Fiscal Area. These systems include the Statewide Strategic Planning and Budgeting System, the Uniform Statewide Accounting System, the Uniform Statewide Accounting Cost Allocation System, the Uniform Statewide Payroll System, the State Property Accounting System, the Statewide Fleet Vehicle Management System, and Funds Consolidation.

Although we anticipated that these new systems would improve the effectiveness of Agency services, the development and implementation of these systems continue to take an incredible amount of Agency human resources. In FY93, approximately 1,500 manhours were spent in training requirements alone, with the majority of the year devoted to planning, converting and implementing these systems. Although there are benefits to each system, it appears that these new systems will not, in fact, reduce Agency workload, but will, in fact, require additional resources to maintain.

(3) Reporting Requirements

A final area of increased demand for the Agency is our response 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 1992 and August 1993, the Agency was required to submit over 54 reports, surveys, and the like. (See Appendix D). The volume of these reports compares to FY90, FY91 and FY92 in the following manner:

-- In FY90, 19 reports and requests for information were submitted.
-- In FY91, 31 reports and seven fiscal notes were submitted.
-- In FY92, 27 reports were submitted.
-- In FY93, 54 reports were submitted - a 184% increase over FY90!

These reports require significant time and efforts of managerial and professional staff. We do not foresee any decline in demand for any Agency services within the next six years. In fact, the Agency expects current trends to continue, and to increase at a minimum of 10% per year for the next six years.

IMPACT ON AGENCY

Given observed growth and increased complexity of pharmacy practice and health care, together with the continued increase in demand for services, the Agency's ability to function efficiently and effectively in the public interest appears to be in jeopardy.

At the current level of operation, there is no *"slack"* in terms of Agency personnel workload. In fact, staff in several Divisions work significant amounts of unacceptable 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 include a decrease in the quality and quantity of Agency services vital to its mission.

Even though TSBP's computer technology has been improved recently, there remains a major need for improvement of the Agency's phone system, just to handle the dramatic increase in calls from FY88 through FY93. If this need remains unaddressed, the Agency's accomplishment of strategic planning goals will certainly suffer.

AGENCY STRENGTHS AND OPPORTUNITIES

(1) Organizational structure, leadership, and management provide the mechanisms necessary to carry out the Agency's mission, and to accomplish its strategic and operational objectives.

(2) 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.

(3) 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.

(4) TSBP has a highly educated, qualified, and forward-thinking staff who carry out their responsibilities in an efficient and effective, customer-service oriented manner.

(5) 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 effective Agency performance.

(6) The Agency has involved itself in Strategic Planning for the past seven years. The Agency's first Strategic Plan was published in 1986. Updated Strategic Plans were published in 1990 and in 1992. The Issue Statements were also updated in November 1991, when the Agency published its self-study report for the Sunset Advisory Commission.

(7) The Agency has an approved Strategic Plan for Information Management that addresses its technology needs for the next six years.

(8) The Agency is serving in a leading role within the newly formed Health Professions Council, and is in a position to share our successful operational strategies with the other regulatory agencies.

(9) The Agency is highly regarded by each type of its customers, including consumers, legislators, and the regulated profession, as well as local communities throughout Texas.

AGENCY WEAKNESSES AND CONSTRAINTS (THREATS)

(1) Demand for all Board services is increasing at a dramatic rate and, unless additional human and technical resources are provided, both quality and quantity of services provided to Board customers will decline, posing a danger to the public health of the citizens of Texas.

(2) The Agency's telecommunication system is obsolete and inadequate to meet the increased number of incoming phone calls.

(3) 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.

(4) Compensation for executive, managerial, and professional staff is significantly lower than comparable positions in the private sector, resulting in high turnover of pharmacist and professional staff.

(5) Increasing, voluminous 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.

(6) Recent establishment of the Office of Administrative Hearings, which requires the Agency to 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.

(7) Despite the resounding national and state need -- and consumer demand -- 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, and yet not being 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 our children, and child and adult protective issues. Medication misuse is not only costing the citizens of Texas billions of dollars, but 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, our hands are tied due

to lack of program and human resource funding. This is a particular area where a relatively small investment of time and money could grow exponentially, and reach the entire state.

AGENCY GOALS

(1) 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].

(2) We will assertively enforce all laws relating to the practice of pharmacy to ensure that the public health and safety is 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].

(3) 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.].

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

OBJECTIVES & 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 minimal licensure 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 investigate or take action on 90% of all complaints received; to resolve 85% of all complaints received within 150 days of receipt; and to institute disciplinary action on 85% of all licenses determined to have violated the laws relating to the practice of pharmacy.

Outcome Measures:

- Percent of Pharmacies Inspected That Were in Compliance With Pharmacy Drug Laws and Rules

- Percent of Complaints Resolved Resulting in Disciplinary Action

- Number of Disciplinary Actions Expressed as a Percentage of Total Licensees (Pharmacists and Pharmacies)

- Recidivism rate of those receiving disciplinary action

- Percent of Documented Complaints Resolved Within Six Months

OBJECTIVE: By 1997, 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 30% of the total value of contracts and subcontracts awarded by the agency in purchasing and public works contracting by fiscal year 1999.

Outcome Measure:

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

STRATEGIES & OUTPUT MEASURES

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

Output Measures:

- Number of Examination Sessions Conducted
- Number of New Licenses Issued to Individuals
- Number of Licenses Renewed (Individuals)

STRATEGY: Emphasize preventive enforcement by conducting compliance inspections of pharmacies, providing technical assistance, licensee information, and education programs; receive, investigate, and resolve complaints; and monitor compliance with disciplinary orders resulting from Board adjudication.

Output Measures:

- Number of Inspections
- Complaints Resolved
- Number of Newsletters Distributed
- Number of Texas Pharmacy Laws and Regulations Distributed

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

APPENDIX A

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 October of 1991 and February of 1992, as a result of the requirements of H.B. 2009.

The 1994 Strategic Plan has been the product of:

- overall review of the 1992 Strategic Plan by the Board members and Agency staff;
- interviews of all Agency Division Directors and the Executive Director/Secretary (Internal Assessment), by a designated Agency staff person;
- comments received from a mailout (External Assessment) of the 1992 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 the 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 each group's response date -- is found in Appendix B.

The questions asked in the External Assessment were the following:

1. 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?

2. How will any of these issues affect the Agency's ability to carry out its mission?

3. Which of these issues poses the greatest challenge for the Agency in its ability to respond, and why?

4. How should the Agency attempt to respond to these issues and challenges?

5. What should be the future of the Agency's Enforcement Efforts?

6. What should be the future of the Agency's Public Information and Education efforts?

7. What do you see as the greatest area of opportunity for the Agency?

Resulting issues to be addressed by the 1994 Strategic Plan were identified as:

1. The Crucial Role of Pharmacists: Improving Patient Outcomes Through Pharmaceutical Care.

2. "Traditional" and "Non-Traditional" Pharmacy Practice Settings: The Delivery of Full Access Patient Care.

3. The Effects on Pharmacy Practice and Patient Care of Technology, Pharmacy Technicians, and Pharmacist Manpower.

4. The Evolution of Drugs, Devices, and Dosage Forms.

5. 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 April 14, 1994, to review the received comments, and 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 3, 1994.

APPENDIX B

MAILING LIST FOR STRATEGIC PLAN LETTER, REQUESTING COMMENTS:

-- LETTERS MAILED 2/7/94, WITH RESPONSES REQUESTED BY 3/15/94.

COLLEGES OF PHARMACY	**DATE RESPONSE RECEIVED**
Dr. Mustafa F. Lokhandwala Dean The University of Houston College of Pharmacy 4800 Calhoun, SR-2.141 Houston, TX 77204	RESPONSE RECEIVED 3/11/94
Dr. Henry Lewis III Dean Texas Southern University College of Pharmacy and Allied Health Sciences 3100 Cleburne Street Houston, TX 77004	NO RESPONSE RECEIVED
Dr. James T. Doluisio Dean The University of Texas College of Pharmacy The University of Texas at Austin Austin, TX 78712	RESPONSE RECEIVED 3/14/94

CONSUMER GROUPS

John Hildreth, Director Texas Consumers Union 1300 Guadalupe, Suite 100 Austin, TX 78701	NO RESPONSE RECEIVED

CONSUMER GROUPS

J. Patrick Luby, Area Director — NO RESPONSE RECEIVED
American Association of Retired Persons, Area VII
8144 Walnut Hill Lane, Suite 700, LB-39
Dallas, TX 75231

Suzy Woodford, Executive Director — NO RESPONSE RECEIVED
Common Cause Texas
1615 Guadalupe, Suite 204
Austin, TX 78701

Tom "Smitty" Smith, Director — NO RESPONSE RECEIVED
Public Citizen Texas
1800 Rio Grande
Austin, TX 78701

Pauline Kress — RESPONSE RECEIVED 3/14/94
National Council of Jewish Women
Greater Dallas Section
219 Preston Royal Village
Dallas, TX 75230-3832

NATIONAL PHARMACY ORGANIZATIONS

John A. Gans, Pharm.D. — NO RESPONSE RECEIVED
Executive Vice President
American Pharmaceutical Association
2215 Constitution Avenue, NW
Washington, DC 20037

Joseph A. Oddis, Sc.D. — NO RESPONSE RECEIVED
Executive Vice President
American Society of Hospital Pharmacists
7272 Wisconsin Avenue
Bethesda, MD 20814

Ronald L. Ziegler, President & CEO — NO RESPONSE RECEIVED
National Association of Chain Drug Stores
413 N. Lee Street
PO Box 1417-D49
Alexandria, VA 22313-1417

NATIONAL PHARMACY ORGANIZATIONS

Carmen A. Catizone, R.Ph.
Executive Director
National Association of Boards of Pharmacy
700 Busse Highway
Park Ridge, IL 60068

NO RESPONSE RECEIVED

TEXAS PHARMACY ORGANIZATIONS

Paul Davis, Executive Director
Texas Pharmaceutical Association
PO Box 14709
Austin, TX 78761-4709

RESPONSE RECEIVED 3/14/94

Mike Knapp, Executive Director
Texas Society of Hospital Pharmacists
6300 La Calma Drive, Suite 410
Austin, TX 78752

NO RESPONSE RECEIVED

Chuck Courtney
Director of Public Affairs
Texas Federation of Drug Stores
504 West 12th St.
Austin, TX 78701

RESPONSE RECEIVED 3/14/94

STATE PUBLIC HEALTH OFFICIALS

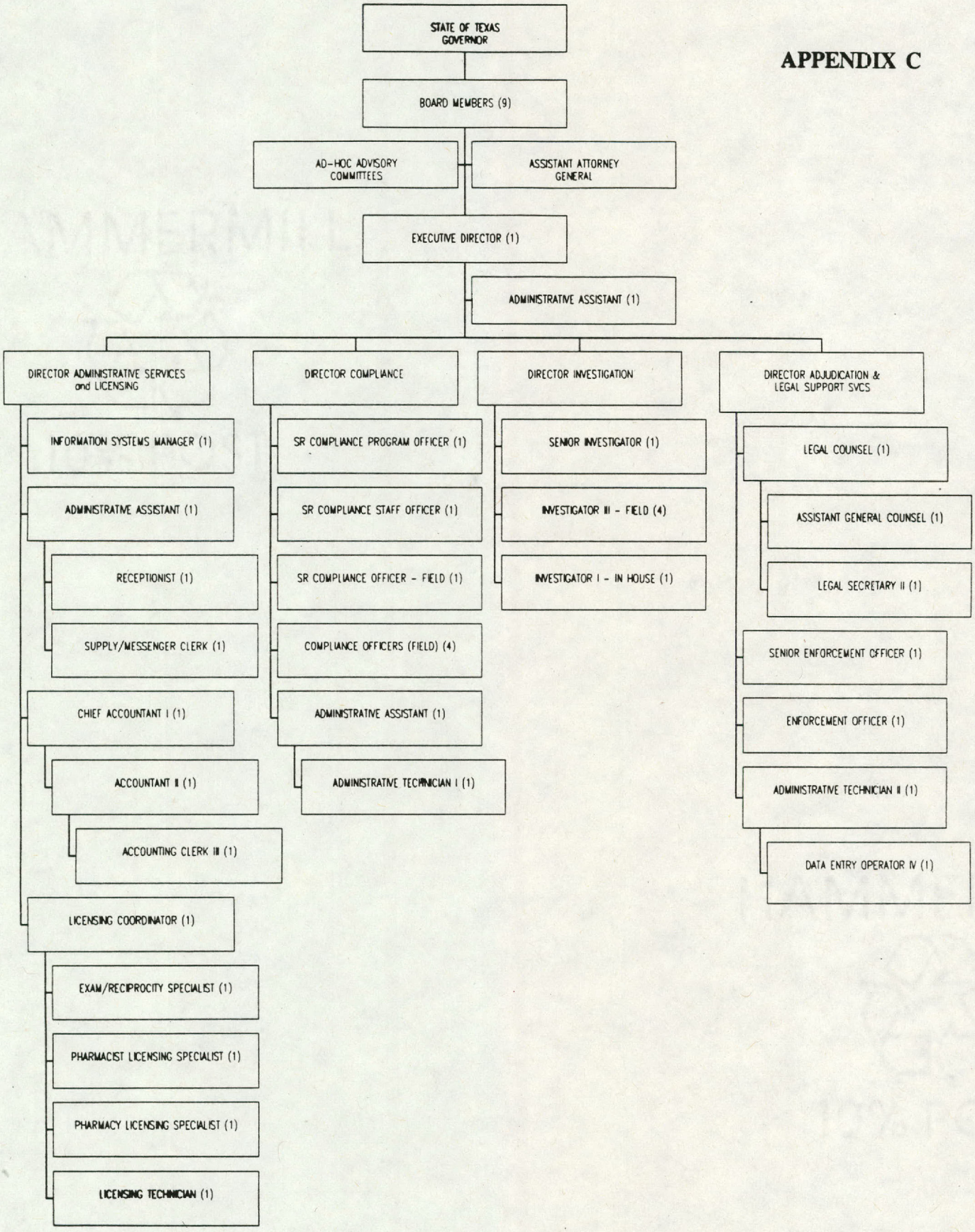
David Smith, MD
Commissioner
Texas Department of Health
1100 West 49th Street
Austin, TX 78756

RESPONDED THROUGH
MARY STEINHAUSEN (BELOW)

Mary Steinhausen, MS Ed.
Healthy Texans Year 2000 Coordinator
Office of Regional Programming
Texas Department of Health
1100 West 49th Street
Austin, TX 78756

RESPONSE RECEIVED 3/25/94

APPENDIX C


STATE OF TEXAS GOVERNOR
BOARD MEMBERS (9)
AD-HOC ADVISORY COMMITTEES
ASSISTANT ATTORNEY GENERAL
EXECUTIVE DIRECTOR (1)
ADMINISTRATIVE ASSISTANT (1)
DIRECTOR ADMINISTRATIVE SERVICES and LICENSING
DIRECTOR COMPLIANCE
DIRECTOR INVESTIGATION
DIRECTOR ADJUDICATION & LEGAL SUPPORT SVCS
INFORMATION SYSTEMS MANAGER (1)
ADMINISTRATIVE ASSISTANT (1)
RECEPTIONIST (1)
SUPPLY/MESSENGER CLERK (1)
CHIEF ACCOUNTANT I (1)
ACCOUNTANT II (1)
ACCOUNTING CLERK III (1)
LICENSING COORDINATOR (1)
EXAM/RECIPROCITY SPECIALIST (1)
PHARMACIST LICENSING SPECIALIST (1)
PHARMACY LICENSING SPECIALIST (1)
LICENSING TECHNICIAN (1)
SR COMPLIANCE PROGRAM OFFICER (1)
SR COMPLIANCE STAFF OFFICER (1)
SR COMPLIANCE OFFICER - FIELD (1)
COMPLIANCE OFFICERS (FIELD) (4)
ADMINISTRATIVE ASSISTANT (1)
ADMINISTRATIVE TECHNICIAN I (1)
SENIOR INVESTIGATOR (1)
INVESTIGATOR III - FIELD (4)
INVESTIGATOR I - IN HOUSE (1)
LEGAL COUNSEL (1)
ASSISTANT GENERAL COUNSEL (1)
LEGAL SECRETARY II (1)
SENIOR ENFORCEMENT OFFICER (1)
ENFORCEMENT OFFICER (1)
ADMINISTRATIVE TECHNICIAN II (1)
DATA ENTRY OPERATOR IV (1)

APPENDIX D

AGENCY REPORTING REQUIREMENTS - FY93

The following is a listing of reports, surveys and requests for information in FY93. The volume of these reports compares to FY90, FY91 and FY92 in the following manner: In FY90, 19 reports and requests for information were submitted; in FY91, 31 reports and 7 fiscal notes were submitted; in FY92, 27 reports were submitted; and in FY93, 54 reports were submitted -- a volume increase of 184% since FY90.

REPORT	REQUESTING AGENCY	DUE DATE
Agency Strategic Plan	Governor's Office	09/01/92
Legislative Appropriation Request	LBB	09/11/92
Sunset Survey re: Purchasing	Sunset Commission	09/14/92
Fiscal Year Payroll Conversion	Department of Information Resources (DIR)	09/14/92
Licensing/Cost Statistics	Sunset Commission	09/22/92
Agency Hiring Policy	Senator Glasgow	09/22/92
LBB Perform. Measure Definitions	LBB	09/25/92
Sunset Data re: Agency Data and Other Pharmacy Related Issues	Sunset Commission	09/28/92
State Classification Report	State Auditor	09/30/92
Funds Consolidation Impact	Comptroller	09/30/92
Procurement Process Survey	Texas Performance Review	09/30/92
Utilization of Merit Funds	Comptroller	09/30/92
Americans with Disabilities Act Licensing Questions	Attorney General	10/09/92
FY92 Performance Report	LBB	10/01/92

Sunset Data - Inactive Licenses	Sunset Commission	10/06/92
Risk Management Questionnaire	Worker's Compensation	10/09/92
Initial Operating Plan	DIR	10/11/92
State Travel Procedures	General Services Comm.	10/12/92
Agency Survey - Printers	Attorney General	10/15/92
Printing Survey	General Services Comm.	10/16/92
Investigative Process Survey	LBB	10/16/92
Review of LAR on LBB Database	LBB	10/22/92
Risk Management Procedures	Worker's Compensation	10/27/92
Annual Loss and Exposure Report	Worker's Compensation	10/30/92
Business Permit Information	Commerce Department	10/30/92
Binding Encumbrance Report	Comptroller	10/30/92
Minority Hirings	Comm. on Human Rights	10/30/92
1992 Annual Report to DIR	DIR	11/02/92
Fund Account. by County Survey	Comptroller	11/06/92
TSBP Response to Sunset Report	Sunset Commission	11/06/92
Attorney General Cost Figures	Attorney General	11/06/92
Functions of Personnel Office	Comptroller	11/12/92
State Agency Fraud Survey	Department of Insurance	11/13/92
Statistics re: Pending Complaints	LBB	11/16/92
Classification Survey	State Auditor	11/16/92
State Agency Recycling & Conservation Program	Governor's Office	12/09/92
State Legalization Impact Assistance Grant Update - Expenditures	Governor's Office	12/09/92
Ann. Financial Report (100 Day)	State Auditor	12/09/92
Customer Satisfaction Survey	DIR	12/15/92
Calendar Year Payroll Conversion	DIR	12/15/92
1st Quarter Performance Report	LBB	01/01/93
DIR Strategic Plan	DIR	01/01/93

Record Retention Schedule Update	Texas State Library	01/01/93
Federal Grant Expenditures	Tx Office of State-Federal Relations	01/01/93
Americans With Disabilities Act Transition Plan & Self Evaluation	Governor's Committee on People with Disabilities	01/26/93
State Employee Demographic Report	Senate Finance	02/01/93
Fiscal Notes re: Sunset Decisions	Sunset Commission	02/05/93
Indirect Cost Allocation Plan (Cost Recovery Program)	Governor's Office	02/93
State Agency Questionnaire re: Criminal Offenses	Texas Justice Court Training Center	03/01/93
2nd Quarter Performance Report	LBB	05/03/93
USAS Certification Process	State Comptroller	06/30/93
3rd Quarter Performance Report	LBB	07/20/93
Final Operating Plan	DIR	08/20/93
Management Control Audit	State Auditor's Office	08/16/93

In addition to the Legislative Appropriation Request, the Agency was also required to prepare the following documents throughout the budgetary process:

a. September 1992: Level of service provided by the Agency in the FY94-95 biennium at the 1992-93 level of funding, submitted to Bob Bullock's office.

b. September 1992: Performance Measures Definitions to the LBB and GBO.

c. October 16, 1992: Survey regarding Investigative Activities of the Agency, submitted to the Legislative Budget Office.

d. January 29, 1993: Fiscal Note regarding Senate Bill 47 relating to requiring certain information to be printed on a practitioner's prescription pad before the prescription may be dispensed.

e. February 23, 1993: Fiscal Note regarding Senate Bill 370.

f. March 2, 1993: Fiscal Note regarding Senate Bill 472 relating to the practice of pharmacy.

g. March 4, 1993: Fiscal Note regarding House Bill 1189 relating to the practice of pharmacy.

h. March 8, 1993: Fiscal Note regarding Senate Bill 589 relating to the Health Care Provider Referral Act.

i. March 12, 1993: Fiscal Note regarding Senate Bill 621 relating to the continuation and functions of the Texas State Board of Pharmacy.

j. March 19, 1993: Fiscal Note regarding House Bill 1513 relating to the continuation and functions of the Texas State Board of Pharmacy.

k. April 13, 1993: Fiscal Note regarding House Bill 2253 relating to minimum standards of uniform practice and procedures for state agencies.

l. May 3, 1993: Fiscal Note regarding Senate Bill 472 as passed by the Senate relating to the practice of pharmacy.

m. May 11, 1993: Fiscal Note regarding C.S.S.B. 674 relating to

the Health Professions Council.

n. July 6, 1993: Appropriation allocation by strategy as a result of Agency Sunset Rider.

OUTCOME PROJECTIONS

Outcome	1995	1996	1997	1998	1999
Percent of Licensees (Pharmacists and Pharmacies) With No Recent Violations (Disciplinary Action)	99	99	99	99	99
Percent of Pharmacies Inspected that were in Compliance with Pharmacy Drug Laws and Rules	80	80	83	84	85
Percent of Complaints Resulting in Disciplinary Action	12	14	15	15	15
Number of Disciplinary Actions Expressed as a Percentage of Total Licensees (Pharmacists and Pharmacies)	0.5	0.5	0.5	0.5	0.5
Recidivism rate of those receiving disciplinary action	6	7	8	10	10
Percent of Documented Complaints Resolved Within Six Months	65	70	75	80	80
Percent of Consumers of Pharmacy Services Aware of TSBP Role and the Need to be informed about their prescription drugs.	0	0.5	2	2	2
Percent of Total Dollar Value of Purchasing and Public Works Contracts and Subcontracts Awarded to HUBs.	30	30	30	30	30